Journal of Participatory Medicine

Advancing the understanding and practice of participatory medicine among health care professionals and patients

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Real-World Data Needs Real-World Doctors: When Automation Advances Faster Than Clinical Workflow

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Abstract

Health care is entering an era of unprecedented detection. Artificial intelligence (AI)–driven monitors and real-world data streams now identify clinical risks in minutes, promising a future of proactive, earlier intervention. While AI automation is often marketed as a tool to reduce administrative burden and allow health care providers to focus more on direct patient care, this unrealized potential currently stands in contrast to our reality. Building high-speed data “freeways” without “off-ramps” such as clinical staffing, workflow synergy, and the patient education required for meaningful response is like building a superhighway without well-engineered off-ramps to provide a safe way to get home, and this creates a dangerous paradox. Earlier detection without earlier care does not improve outcomes; it simply redistributes anxiety and extends the patient’s period of uncertainty. We argue that the “public as a sensor” is already signaling a systemic infrastructure gap. True safety in clinical AI isn’t found in more algorithmic guardrails, but in participatory co-design that ensures every digital alert has a viable human pathway to care and resolution. We must stop building high-speed roads that lead to a cliff edge of clinical unavailability and consider that while the technology is a feat of engineering, it’s our human architecture that makes it medicine.

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KEYWORDS

artificial intelligence in medicine; clinical AI; real-world data; remote patient monitoring; digital health infrastructure; clinical decision support systems; diagnostic accuracy; clinical workflow integration; alert fatigue; physician burnout; workforce capacity; implementation science; care coordination; participatory medicine; coproduction of health care; patient-led research; health equity in AI; algorithmic governance; patient-centered care

Introduction

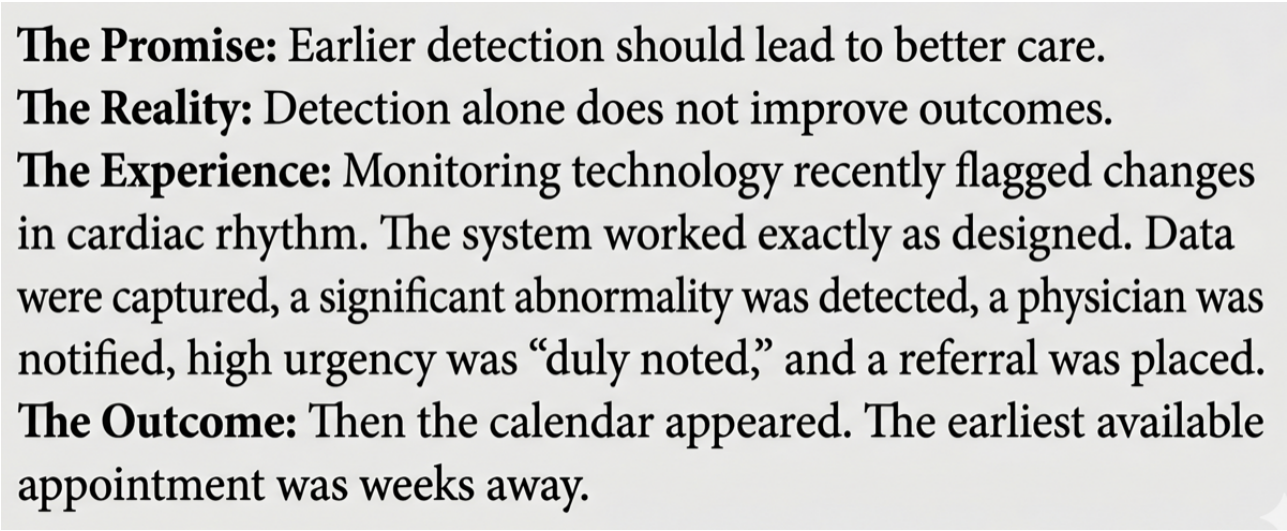
Health care systems can detect clinical problems earlier than at any point in history. Continuous cardiac monitors record rhythms for weeks, wearable devices capture subtle physiological changes throughout the day, and artificial intelligence (AI) algorithms analyze real-world data to identify patterns clinicians might otherwise miss [1-3]. Alerts generated by these systems move rapidly through electronic health records, often within minutes. The promise underlying this innovation is clear: earlier detection should lead to earlier intervention and better outcomes [4].

However, detection alone does not improve care [5]. Without a timely clinical response, earlier identification of risk can simply extend the period of uncertainty experienced by patients. This uncertainty is not neutral. It can be distressing, particularly when patients receive alerts suggesting potential clinical deterioration but cannot access timely evaluation.

At the same time, discussions about clinical AI frequently emphasize guardrails designed to protect patients [6], while access to timely care remains constrained [7]. Patients experience a paradox: increased monitoring and earlier detection paired with delayed clinical response. In this context, safety narratives focused solely on algorithmic governance risk overlooking the lived experience of patients navigating uncertainty without timely clinical support [8]. This is detailed in Figure 1, which provides a narrative account of a patient encountering this systemic delay.

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Figure 1. the When detection outpaces care: the patient's voice.



Building Participatory Off-Ramps

Despite growing adoption of clinical AI, patients and the public are still rarely invited into meaningful partnerships to shape implementation, co-design workflows, or develop AI literacy initiatives. This absence is notable given that patients are often the first to experience the downstream consequences of a delayed response, increased alerting, and fragmented workflows [9].

Emerging research suggests that AI-enabled monitoring increases clinical signals and alerts, yet workflows and workforce capacity have not evolved at the same pace [10,11]. Without corresponding investment in response pathways, automation risks amplifying uncertainty rather than improving care.

This experience referenced in is increasingly common, even within large academic medical centers in the United States designed to provide rapid access to subspecialty expertise. In the US health care context, policy initiatives have encouraged the generation and use of real-world data. The issue is not technological capability alone, but whether health care systems have sufficient clinical capacity and workflow infrastructure to respond when new information emerges [12,13].

The Paradox of Progress

Over the past decade, US policy initiatives have encouraged the generation and use of real-world data, including remote physiologic monitoring, patient-generated health data, and AI-supported triage systems. These technologies have expanded rapidly and demonstrated improved detection of deterioration across cardiovascular, metabolic, and chronic disease populations [4].

The engineering feats we are witnessing are nothing short of miraculous. We now have AI models identifying pancreatic cancer 3 years before a traditional diagnosis and wearable technology detecting silent heart failure from a wristband [14-16]. These are the high-speed lanes on the freeway of a new era in medicine.

To truly honor these breakthroughs, we must match this digital brilliance with an equally sophisticated human infrastructure. Our task is not to slow down the "freeway," but to build the robust, graded "off-ramps," the clinical time, the team-based staffing, and the participatory co-design that ensure every signal reaches its destination: a healthy patient. When we invite the public to coproduce technology as "sensors" and co-designers, we aren't just fixing a workflow; we are building a health care system worthy of the technology we've created [17]. Table 1 shows the promise, reality, and proposed solutions.

Productive AI requires the meaningful involvement of patients and clinicians throughout the entire process, from co-design and ethics to defining alert thresholds, testing prototypes, assessing application quality, and shaping both feedforward concerns and feedback solutions, all while evaluating workflow integration. To ensure AI implementation truly serves those it is meant to help, we recommend fully compensated [18] "patient" and "clinician-in-the-loop" team roles, with genuine voting power over co-created outcomes.

Real-world data hold enormous promise for improving outcomes and personalizing care. They allow clinicians to observe disease trajectories in everyday settings and identify changes earlier than traditional episodic visits permit. Yet data alone do not improve health. Without clinicians available to interpret signals and systems capable of responding quickly, detection may simply shift the burden of waiting from before diagnosis to after notification and before timely intervention.

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Table . Mapping the paradox of progress in clinical artificial intelligence (AI).

The promise	The reality gap	The participatory solution
Earlier detection	Alerts outpace workforce capacity. Detection happens in minutes; clinical response can take weeks.	Workflow co-design: involving patients and clinicians in prioritizing alerts and defining response expectations for high-quality health care.
Continuous monitoring	Increased patient anxiety. Earlier awareness without earlier care simply extends the period of uncertainty.	Human-centered guardrails: shifting focus from purely algorithmic governance to systemic safety, ethical agreement, and patient-supported partnership.
AI efficiency	Fragmented, "siloed" responses. Automation shifts effort toward interpretation and coordination, increasing cognitive demands.	Integrated care pathways: co-constructing response infrastructure, such as customer support and team-based care, as a primary part of deployment.

Participatory Medicine Declaration

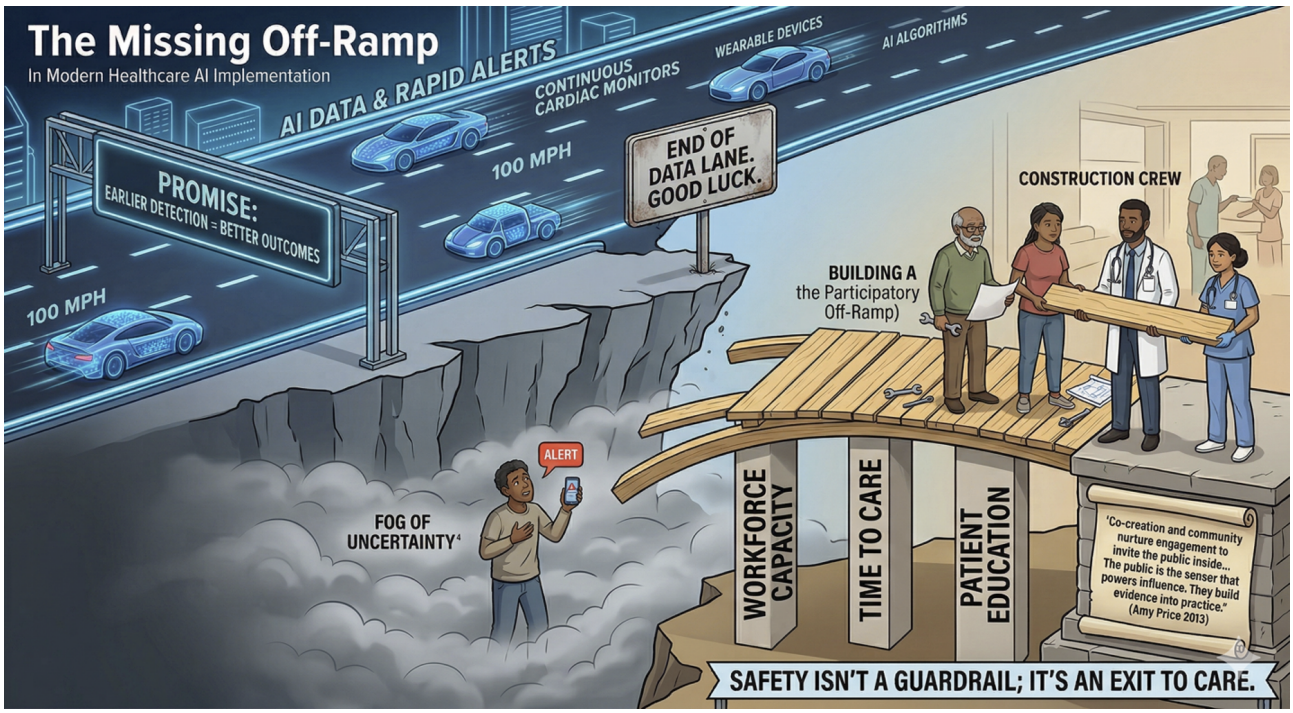
This work was co-produced, co-authored and pre–peer reviewed with patients.

The Structure-Infrastructure Gap

As emphasized above, we seek not to slow down the freeway, but to build off-ramps to ensure access to the destination: high-quality health care. Figure 2 illustrates the missing off-ramp for AI in health care.

AI automation is marketed as an efficient, cost-cutting solution to workforce shortages. Yet emerging evidence suggests a more complex reality. AI-enabled alerting systems, ambient documentation tools, and automated triage systems frequently introduce new cognitive demands, increase alert fatigue, and create additional coordination work for clinicians when workflows are not redesigned accordingly [19,20]. Rather than reducing workload, automation can shift effort from documentation to interpretation, triage, and coordination, tasks that still require complex and expert human clinical judgment [21].

Figure 2. The missing off-ramp in modern health care artificial intelligence (AI) implementation. This conceptual illustration depicts the current disconnect between high-speed AI detection (the freeway) and the necessary systemic infrastructure required for clinical response (the off-ramp). Safe passage to high-quality health care requires bridging the gap between automated alerts and human-centered care through workforce capacity, protected clinical time, and participatory co-design. Image generated with the assistance of Google Gemini 3 Flash.



Workforce and Workflow Challenges

These workflow challenges occur in the context of worsening workforce shortages. Projections suggest significant physician shortages across primary care and subspecialties in the coming decade, further limiting the system's ability to respond to newly detected risks. At the same time, structural barriers limit workforce expansion [22,23]. Medical school costs have risen substantially, creating financial barriers for many prospective physicians and influencing specialty choice toward higher-compensation fields, exacerbating shortages in primary care and community-based settings [24].

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Training bottlenecks further constrain workforce growth. Residency and fellowship placements remain limited, meaning that even when medical school enrollment increases, postgraduate training capacity may not expand in proportion to the need [25]. This creates a structural mismatch between educational output and workforce needs, particularly as digital health technologies generate more clinical signals requiring interpretation [11].

Advanced practice clinicians, including nurse practitioners and physician associates, are increasingly expected to help address these shortages [26]. However, they often face a paradoxical situation: in some contexts, they are criticized for perceived gaps in expertise, while in others they are expected to manage increasingly complex patient populations and respond to AI-generated alerts beyond traditional scope-of-practice boundaries [27]. Evidence suggests that team-based care models improve outcomes when roles are clearly defined and supported, rather than when advanced practice clinicians are used as substitutes for unavailable physicians [27].

For patients, this gap shifts responsibility in subtle but important ways. When notified of abnormal findings, individuals often monitor symptoms more closely, search for information, and attempt to interpret data while waiting for professional guidance [13]. For those living with chronic or complex conditions, this period can be particularly challenging. Instead of reducing uncertainty, earlier detection may extend it. In this sense, automation without response capacity risks creating a new form of harm: early awareness without early care [13,28].

Conclusion: Toward a Sociotechnical Solution

Emerging informatics and implementation science emphasizes that successful digital transformation requires co-design with clinicians and patients, workflow redesign, and evaluation of downstream response capacity, not simply detection accuracy [7,29]. These findings reinforce the view that AI implementation is fundamentally a sociotechnical challenge rather than a purely technological one.

The next phase of digital health policy must move beyond generating data and toward ensuring that care systems can act on the information they produce. Praising automation while neglecting clinical workflow and workforce capacity risks creating unintended harm. Real-world data will only transform health care if real-world doctors, and the teams who support them, are available to respond.

We have invested billions in data infrastructure, that is, the high-speed lanes, while neglecting the off-ramps that reduce mortality and increase safety: the clinicians, time to task, patient education, and cost required to transition from a digital alert to a clinical resolution. As highlighted in Figure 2, safety is not just a guardrail; it means ensuring there is a safe way to get home.

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Authors' Contributions

CVR and AP contributed to all aspects of the publication.

Conflicts of Interest

AP is the editor-in-chief of the *Journal of Participatory Medicine*, and CVR is on the patient advisory board.

Multimedia Appendix 1
Prompt used in image generation.
[DOCX File, 22 KB - jopm_v18i1e97972_app1.docx]

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Abbreviations

AI: artificial intelligence

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A Call to Recognize the Integral Role of Physician Associates and Nurse Practitioners in Modern Health Care: Editorial

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Abstract

Policies governing health care professionals must be evidence-informed and include meaningful representation of all stakeholders, or commitments to quality and equity will remain shallow rhetoric. Physician associates (PAs), nurse practitioners (NPs), and patients deserve full participation in decisions affecting practice and patient care. The current health care landscape faces unprecedented workforce challenges, requiring a shift toward evidence-informed policy and the meaningful representation of all stakeholders. This editorial aims to advocate for the full participation of PAs, NPs, or advanced practice providers and patient representatives in clinical and policy decisions, contrasting established global models with emerging frameworks to promote a more practical, team-based hierarchy. While recent reviews in the United Kingdom highlight a lack of localized, high-quality data, extensive evidence from the United States and other international contexts demonstrates that PAs and NPs provide safe, effective care with clinical outcomes comparable to physicians. We argue that recognizing these professionals as integral members of the health care workforce, rather than mere stopgaps, is essential for improving care quality and patient well-being. This editorial recommends standardized credentialing, integrated educational pathways, and the inclusion of patient representatives as voting members in policy decisions to foster a truly participatory medicine model.

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KEYWORDS

nurse practitioner; nurse anesthetist; physician assistant; participatory medicine; equity; evidence-based policy; patient safety

Introduction

We appreciate the thoughtful, emergent review by Greenhalgh and McKee [1], which provides timely insights into the evolving roles of physician associates (PAs) in the UK health care system. The authors' rapid scoping review, while acknowledging the limited and variable-quality data, emphasizes the need for robust evidence to inform policy and practice. We share their commitment to high-quality research and believe it is time to honor the significant contributions of PAs and nurse practitioners (NPs) as advanced practice providers, who are integral as professionals in health care, with equal access to recognized professional designations to include educational and research funding, especially given the substantial evidence of benefit from the United States.

Understanding the Roles of PAs and NPs as Advanced Practice Providers

It is critical we understand that in other countries, training and roles vary. For example, in the United States, NPs are advanced practice registered nurses who complete graduate-level education (master's or doctoral) and are nationally certified in their specialty areas. They practice independently or collaboratively, depending on state regulations, while providing a wide range of health care services in primary, acute, and specialty care settings [2]. PAs in the United States undergo rigorous medical education, including obtaining a master's degree and performing clinical rotations, equipping them to diagnose, treat, and manage patient care collaboratively with physicians, delivering care in primary, emergency, and specialty settings.

In the United Kingdom, PAs undergo a shorter training pathway, typically including a first degree and 2 years of postgraduate education, and work only under physician supervision. Unlike in the United States, PAs in the United Kingdom are not yet authorized to prescribe medications or order ionizing radiation independently [1]. The United Kingdom's PA/NP model is still evolving, and comparisons with the more established US model can provide valuable insights into optimizing their roles.

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Evidence of Safety, Efficacy, and Value

Contrary to perceptions of limited evidence, global data demonstrate that advanced practice providers contribute significantly to health care systems, particularly in underserved and rural areas. These professionals provide safe, effective care, with clinical outcomes comparable to those of physicians [3]. Quantitative evidence from the United States and Canada further supports their value:

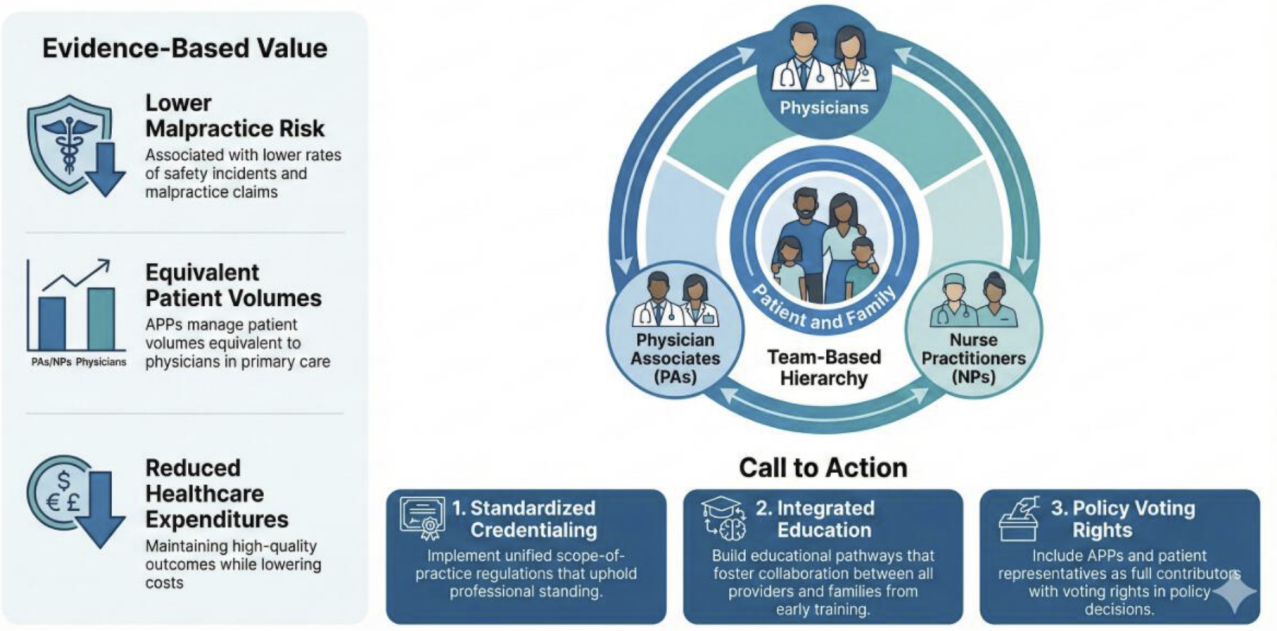
- Safety and malpractice—advanced practice providers are associated with lower rates of safety incidents and malpractice claims compared to traditional models, suggesting a high standard of patient safety and adherence to scope of practice [4].
- Cost and efficiency—meta-analyses of randomized controlled trials indicate that advanced practice providers positively impact health care costs while maintaining or improving quality of care and patient well-being [5-8].
- Primary care performance—in primary care environments, advanced practice providers consistently manage patient volumes equivalent to physicians while maintaining high patient satisfaction and positive health outcomes [8,9].
- Economic impact—systematic reviews of economic evaluations confirm that incorporating advanced practice providers can reduce overall health care expenditures while maintaining high-quality outcomes [9,10].

Furthermore, advanced practice providers demonstrated remarkable adaptability during the COVID-19 pandemic, filling critical gaps and maintaining care continuity during extreme system stress. Responsible advanced practice providers carefully work within their scope of practice to protect the best interests of their patients and reduce institutional liability.

Addressing Concerns With Collaboration and Clarity

Concerns about supervision and accountability, as highlighted in Greenhalgh and McKee's review [1], underscore the need for clear scopes of practice and well-defined roles within health care teams. In the United States, supervisory and collaborative agreements between PAs, NPs, other advanced practice providers, and physicians are governed by state laws and institutional policies, providing structured frameworks for safe and effective practice. Such frameworks could serve as models for the United Kingdom and in other areas where a national scope of practice for advanced practice providers is still under development. We draw the attention of readers to the integrated care model shown in Figure 1.

Figure 1. The integrated care model: beyond the stopgap. APP: advanced practice provider.



The collaborative nature of advanced practice providers enhances, rather than burdens, physician workflows. By managing lower-acuity cases and supporting team-based care, they allow physicians to focus on more complex cases, ultimately improving care delivery and reducing burnout among all health care providers. Recent research highlights how advanced practice providers play an essential role in sustaining health care systems amid workforce shortages, particularly in rural and underserved areas; worldwide, we face acute shortages of medical providers, particularly in rural and low-income areas [10].

Conclusion: A Path Forward With Evidence and Appreciation

As health care systems worldwide grapple with workforce challenges and rising costs, it is crucial to acknowledge and support the roles of advanced care providers, inclusive of PAs and NPs. We recommend a call to action:

First, develop standardized credentialing and scope-of-practice regulations that recognize and uphold advanced practice provider credentialing in state, federal, and international policy and provide advanced care providers with the same access to funding

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and principal investigator status as other medical professionals. Second, ensure recognition and respect for advanced practice providers. While patients and families anecdotally praise their advanced practice providers for compassionate care and sensitivity in end-of-life discussions, informed shared decision-making, and coordination with other services, this is notably absent in the literature. Third, create integrated educational pathways that foster collaboration between physicians, PAs, NPs, patients, and their families from early training stages. Fourth, implement supportive supervision models that balance autonomy with appropriate oversight. Fifth, include advanced practice providers and patient representatives as full contributors with voting rights in policy decisions that affect practice and patient care. Sixth, issue an urgent call to societies and national funding bodies to recognize and fund the current gap in advanced practice provider research and policy with participatory research.

Advanced practice providers are not merely stopgaps but highly skilled professionals who contribute to safe, effective, and compassionate patient care. We advocate for a balanced, evidence-based approach to evaluating their roles, embracing opportunities to enhance their training, support their integration into health care teams, and recognize their contributions as essential members of the health care workforce.

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Authors' Contributions

KP and AP contributed jointly to the conceptualization, methodology, investigation, resources, data curation, writing (original draft), and writing (review and editing).

Conflicts of Interest

KP is a practicing nurse practitioner; AP is the editor-in-chief of the *Journal of Participatory Medicine*, published by JMIR Publishing, as of the time of publication.

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Abbreviations

NP: nurse practitioner
PA: physician associate

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Original Paper

A Care Transitions Electronic Clinical Pathway for Patients With Chronic Conditions: Qualitative Secondary Analysis

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Abstract

Background: Understanding patient educational requirements for care transitions is crucial for ensuring safe and effective care for patients with multiple chronic conditions (MCCs).

Objective: Within a larger study developing an electronic clinical (e-clinical) pathway to support the safe transition for patients with MCCs from hospital to home and then to primary care, this study identified, evaluated, and integrated content to meet the educational requirements of potential end users of the e-clinical pathway. Participants in the primary study described preferred education content, education considerations, and education presentation and display.

Methods: This study conducted a secondary qualitative analysis of transcripts from individual interviews (n=12 health care providers and staff) and focus groups (n=11 patient advisors) by using an inductive/deductive hybrid thematic analysis to explore the educational requirements of patients with MCCs for the e-clinical pathway.

Results: We identified the following themes regarding specific education requirements for MCC transitions: (1) essential end-user education includes condition-specific, nutrition-specific, and medication-related content; (2) education must be truthful, accessible, and consider end-user health literacy; and (3) education presentation can be enhanced with graphics, reminders, and end-user resources.

Conclusions: The findings were used to develop an educational pathway with targeted and tailored content to support patients with MCCs as they transition from acute hospitalization back to their primary care provider, which was implemented in the study app. Study findings contribute to a more nuanced understanding of end-user education requirements and informed enhancements to the patient-facing app used in the primary study.

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KEYWORDS

care transitions; electronic clinical pathway; hospitals; multiple chronic conditions; patient education; primary care

Introduction

Care transitions from hospital discharge to follow-up with primary care are critical moments for patients that involve the transfer of vital information [1]. This process requires close collaboration among hospital care teams, primary care providers, specialists, patients, and family or caregivers [2,3] to minimize the chance of miscommunication or information loss and to bridge potential gaps in care continuity. For patients with multiple chronic conditions (MCCs), the risks during this transition are particularly high, including an increased risk for hospital readmissions [4]. A 2018 analysis of the National

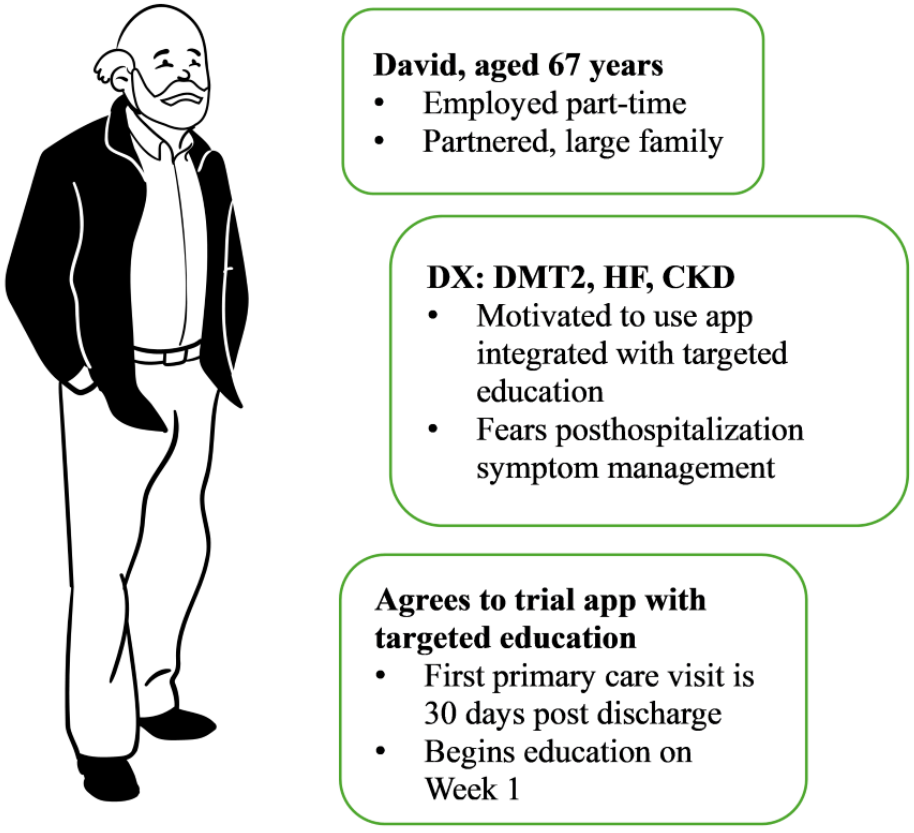
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Health Interview Study found that 27.2% of US adults had multiple (≥2) chronic conditions [5]. Patients with MCCs including diabetes mellitus (DM), congestive heart failure (CHF), and/or chronic kidney disease (CKD) face significant challenges as these and other comorbidities contribute to a higher disease burden and increased health care costs [6,7].

Understanding the patient educational requirements for care transitions is crucial for ensuring safe and effective care for patients with MCCs. For example, increasing services and touch points for high-risk populations can improve health care during critically important care transitions [8]. Digital health interventions that incorporate health education components are linked to greater user success [9]. In addition, effective patient education can enhance health literacy, which in turn supports self-management [10]. Research shows that mobile apps can improve health outcomes for individuals living with chronic illness [11], but a major challenge is the high dropout rate associated with app-based interventions [12]. Many older adults with MCCs and their caregivers express interest in using digital health portals, provided they offer features that patients find both useful and easy to navigate [13].

The electronic clinical (e-clinical) pathway configured within the MassGeneral Brigham patient portal specifically targets the transition from hospital to home for patients with MCC. This includes patients with varying combinations of DM, CKD, and CHF, or just one of these conditions along with another chronic illness (Figure 1). Previous work on the technical development of the e-clinical pathway has been described elsewhere [14]. In brief, the e-clinical pathway leverages Epic's Care Companion module, which is an extension of the Epic MyChart patient portal [15]. The primary goal of the e-clinical pathway is to support patients in an outpatient setting and reduce the likelihood of readmissions. Epic provides a template that includes a selection of curated educational materials, and health care providers can customize and enhance this education as needed. Currently, Epic has not created a care plan specifically designed for discharged patients with MCCs to assist them and their caregivers during the transition from hospital to primary care.

Figure 1. Sample persona of a potential intervention end user with multiple chronic conditions. CKD: chronic kidney disease; DMT2: type 2 diabetes mellitus; DX: diagnosis; HF: heart failure.



This manuscript describes the process and key learnings from identifying, evaluating, and integrating educational content to address the needs of patients with MCCs and their caregivers: the end users of the e-clinical pathway. These efforts were guided by participant feedback from the primary study, which emphasized the need for information reinforcement (Figure 2) during the critical transition from acute hospitalization to home and ongoing care with their primary care provider. Thereafter, a secondary analysis of qualitative interview data explored the education needs of end users during the transition from acute care to home and primary care follow-up. To our knowledge, no publicly available content library currently addresses this specific care transition. This study aimed to identify, evaluate, and integrate content that meets these needs and to develop an education pathway that offers curated, personalized resources to support effective self-management at home.

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Figure 2. Educational content process. e-clinical: electronic clinical; MCCs: multiple chronic conditions.



The following were this study's research questions:

- What educational requirements do patients with MCCs have during their transition from hospital to home and back to primary care?
- What educational materials will support patient self-management of their conditions and symptoms during the transition from acute hospitalization back to primary care?

Methods

Design

This was a qualitative secondary analysis of individual interviews and focus group data from a larger primary study that developed an electronic care transition tool to improve health outcomes of patients with MCCs using a stakeholder-centered design approach [14].

Setting and Participants

The original primary study was conducted at Brigham and Women's Hospital, a major academic medical center in New England, in the Northeastern United States. Health care providers and staff including hospitalists, outpatient physicians, physician assistants, nurse practitioners, nurses, and case managers were eligible to participate, as were patient advisors from the Brigham and Women's Hospital patient and family advisory council who were patients with MCCs who had been previously hospitalized. Purposive [16] recruitment occurred through email, including a detailed study purpose description. Health care providers and staff completed individual interviews, while patient advisors were randomly assigned to 1 of 3 focus groups for the ease, comfort, and schedules of the participants and to support open stakeholder communication with the study team.

Data Collection and Analysis

For the primary study, the study team used a stakeholder-centered [17] design approach as the underlying conceptual basis for the planned research. The study team conducted both individual, virtual interviews involving multidisciplinary care providers and clinical staff, along with virtual focus groups involving patient advisors. Interviews and focus groups, conducted by multiple experienced team members and not exceeding 1 hour in length, continued until saturation [18] was reached. As part of the data collection in the primary study [14], participants openly shared and expounded on their views of educational content necessary for an effective electronic care transition tool. A secondary qualitative analysis was conducted to explore specific educational content research questions, yielding insights beyond the original scope of the primary study and addressing issues identified as important to the participants [19,20]. This report details this secondary qualitative analysis and the results. The methods used to collect the data used in the primary study have been published previously, as were the participant demographics [14]. Therefore, the purpose of this secondary analysis was to identify and explore the educational requirements of patients with MCCs for the e-clinical pathway as expressed by the participants in the primary study.

Interview guides, developed based on a literature review and reviewed by experts, were used for the focus groups and interviews, which were conducted with 12 health care providers and staff and 11 patient advisors in the primary study. The resulting transcripts, transcribed verbatim and anonymized, were the data corpus for this secondary qualitative analysis. Codes were generated both deductively from the interview guide and research questions using a template and framework matrix [21] and inductively from the primary study data, resulting in an inductive and deductive hybrid thematic analysis [22-24]. Three authors (CT, HW, and JRJ) performed the coding and deliberated the results. The remaining authors reviewed the analysis; discrepancies were discussed and resolved through team consensus. The analysis was iterative [25,26] and included team members to contribute to study reliability [27]. Throughout the process, regular team meetings and communications were conducted to calibrate data collection, to discuss findings, and to examine patterns and potential conclusions, encouraging team reflexivity [28,29]. The qualitative results were thereafter used to build an educational requirements Microsoft Excel spreadsheet, which was vetted by clinical experts and iteratively refined.

Ethical Considerations

The Mass General Brigham Institutional Review Board (IRB) reviewed and approved all study activities (protocol 2022P001475) in addition to the University of Massachusetts

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Boston IRB (IRB ID 3476). Informed consent, including participants' ability to opt out, was received from all study participants before study participation. Resulting data were anonymized and deidentified, and strict confidence was maintained. All participants received a US $50 gift card at the end of study participation.

Results

Overview

A total of 23 individuals (n=12 clinical staff or primary care providers and n=11 patient advisors) participated in the original study; the majority were female (n=18) and White (n=19). The clinical staff or health care providers did not provide their ages; however, the ages of 10 of the 11 patient advisors ranged from 60 to 79 years. Participants in the original study described preferred education content, education considerations, and education presentation and display, and we identified through the qualitative secondary analysis the following themes regarding specific education requirements for MCC transitions: (1) essential end-user education includes condition-specific, nutrition-specific, and medication-related content; (2) education must be accurate, accessible, and consider end-user health literacy; and (3) education presentation can be enhanced with graphics, reminders, and end-user resources. The findings further resulted in a completed education pathway (Multimedia Appendix 1), with targeted and specific content for MCC transitions.

Themes

Theme 1: Essential End-User Education Includes Condition-Specific, Nutrition, and Medication Content

Participants described frequently consuming online sources of medical information (“It’s my first go to,...I look at the medical websites” [Patient #2]) when searching out resources and references regarding their own medical conditions and drug interactions (“I do…reading on my own too.” [Patient #3]). Participants shared that patient education at discharge includes information about a new diagnosis or condition-specific information (“problem-based documentation…tailored to every single specific patient and their stay” [Clinician #6]). Condition-specific content is critical because, as 1 participant shared, “a lot of patients...just don’t understand their condition” (Clinician #2). Nutrition content is also important at discharge, including any specific “dietary restrictions” (Clinician #4). Dieticians routinely educate patients and caregivers (“anything about their diet” [Patient #4]) before hospital discharge. Medication changes, new medication information, or potential medication side effects are also critical education points for participants after discharge: “medication, education, and medication reconciliation,...that’s what the primary responsibility of the patient [is] when they are discharged from the hospital” (Clinician #6).

Theme 2: Education Must Be Accurate, Accessible, and Consider End-User Health Literacy

Potential patient end users want accurate education; participants shared that although they do reference medical information for their conditions online, at times internet sources “can raise a lot more questions” (Patient #2). Participants shared that they verify accuracy by confirming online information either with a trusted family member who is a clinician or another online source of information (“to validate what I read” [Patient #2]). For example, 1 patient-adviser participant shared that if “it’s something new or different or frightening I just pick up the phone and call my brother [the surgeon]” (Patient #3). Potential patient end users also want information that is accessible and “written clearly” (Patient #3). Participants appreciated the content of MedlinePlus [30] that specified “when to do what and...[that contained] enough information in plain language...so that people can refer to it. They’re not having to go elsewhere” (Patient #1).

However, and as one clinician participant explained, it is important to balance information requirements along with “the patient’s mental state [and] information overload” (Clinician #6), further sharing that the goal for discharge education is to provide “the most accurate and clear patient accessible information without overwhelming them with so much information...keeping it to the key points” (Clinician #6). Critically, patient education must consider “a patient’s health literacy so that when you are explaining these things, you’re not just assuming that they understand you” (Clinician #8). The education must also consider the potential patient end-user’s language of origin; for example, one patient participant shared: “one of the areas that I focus on a lot is...literacy...I think about the patient [who] doesn’t speak English perhaps, as a first language...and when I look at this in terms of multi syllable words and making an assumption that a patient can understand all of this. I see some opportunities. Maybe you could make this a little bit easier for those patients to follow” (Patient #5).

Participants indicated that education content intensity should vary by the individual patient need. As one clinician participant explained, every patient has “different ways of absorbing information” (Clinician #4). The study team configuring the e-clinical pathway presented 2 potential levels of education prepared for patients: one “standard” education pathway and one “superuser” education pathway. This would allow the app to push a smaller set of tasks to users that engage with tasks less frequently, including educational content. For example, superusers would receive 1 recommended reading per day; standard users would receive less content. Similarly, participants shared that potential end users may approach education content and intensity based on their individual background, needs, and comfort levels. For example, 1 participant shared that they would review content first on “the Brigham [website]...and then I’d look at Cleveland Clinic which I know is good for cardiac stuff...[but] that’s probably not the normal person” (Patient #2). In contrast, another participant indicated: “And I will read what’s on the Brigham...I mean I know nothing, so I have to presume what they’re...writing is accurate” (Patient #3).

Theme 3: Education Presentation Can Be Enhanced With Graphics, Reminders, and End-User Resources

The presentation of the education should integrate appealing graphics and/or visuals to enhance education understanding and readability. For example, one participant explained that they

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shared with the patient "a cup that we have in the hospital,...just to give them a visual...[to think of that much fluid]" (Clinician #5). Participants particularly appreciated the graphics on MedlinePlus ("some nice graphics" [Patient #1]; "really good graphics" [Patient #2]). Hospital discharge information similarly uses easily identifiable graphics: "stop signs and green lights and arrows. ...very clear and patient friendly" (Clinician #6). Education content can also be enhanced with reminders, including nutrition or diet reminders ("remember to stay away from extra salt" [Clinician #4]) or medication reminders. One participant shared: "I do find it very convenient to have that alarm...because regardless of age,...to help for compliance" (Patient #1). Another participant also suggested a digital health navigator ("if you had a helper" [Patient #2]) to support education and app use ("I would absolutely do it as long as I learned how" [Patient #2]).

Sources of Education Content and Education Pathway Implications

As detailed in Table 1, the participant preferences expressed through the themes resulted in several implications for the sources of education content and the education pathway. The education content included medical condition–specific content for all 3 included conditions, with nutrition and medication content tailored to each condition. The primary education source was MedlinePlus, along with other reputable health websites, and all education links were structured and organized for end-user accessibility and health literacy.

Table 1. Secondary analysis findings and implications.

Constructs	Exemplar codes	Themes	Implications
Education content	• Discharge topics include new medications and any medication changes • Discharge teaching includes condition-specific nutrition and dietary information • Education should be specific to the patient's medical condition	Essential end user education includes condition-specific, nutrition, and medication content	• Education included medical condition–specific content for all 3 included conditions • Nutrition and medication content were tailored for each condition
Education considerations	• Information should be accurate • Education must consider end-user health literacy • Education must be easily accessible	Education must be accurate, accessible, and consider end-user health literacy	• Medline Plus was the primary education source, along with other reputable health websites • All education links were structured for end-user accessibility and health literacy
Education presentation and display	• Graphics can improve education understanding • Reminders can support end-user needs • Resources can support end-user uptake	Education presentation can be enhanced with graphics, reminders, and end-user resources	• Education sources included visual aids and appropriate graphics to enhance education • Reminders alert end-users to available education content • Resources including a digital health navigator, with in-hospital support involving education access

The presentation of education included visual aids and graphics to enhance education; reminders to alert end users to available education content; and resources including a digital health navigator for end-user support (Table 1). These resulting implications were all directly addressed as the team developed and refined the education content pathway ("education pathway;" Multimedia Appendix 1).

The 3 conditions (and combinations of MCCs including DM, CHF, and CKD) were mapped onto an education pathway organized by postdischarge day and then curated, prioritized, and linked. Education will be pushed to the participant's app interface, depending on the participant's condition and postdischarge day, following the pathway. A section of the education pathway is excerpted in Table 2; the full spreadsheet of the final resulting education pathway is included in Multimedia Appendix 1, with live hyperlinks for freely available education content.

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Table 2. Excerpt of the final education content pathway.

	Week 1			Week 2		
	Day 1	Day 2	Day 3	Day 1	Day 2	Day 3
Heart failure	Heart failure—discharge	Heart failure—medicine	Heart failure—home monitoring	Heart failure—overview	Heart failure—fluids and diuretics	Low salt diet
Diabetes	Diabetes type 2	Diabetes medicines	Diabetes type 2—meal planning	Managing your blood sugar	High blood sugar—self care	Low blood sugar—self care
Diabetes, CKD[a], and HF[b]	Heart failure—discharge	Diabetes type 2	CKD (AKF[c])	Heart failure—fluids and diuretics	Diabetes medicines	Keeping kidneys safe: smart choices about medicines (NIDDK[d])

[a]CKD: chronic kidney disease.

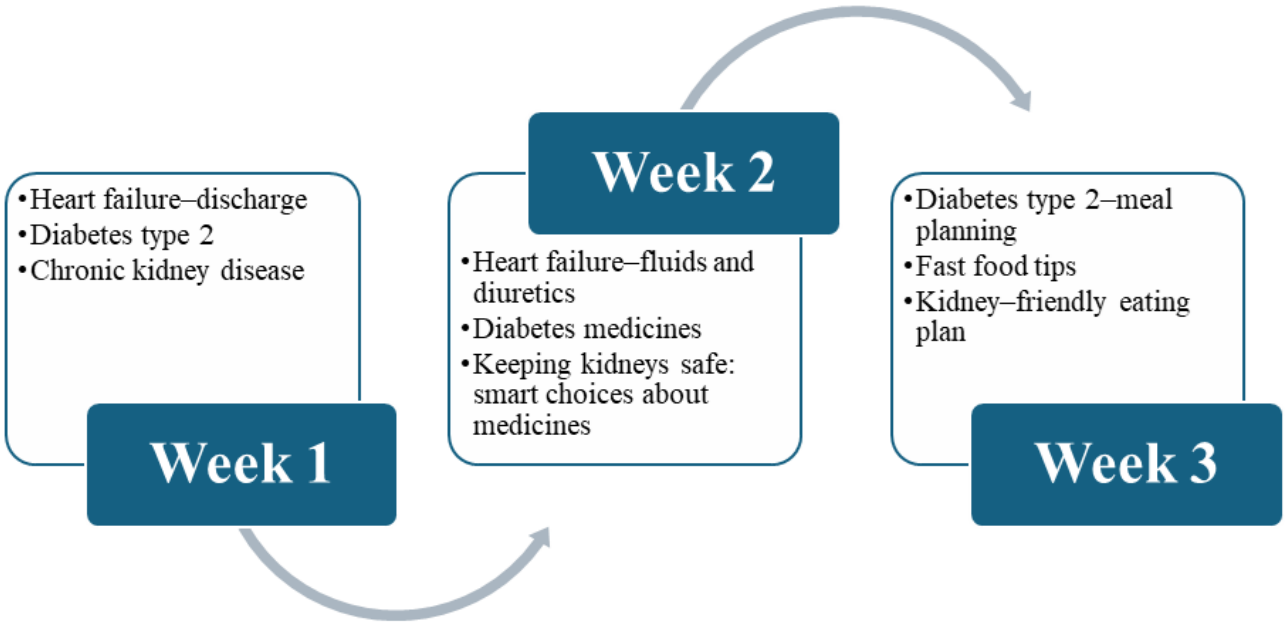
[b]HF: heart failure.

[c]AKF: American Kidney Fund.

[d]NIDDK: National Institute of Diabetes and Digestive and Kidney Diseases.

While MedlinePlus [30] education sources make up most of the knowledge links, additional information was added to supplement CKD education, including information from the American Kidney Fund and the National Institute of Diabetes and Digestive and Kidney Diseases, which are also open source. As indicated in Table 2, several education content topics were included within each week, and this is further depicted in Figure 3. The article title is displayed as the display text, and these titles are hyperlinks directly linked to web pages (and live). Noted with more detail in the full education pathway in Multimedia Appendix 1 are the additional scripts that help orient the patient or user to the learning objective anticipated if the article link is clicked and read.

Figure 3. Weeks 1, 2, and 3 education topics for a multiple chronic conditions intervention end user with diabetes, chronic kidney disease, and heart failure.



Discussion

Principal Findings

Through the secondary qualitative analysis of the data corpus, we identified necessary educational requirements of postdischarge information for patients with MCC, along with critical aspects of online patient education and, thereafter, transformed the findings into a targeted education content pathway. In sum, we have developed MCC care transition educational content that was integrated into our e-clinical pathway and application, also described in additional detail in a previous publication [14].

Barriers to self-efficacy for patients with chronic disease, including health literacy, access, and support, can be addressed with mobile apps and self-management programs [31,32]. Existing literature confirms the focus of this study and its findings, including the potential for apps to support self-management [33]. One randomized controlled trial of a personal health record mobile app found a maintained vs declining quality of care among participants who experienced the intervention [34]. Other literature has detailed how participants felt supported in their goal tracking through a mobile app [35] and reported increased motivation for behavior change [36]. As such, digital health technologies do have the potential to support patient outcomes. However, digital health

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technologies with targeted information for the education of patients with MCCs are key. Targeting self-management in the transition from hospital to home is critical in the education of patients with MCC. Despite the need, many educational resources, including online applications, only target one chronic illness, such as heart failure [37], or a specific self-management concept, such as fluid tracking [38]. Here, the team focused on providing comprehensive MCC educational content without contributing to cognitive overload. MedlinePlus [30] is the primary education source for the app education pathway and is a validated and free source of consumer health care educational content. In contrast to the available education from MedlinePlus for DM and CHF, unfortunately, detailed CKD information was insufficient for the established educational requirements. This is further illustrative of similar challenges with education scholarship for patients with CKD. For example, 1 review of available CKD apps found that nephrologists' app evaluations indicated the health care providers perceived a lack in quality in the available content [39]. Another study evaluating CKD websites found that their evaluation justified the recommendation for content improvements [40]. Furthermore, existing literature also reflects the continued challenges with inadequate app use rates and insufficient engagement with digital health interventions [41,42], reflecting an ongoing tension with the app intentions and their ultimate success. We further note that although this study focused on the isolated component of education (within a larger MCC app with a core innovation of integration across the care continuum), the bidirectional data exchange between the app and the electronic health record system has the potential to enhance shared decision making [43] and information exchange, including among patients, caregivers, and health care providers. This potential remains a future area of interest and scholarship.

Additionally, the educational pathway is generalizable and reproducible in other health care systems. It is also potentially useful outside of health care institutions as a structure establishing an end-user guided process on a mobile app. The work and process of the study team and the resulting education pathway are detailed and included in this manuscript specifically so that other health care systems, or others, can freely replicate the process. This information provided could be used by another facility to adjust the e-clinical pathway for their own needs, based on the description of the process in this manuscript and other related manuscripts [14], minimizing process burden and cost. The team used content in the public domain, which is generalizable as this content can be easily adopted and used in low resource settings. Stakeholder involvement in the educational requirement process was intended to increase potential uptake and dissemination [44]; disseminating knowledge increases the potential for impact [45]. Although other educational sources were considered, often with many benefits, including curated and organized content, one critical aim was to make the education pathway a process that could be replicated. As such, the study team decided to primarily use MedlinePlus [30] for the educational content, along with open-source CKD education from the American Kidney Fund and the National Institute of Diabetes and Digestive and Kidney Diseases. While MedlinePlus [30] is an exceptional, well-sourced, federally backed, and free education source, there were aspects of this education source that were oftentimes unwieldy, expansive, and not limited to care transitions information. Future work should consider positioning analysis within a framework of integrated care [46] or collaborative care models [47] to emphasize system-level requirements for cross-sector information flow and accountability.

Finally, the importance of accessible language, digital health navigators, and family involvement evident in the results also indicates concordance with the existing literature. Adult health literacy proficiency remains low and mobile apps focused on language and end-user accessibility can support aspects of health literacy, including health information seeking [48]. Participants in this study expressed their desire for robust support, such as through a digital navigator, and this is reflected in the available science expounding on the potential positive impact of digital health navigators on patient app use [49]. Participants also brought up the positive impact of family involvement in their own digital health technology experiences; existing scholarship confirms that family engagement and support can facilitate patients' adoption of a digital health solution [50], although further studies should also consider the digital literacy of caregivers as a complementary identified need [51]. In sum, future work involving mobile apps and other digital health technologies should remain mindful of the many barriers to participant recruitment and technology use, although our results suggest patient and family engagement, digital health navigator involvement, and language accessibility may be modifiable and successful factors to consider.

Limitations

This work has some limitations that should be noted. First, this study was conducted among participants very engaged with health care services and knowledgeable about the postdischarge process. However, this study intentionally and purposefully included early stakeholder involvement, extensive health care provider and patient representative reviews and feedback, and iterative work with the study team and experts to succinctly create targeted and essential educational content. Second, the secondary qualitative analysis of educational requirements was conducted before app completion and testing. Future work will be needed to confirm and validate educational content fit with app end-user needs and larger primary study aims. Future work will also need to consider sustainability of the app overall, including maintenance of education content and user feedback. Third, the secondary qualitative analysis methodology of the original dataset inherently constrains a full understanding of e-care team coordination and interprofessional perspectives. Future scholarship directly addressing these critical perspectives is needed.

Conclusions

This study effectively produced, organized, and vetted the educational requirements to support a patient with MCCs during the critical posthospitalization transition period. Our secondary qualitative analysis extended the work of the primary study with a conceptual focus on patient and caregiver educational requirements. Study findings support a deeper understanding of end-user education requirements and further enhanced the resulting education resources intended for the app in the primary

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study. The end-user educational requirements and the included resulting education pathway implemented in the study app are freely available to support future research, implementation, and evaluation efforts (including, potentially, contextual tailoring, scalability, and impact testing) aimed at improving care transitions for individuals with MCCs.

Acknowledgments

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Data Availability

The resulting education pathway table is provided as Multimedia Appendix 1, together with the manuscript. In addition, the datasets generated or analyzed during this study are available from the corresponding author upon reasonable request.

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Authors' Contributions

PCD and LS conceptualized the grant and acquired funding. PCD, LS, and JRJ conceptualized and wrote the original draft of the manuscript. JRJ, HW, CJT, ABM, LS, and PCD assisted with the conceptualization, conduct, and interpretation of the formal analysis and manuscript writing, reviewing, editing, and approval.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Completed education pathway.
[PDF File (Adobe PDF File), 76 KB - jopm_v18i1e83235_app1.pdf]

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Abbreviations

CHF: congestive heart failure

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CKD: chronic kidney disease
DM: diabetes mellitus
e-clinical: electronic clinical
IRB: institutional review board
MCCs: multiple chronic conditions

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Don’t Worry, We’ll Call You: An Anticipatory Guidance Framework for Addressing Test-Related Anxiety—Scanxiety

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Abstract

The 21st Century Cures Act information blocking rule that went into effect in 2021 in the United States requires that health systems not interfere with delivering test results to patients, including laboratory, pathology, and imaging results. Consequently, many health systems release results immediately, and patients often view results before the ordering clinician has seen them. Patients overwhelmingly want this access. In a 2023 multisite survey, 95.7% (7520/7859) of patients preferred immediate release. Yet the same survey found that 16.5% (403/2442) of patients receiving abnormal results reported increased worry from reading them before clinician contact. In this viewpoint, written with a patient coauthor living with a grade 2 astrocytoma, we argue that there are 2 distinct forms of anxiety. The distress of serious medical news is unavoidable. The anxiety of not knowing what a phrase means or when someone will contact the patient can be reduced. We propose that clinicians address the second form of anxiety at the moment of test ordering rather than when the result arrives. We identify 3 sources of distress when a result appears in a portal: threat, uncertainty, and loss of control. We use a real radiology result, “suspicious for tumor progression,” and the patient coauthor’s experience of the distress that patients call “scanxiety,” to illustrate these themes in an anticipatory guidance conversation. Borrowing the framework of anticipatory guidance from pediatric practice, we offer a 5-step conversation guide for clinicians at the time of test ordering: (1) inform the patient they are likely to see the result before the clinician can contact them, (2) tell the patient they have a choice whether to look immediately, (3) mention there are trusted resources for the patient to read about the result, (4) describe to the patient the best and worst case scenarios and how they would be contacted in each case, and (5) solicit questions. We pair this with recommendations for health systems and electronic health record vendors, principally that portals distinguish “you have a new test result” from “you have a message from your team” and that notification settings be easy to silence. We believe immediate patient access to test results is the right direction. We propose that anticipatory guidance is an important framework to reduce a major component of test-related anxiety and that it should be widely adopted by clinicians.

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KEYWORDS

patient-physician communication; patient portal; open notes; open results; patient engagement; patient anxiety; electronic health record; test result management

Introduction

Cancer diagnoses are bad news. Even more so, the anxiety surrounding a cancer diagnosis is magnified when the patient does not understand the report and it is unclear when a clinician will contact them about next steps. The first situation is unavoidable, while the second is entirely avoidable. In an ideal situation, patients would receive a biopsy, have it immediately reviewed, and then a trusted clinician would deliver the information in-person. However, in the context of the 21st Century Cures Act information blocking rule, immediacy is unrealistic for most clinicians. The rule, effective in April 2021 in the United States, prohibits health care organizations from interfering with patients’ access to their electronic health information [1,2]. In practice, laboratory, pathology, and imaging results are released to the patient portal as soon as they are finalized, and routinely before the ordering clinician has seen them. The old sayings “don’t worry, we’ll call you” and “no news is good news” are no longer acceptable practice. A new approach is needed for communicating with patients about the release of test results. This viewpoint has two aims: (1) to explain why the immediate release of test results creates a form of anxiety that is separate from the news itself; and (2) to offer clinicians a short, specific conversation—delivered when the test is ordered and not when the result arrives—that reduces

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that anxiety. We propose a 5-step guide for clinicians and companion recommendations for health systems and electronic health record (EHR) vendors.

Patient-Partnered Case Study

LS is a 42-year-old woman with grade 2 astrocytoma. She is clinically doing well and continues to recover from surgery. Unfortunately, there are concerning changes in her imaging results (Textbox 1).

Textbox 1. Actual radiology result.

Impression: since [January], new enhancing nodular FLAIR [fluid-attenuated inversion recovery] hyperintensity at the anterior aspect of the left parietal resection cavity, suspicious for tumor progression.

The patient expresses how she feels in the following comment.

> *I've lived with a slow-growing, malignant brain tumor (grade 2 astrocytoma) for more than a decade. The issue of recurrence isn't a matter of if, but rather, when. When it comes to scan-related anxiety—or "scanxiety," as it's better known among us patients—it doesn't matter how informed I am, I still feel it. Despite best efforts, I know that much of the cancer experience is out of my control.*
>
> *For me, the optimal waiting period between scan and answer should be as short as possible. Do I want the results shared with me in a face-to-face discussion with my oncologist? That is preferred. But would I prefer to wait 24 hours or longer for that answer to be delivered personally? Absolutely not.* [LS]

The term "scanxiety" was coined in 2011 by the writer and cancer survivor Bruce Feiler, describing the distress surrounding an imaging test in post-cancer follow-up, before the scan and until the result is announced [3]. It has since entered into use in peer-reviewed literature, including 2 scoping reviews and an analysis of how patients discuss scanxiety with one another on social media [4-6].

After the 21st Century Cures Act went into effect in 2021, LS and millions of other US adults had immediate access to their test results through online patient portals. In a 2023 multisite survey of patients and care partners, most respondents (7520/7859, 95.7%) preferred to receive results immediately, including 2337 of 2453 (95.3%) who received results they perceived as not normal [7]. Overall, few respondents (411/5473, 7.5%) reported that reviewing results before a clinician contacted them increased their worry. However, that figure was considerably higher among those receiving abnormal results (403/2442, 16.5%) than among those whose results were normal (294/5918, 5.0%; odds ratio 2.71, 99% CI 1.96 - 3.74). An earlier 2013 study published by Kaiser Permanente found similar results [8].

There is tension in the drive toward information immediacy and transparency vs the consequences of unintended psychological harm. Scan-associated anxiety is common and has been characterized in peer-reviewed literature, including 2 scoping reviews of adults with cancer [4,5]. Its scale is also visible in portal behavior. In an analysis of 968,774 results reviewed by 290,349 patients, patients repeatedly refreshed the portal while awaiting 250,796 (25.9%) results overall, including 25,280 of 64,356 (39.3%) results from tests that the authors classified as high sensitivity. This was a pattern the investigators interpret as a potential marker of worry during the waiting period [9]. There have also been anecdotal reports of increased anger, anxiety, and stress among patients receiving bad news through immediate test result access [10]. The American Medical Association reports that a number of states are moving to enable exceptions to the federal rule on prohibition of information blocking [11].

How might we help LS and her oncologist resolve this common scenario? We believe there is an effective way forward.

Anticipatory Guidance Framework

The framework of anticipatory guidance can help. This term has been used in pediatric literature to indicate guidance that a provider gives a parent as their child grows, including common expectations about development in the coming months and years [12]. In the case of LS and others, we use the term to forecast possible patient reactions to an unknown test result as a means of reducing associated anxiety.

Test-related anxiety is not a disease. Instead, scanxiety is a normal reaction to a potentially life-threatening situation. As medical professionals, we have a duty to validate, to understand, and to improve this experience for patients.

Patients who receive test results without context through online patient portals face 3 risks.

1. *Threat state*. Anxiety arises from real or perceived threat. The greater the threat, the more likely the anxiety. Thus, anxiety is magnified when test results pose a threat to a person's health or life.
2. *Uncertainty*. Patients experience uncertainty in 3 ways. There is uncertainty over the meaning of medical terms, uncertainty over the timing of discussing the results with their provider, and uncertainty of what their treatment choices are.
3. *Lack of control*. Patients experience lack of control when they receive test results at unpredictable times with notifications that may be unwanted and when they cannot reach their doctor immediately to discuss the results.

When considering patient LS, her situation contains all 3 risks. "Suspicious for tumor progression" is a threat to health and to life. Uncertainty appears twice: in the meaning of "new enhancing nodular FLAIR [fluid-attenuated inversion recovery] hyperintensity" and in not knowing when her oncologist will call. Lack of control is in the timing: the result arrived when the radiologist signed it, not when she was ready to read it.

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Anticipatory guidance offered when the scan was ordered would not have changed the finding; yet, it would have addressed the second and third risks.

Efforts to reduce test-related anxiety have concentrated on how a result is presented once it has been released; a 2024 systematic review found that presentation format measurably affects patient understanding [13]. Less attention has been given to what is said before the test is ordered. Notably, the 2023 survey found no association between precounseling and reduced worry (odds ratio 0.70, 99% CI 0.31 - 1.59) [7]. That null result described existing practice: "precounseled" was an unstructured and undefined yes/no survey item covering everything from a thorough conversation to a passing remark. Specifying what the conversation should contain is precisely the gap this framework fills.

Patient Perspective

The patient shares her perspective on offering guidance:

> *As a veteran portal user, I'm fine reviewing results online while waiting for a more formal discussion with my oncologist. However—as a patient advocate who connects across diverse patient communities—I've learned not all people wish to receive results at the same pace as myself.*
>
> *Before ordering any new test, clinicians should offer guidance about what a patient can expect when results are released to online portals. A conversation as simple as the following could be deployed at the time the test is ordered: "I'm ordering a test. You might see the result before me. Worst case, this could be X. and this is how I would reach you. Best case, this could be Y. and this is how we would reach you. What questions do you have?"* [LS]

Recommendations for Clinicians

Clinicians should adopt anticipatory guidance as a standard process when ordering tests to help patients manage threat, reduce uncertainty, and regain agency (Textbox 2). Clinicians can empathize with patients that receiving test results via the portal can be anxiety-producing, and that this is a normal human reaction. Clinicians can assure patients, "We will work together on this." Clinicians can also state how and when the patient can expect contact with the health care team to reduce uncertainty. Clinicians can remind patients that they have control over when to view results, including their ability to turn off notifications in the portal and reduce unwanted early notifications. The intensity of anticipatory guidance should scale with the stakes of the test. A routine lipid panel may warrant no more than a brief statement that results will appear in the portal; complex imaging, genetic testing, and pathology warrant the full conversation in Textbox 2.

Textbox 2. Anticipatory guidance: 5-step conversation guide for clinicians and patients.

- I am ordering a test. *You may see results before I can contact you.*
- *You have a choice*: look immediately or wait to hear from me.
- *If you choose to look*: medlineplus.gov is a trusted resource [14].
- *Here are the best and worst cases*, and how we would contact you.
- *What questions do you have?*

Recommendations for Health Systems and EHR Vendors

EHR systems should implement features on patient portals that make it as easy for patients to "turn off notifications" as it is to silence a cell phone. Further, portal notifications should distinguish between "You have a new test result" and "You have a message from your provider/team" [15]. This way, patients can choose to ignore the automated result and wait for a personal message. We believe a better understanding of a person's control will be beneficial for patients who experience increased worry when viewing test results, without impairing the experience of patients who prefer immediate access to results. We also recommend all clinicians move the discussion on the possible meaning of test results to the time of test ordering. This can be done with a brief anticipatory guidance discussion (Textboxes 2 and 3) at the time testing is conducted, rather than waiting until results are available (Multimedia Appendices 1 and 2).

Textbox 3. Anticipatory guidance: guidance and proposed policy for health systems.

- *Inform clinicians and staff*: test results deliver to the patient portal immediately.
- *Pre-visit testing*: make it easy for clinicians to order tests *before* appointments.
- Develop and distribute the *1-page anticipatory guidance education for clinicians.*
- Develop and distribute the *1-page anticipatory guidance education for patients* at laboratory draw stations, radiology, etc.
- *Add anticipatory guidance language* to the results section of the patient portal.
- Make it easy for patients to *adjust their notification settings* within the portal.

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Anticipatory guidance is not equally available to every patient. Those with limited English proficiency, limited health or digital literacy, unreliable internet access, cognitive impairment, or high baseline anxiety may be the least equipped to interpret an unaccompanied result and least likely to find a notification setting to change. Some rely on a caregiver to read results. Guidance offered at the time of ordering must therefore be delivered in the patient's language and at an accessible reading level, and health systems should not treat portal notification controls as a substitute for direct contact with patients who are unlikely to use a portal at all.

Anticipatory guidance will not change the fact that some health news will be serious or life-threatening. However, this framework offers an opportunity to understand the patient experience and reduce unintended negative impact to patients as they receive unfiltered test results and wait for guidance from their care team.

Whether anticipatory guidance changes what patients experience is an empirical question. The outcomes most worth measuring are patient-reported anxiety while awaiting results, the interval from result release to clinician contact, and the volume of patient-initiated messages after release.

We want to be clear about what this framework does and does not do. It addresses the avoidable anxiety of uncertainty and lack of control: not knowing what a word means or what happens next. It will not reduce the distress of serious medical news.

Conclusions

The immediate release of test results to patients improves information transparency and timeliness. At the same time, it could increase the anxiety of patients receiving unfiltered results via the patient portal. Anticipatory guidance for test results is a 5-step conversation guide that can reduce patient anxiety about next steps (Textbox 2). A patient who reads "suspicious for tumor progression" should feel something. Our aim is that she not also be left alone with it.

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Generative AI Use

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Conflicts of Interest

The authors all declare no conflict of interest in relation to the content included in this manuscript.

Multimedia Appendix 1
Example of patient education on anticipatory guidance.
[PDF File, 829 KB - jopm_v18i1e89201_app1.pdf]

Multimedia Appendix 2
Example of clinician education on anticipatory guidance.
[PDF File, 968 KB - jopm_v18i1e89201_app2.pdf]

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Abbreviations

EHR: electronic health record
FLAIR: fluid-attenuated inversion recovery

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Participatory Digital Twins for Chronic Care: From Predictive Models to Shared Sensemaking

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Abstract

Health digital twins, computational models that integrate longitudinal data, simulation, and forecasting, are increasingly proposed as tools for chronic care management. However, most current implementations are expert oriented, prioritizing technical optimization and clinical prediction while offering limited support for patient understanding, engagement, or participation. This orientation is particularly misaligned with chronic care, which unfolds largely outside clinical settings and depends on patients' daily decisions, social context, and sustained engagement over time. In this viewpoint, we argue for reframing digital twins as participatory systems that support shared sensemaking among patients, caregivers, and clinicians rather than functioning solely as directive, expert-facing tools. We propose a conceptual framework that positions participatory digital twins as boundary objects capable of bridging computational models, clinical reasoning, and lived experience. Within this framework, generative artificial intelligence serves as a translation and interaction layer, enabling plain-language dialogue, exploration of uncertainty, and "what-if" reasoning that allows users to interpret model outputs in relation to their own contexts, goals, and constraints. We outline key design principles for participatory digital twins, including visible uncertainty, negotiated rather than prescriptive care, mechanisms for incorporating patient context and social drivers of health, and governance structures that support accountability and recourse. At the same time, this approach depends on meaningful opportunities for participation; appropriate safeguards around generative interaction; and careful attention to privacy, consent, and uneven access to digital resources. By shifting the focus from optimization alone to understanding, interaction, and trust, participatory digital twins offer a pathway toward more equitable, human-centered, and sustainable models of artificial intelligence–enabled chronic care.

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KEYWORDS

participatory artificial intelligence; digital twins; chronic care; shared sensemaking; human-centered artificial intelligence; human-centered AI; artificial intelligence; AI

Introduction

Digital twins have rapidly emerged as a promising paradigm in health care, particularly for chronic care management [1,2]. By integrating longitudinal data, computational models, and simulation capabilities, health digital twins aim to represent an individual's evolving physiological state and support forecasting, scenario analysis, and clinical decision-making. In managing chronic conditions such as diabetes, hypertension, and cardiovascular disease, where day-to-day self-management, longitudinal monitoring, and repeated behavioral trade-offs are central, digital twins offer the potential to shift from episodic care toward continuous, data-informed management [3-5].

However, to date, most health digital twin efforts have been designed primarily as expert-oriented systems [2,6]. Their core functionalities—prediction, simulation, and optimization—are typically intended for interpretation and use by clinicians, researchers, or health systems, with success evaluated using technical performance metrics such as accuracy or predictive error [6]. In this context, "human in the loop" most often refers to clinical oversight rather than meaningful engagement by patients or caregivers.

This orientation presents a critical limitation for chronic care. Unlike acute conditions, chronic care is continuous; unfolds largely outside of clinical settings; and depends heavily on patients' daily decisions, contextual knowledge, and sustained engagement [7-9]. Patients are not merely data sources for digital twins; they are the individuals who live with uncertainty, interpret bodily signals, and negotiate trade-offs between medical recommendations and everyday life. When digital twins

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function as opaque or directive tools, they risk reinforcing passive roles for patients, undermining trust, and limiting their real-world impact.

At the same time, advances in generative artificial intelligence (GenAI), particularly large language models (LLMs), have created new opportunities to reimagine how people interact with complex computational systems [10,11]. In the context of participatory digital twins (PDTs), the value of GenAI lies less in generating de novo medical advice than in serving as a constrained translation and interaction layer around model-based outputs, helping users ask questions, surface missing context, and explore alternative scenarios in plain language. However, this role should not be treated uncritically. In health contexts, LLMs may hallucinate facts; present incorrect statements with unwarranted fluency; produce variable responses across prompts or sessions; and communicate uncertainty unreliably, particularly when asked to express risk numerically or probabilistically [11-13]. For this reason, any use of GenAI in PDTs should remain grounded in traceable model outputs, explicitly uncertainty aware, and subject to appropriate clinical oversight rather than positioned as a stand-alone source of medical advice [12,14,15].

This shift is also timely because members of the public are increasingly turning to general-purpose LLMs for health information and advice. Recent survey studies suggest that LLM-based chatbots are already being used for health queries by a substantial minority of users, particularly younger adults, whereas broader US survey data indicate that artificial intelligence (AI) chatbots have become an emerging source of health information for the public. This trend does not make general-purpose LLM use clinically reliable; rather, it underscores the urgency of developing health AI systems that offer bounded interaction, traceable outputs, explicit uncertainty, and clinician-grounded sensemaking instead of decontextualized stand-alone chatbot advice. In this respect, PDTs can be understood not simply as another application of conversational AI but as a more accountable sociotechnical response to a landscape in which conversational systems are already shaping how people seek and interpret health guidance.

This reframing should be understood as building on rather than displacing established traditions of participatory design, co-design, and patient-centered technology development in health informatics [16-19]. Prior work in these traditions has shown that patients, caregivers, and clinicians can contribute experiential, practical, and organizational knowledge that improves the relevance and usability of health technologies. In particular, participatory design has emphasized the active involvement of users in shaping technologies that affect care, whereas co-design scholarship has framed such work as a form of collective creativity and shared problem formulation [18,20]. PDTs extend this literature in a more specific direction: they are concerned not only with who participates in designing a system but also with how participation is sustained during system use, when model outputs, uncertainty, contextual annotations, and care trade-offs must be interpreted and negotiated over time [19]. In this sense, PDTs move participation from a primarily design-stage methodology toward an ongoing, model-mediated practice of shared sensemaking in chronic care.

In this viewpoint, we argue for a reframing of health digital twins as participatory systems for chronic care. We propose that digital twins should be designed not only to predict or simulate future states but also to support shared understanding; patient and caregiver agency; and collaborative decision-making among patients, caregivers, and clinicians. Drawing on principles from participatory medicine and human-centered AI, we introduce a conceptual framework for PDTs and outline design principles that prioritize interaction, transparency, and trust. Through this reframing, we aim to highlight how PDTs can contribute to more equitable, sustainable, and democratically governed chronic care.

Limitations of Expert-Oriented Digital Twins in Chronic Care

Health digital twins have advanced rapidly in technical sophistication, integrating diverse data streams, physiological models, and simulation capabilities to support prediction and decision-making [1,2]. Despite these advances, most existing digital twin implementations in chronic care remain expert oriented by design [2,6]. Their interfaces, outputs, and evaluation frameworks primarily assume users with clinical or technical expertise, leaving limited room for meaningful patient interaction, interpretation, or participation.

A central limitation of expert-oriented digital twins lies in their reliance on opaque or directive outputs [21,22]. Predictions or recommendations are often presented as single-point alerts, optimized actions, or summarized risk scores, with minimal explanation of underlying assumptions, uncertainty, or contextual dependencies. For patients managing chronic conditions in everyday life, such outputs can be difficult to reconcile with lived experience. When system reasoning is hidden, patients may be unable to assess whether a recommendation aligns with their immediate context (eg, a skipped meal, acute stress, or unexpected physical activity) or long-term goals, leading to confusion, mistrust, or disengagement [23,24].

Expert-oriented designs also tend to treat patient involvement primarily as data contribution rather than knowledge participation or decision-making [1,6]. Patients generate large volumes of longitudinal data through wearables, sensors, and self-reports, yet their experiential insights, such as stress, fatigue, social obligations, or deviations from routine, are rarely incorporated in ways that influence model interpretation or behavior. As a result, digital twins may accurately capture physiological signals while overlooking contextual and social drivers of health—such as caregiving demands, work conditions, or social support—that shape real-world behaviors and outcomes. Consequently, a digital twin may be mathematically robust but ecologically invalid, limiting its usefulness in real-world chronic care [25].

This asymmetry has important implications for patient behavior and engagement. Effective chronic care depends not only on accurate forecasting or simulation but also on patients' understanding of why certain trajectories are predicted and how alternative actions may influence outcomes [26]. Systems that

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prioritize optimization over comprehension risk reinforcing passive roles for patients, positioning them as recipients of algorithmic directives rather than active partners in care. Over time, this dynamic can erode trust, reduce adherence, and undermine sustained engagement.

Finally, expert-oriented digital twins are typically evaluated using technical performance metrics such as prediction accuracy, error reduction, or computational efficiency that fail to capture participatory value [27,28]. These metrics provide little insight into whether patients understand model outputs, feel confident using them, or perceive the system as supporting shared decision-making. Even highly accurate digital twins may have limited real-world value if patients do not understand, trust, or meaningfully use their outputs in care [28,29]. Without evaluation criteria that reflect patient engagement, patients' ability to understand and reason about model outputs, and trust, the benefits of digital twins may remain confined to controlled clinical settings rather than extending into everyday chronic care.

Taken together, these limitations suggest that advancing digital twins for chronic care requires more than incremental improvements in modeling or simulation. It calls for a fundamental reorientation toward participatory interaction, in which patients are recognized as knowledgeable stakeholders who can interpret, question, and shape digital twin–driven insights. This shift sets the stage for redefining digital twins as shared systems rather than expert-only tools.

Defining PDTs

To address the limitations of expert-oriented digital twins in chronic care, we propose the concept of PDTs. Rather than positioning digital twins solely as technical systems for prediction or simulation, PDTs are designed as shared sociotechnical systems that enable patients, caregivers, and clinicians to jointly explore, interpret, and reason about health trajectories over time.

Therefore, PDTs are not intended as a substitute for participatory design or co-design approaches. Rather, they build on those traditions while addressing a problem that becomes especially salient in data-intensive, model-driven chronic care: participation must continue after deployment, at the point where predictions are produced, uncertainty is encountered, and recommendations are interpreted in everyday life [16,19,20]. A system may be co-designed during development and still function as an opaque, expert-oriented artifact in use. PDTs seek to address this gap by treating participation not only as an upstream design principle but also as a downstream interpretive practice through which patients, caregivers, and clinicians can question, contextualize, and negotiate model-driven insights over time.

At the core of this reframing is a shift in how participation is understood. In most existing implementations, patient participation is implicit and largely confined to data generation (ie, patients contribute data), whereas interpretation and decision-making remain centralized within expert workflows. PDTs, in contrast, treat patients as epistemic agents: individuals capable of generating, interpreting, and applying knowledge about their own bodies in collaboration with clinical expertise. This framing recognizes that patients possess contextual and experiential knowledge—such as symptoms, stressors, routines, preferences, and social circumstances—that is essential for meaningful chronic care but is often absent from purely clinician-driven representations.

However, caregiver participation should not be assumed to be equivalent to direct patient input. Caregivers often contribute important observational, relational, and logistical knowledge about daily routines, functional changes, treatment adherence, and the social context of care. Such input can substantially enrich interpretation, particularly when chronic care is practically shared or when a patient's ability to engage directly is temporary, fluctuating, or limited. At the same time, caregiver accounts remain second-person perspectives rather than direct expressions of the patient's lived experience, priorities, or preferences. For this reason, PDTs should treat caregiver input as complementary, role specific, and explicitly attributed rather than interchangeable with patient-reported knowledge. Mediated participation may be appropriate when direct patient engagement is constrained by age, illness severity, cognitive or communication limitations, or other barriers to sustained interaction; however, the scope of such substitution should remain transparent and, where possible, distinguish among observed circumstances, inferred needs, and explicitly expressed patient goals. In this way, caregiver involvement can support participatory sensemaking without collapsing proxy contribution into first-person patient agency.

PDTs function as boundary objects [30] that bridge diverse forms of expertise. In this context, the term is used in a more specific sense than simply referring to a mediating artifact or communication aid. PDTs have a shared underlying structure that is a common model, data substrate, and evolving representation of the patient's condition while still allowing for interpretive flexibility across stakeholders. Clinicians may use the twin to examine risk trajectories and treatment implications; patients and caregivers may use the same representation to understand trade-offs, surface missing context, and relate model outputs to daily life. PDTs qualify as boundary objects not merely because they sit between groups but because they enable coordination across communities of practice without requiring those communities to adopt identical interpretations, vocabularies, or priorities.

A defining feature of PDTs is their support for interactive sensemaking. Rather than delivering static predictions or optimized recommendations, PDTs enable users to ask questions, explore alternatives, and examine uncertainty. Patients can engage in "what-if" reasoning, reflect on how contextual factors influence outcomes, and negotiate trade-offs between competing goals (eg, maintaining strict glycemic control vs enjoying a holiday meal with family). Through this process, the digital twin becomes a tool for understanding and learning, not merely for compliance.

Importantly, participation in this context does not imply transferring clinical responsibility to patients or diminishing the role of professional expertise. Instead, PDTs are intended to reconfigure collaboration in chronic care. Clinicians retain

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their interpretive and decision-making authority, whereas patients gain greater insight into model assumptions, reasoning processes, and potential consequences of different actions. This shared engagement supports trust, aligns expectations, and enables more nuanced and personalized care decisions.

Finally, PDTs emphasize bidirectional influence between human input and computational models. Patient and caregiver feedback, such as corrections, contextual annotations, or deviations from predicted behavior, can refine how outputs are interpreted and how future interactions are configured. However, such feedback should not be treated as a uniform or sufficient mechanism for correcting bias across all users. Its value depends on whether participation is meaningful, attributable, and adequately supported; when those conditions are absent, PDTs still require clinician oversight and other governance safeguards to prevent model outputs from acquiring unwarranted authority.

Together, these characteristics distinguish PDTs not only from conventional expert-oriented systems but also from approaches in which participation is concentrated primarily at the stage of system design. By centering epistemic agency, boundary object functionality, and interactive sensemaking, PDTs provide a conceptual foundation for reimagining how AI-enabled systems can support shared understanding and democratic engagement in chronic care.

The feasibility and value of PDTs are likely to vary across chronic care contexts. PDTs are most plausibly suited to conditions in which care depends on ongoing self-management; recurrent behavioral trade-offs; and sufficient opportunity for reflection, communication, and iterative dialogue, such as type 2 diabetes, hypertension, and selected forms of cardiovascular risk management. Their applicability is less straightforward in contexts where direct participation is developmentally, cognitively, or structurally constrained. In pediatric chronic care, for example, participation is often necessarily mediated through parents or guardians; in advanced dementia or other conditions involving substantially impaired decisional capacity, sustained interpretive dialogue may be limited or infeasible. Similarly, patients with low digital literacy, limited language concordance, or unreliable access to digital tools may be excluded from participatory features unless accommodations, supported pathways, and nondigital alternatives are deliberately built in. In such settings, participation may still occur in mediated form, but it should not be treated as equivalent to first-person patient engagement. Therefore, PDTs should be understood not as a universal model for all chronic illnesses but as a condition-sensitive design framework whose appropriateness depends on the clinical scenario, the capacities of the people involved, and the organizational and relational supports available to make participation meaningful in practice.

In the next section, we translate this definition into a conceptual framework that illustrates where and how participation can be operationalized within digital twin architectures.

A Conceptual Framework for PDTs

To operationalize the concept of PDTs, we propose a layered conceptual framework—the PDT framework—that makes explicit where and how participation occurs within digital twin–enabled chronic care systems. This framework reframes digital twins not as isolated technical artifacts but as sociotechnical infrastructures that integrate computation, interaction, and governance to support shared understanding and collaborative decision-making.

Core Data and Modeling Layer

At the core of the framework is the data and modeling layer, which corresponds to the traditional technical foundation of a digital twin. This layer integrates longitudinal clinical data; patient-generated data (eg, wearable sensors and self-reports); and computational models that support state estimation, simulation, and forecasting. Its primary function is to represent the evolving physiological dynamics relevant to chronic care.

In conventional digital twin architectures, this layer is largely invisible to patients and is accessed primarily by clinicians or technical experts. In participatory frameworks, while the computational complexity may remain hidden, the provenance and selection of data must be transparent, allowing patients to verify what information is driving the model. Insight into data sources such as recent activity, sensor readings, or contextual annotations enables patients to recognize omissions, question assumptions, and meaningfully engage with model outputs without requiring technical expertise.

Interaction and Translation Layer: The Role of GenAI

Surrounding the core technical layer is the interaction and translation layer, where participation becomes possible. This layer mediates between mathematically complex models and human understanding, enabling users to engage with digital twin outputs through dialogue, exploration, and explanation.

GenAI, particularly LLMs, can play an important but bounded role at this layer. Rather than functioning as autonomous decision-makers, LLMs are better understood as translational agents that help render digital twin outputs more accessible through plain-language explanation, interactive questioning, and scenario-based reasoning. Used in this constrained way, GenAI can support “why” and “what-if” inquiries; help elicit missing contextual information; and make model-based trade-offs more discussable for patients, caregivers, and clinicians [11].

At the same time, this layer introduces nontrivial risks. LLMs may hallucinate content; generate fluent but incorrect explanations; respond inconsistently across prompts or sessions; and struggle to represent uncertainty faithfully, especially when numerical risk or confidence estimates are implied [11-13]. In a chronic care setting, these failure modes could distort rather than clarify the relationship among model output, lived context, and clinical judgment.

For this reason, GenAI within PDTs should be constrained by design. It should be grounded in traceable digital twin data and scenario outputs; limited to interpretable tasks such as explanation, contextual elicitation, and comparison of predefined alternatives; and paired with safeguards such as explicit source attribution, audit trails, uncertainty signaling, and clinician review in higher-risk situations [14,15]. Under these conditions,

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the interaction layer can support shared sensemaking without treating conversational fluency itself as evidence of clinical reliability.

Governance and Social Layer

The outer layer of the framework is the governance and social layer, which situates PDTs within broader ethical, organizational, and relational contexts. Participation in chronic care is not only a matter of interface design; it also depends on how responsibility, authority, and accountability are negotiated among patients, clinicians, caregivers, and health systems.

This layer encompasses mechanisms for communicating uncertainty, managing consent, providing avenues for recourse when models fail, and supporting shared responsibility for outcomes. By explicitly addressing what happens when a digital twin's guidance is questioned or ignored or leads to adverse outcomes, participatory systems acknowledge the inherently probabilistic nature of model-driven care. This governance layer is also where issues of equity, trust, and democratic deliberation become salient, ensuring that participation is accompanied by meaningful safeguards rather than symbolic inclusion.

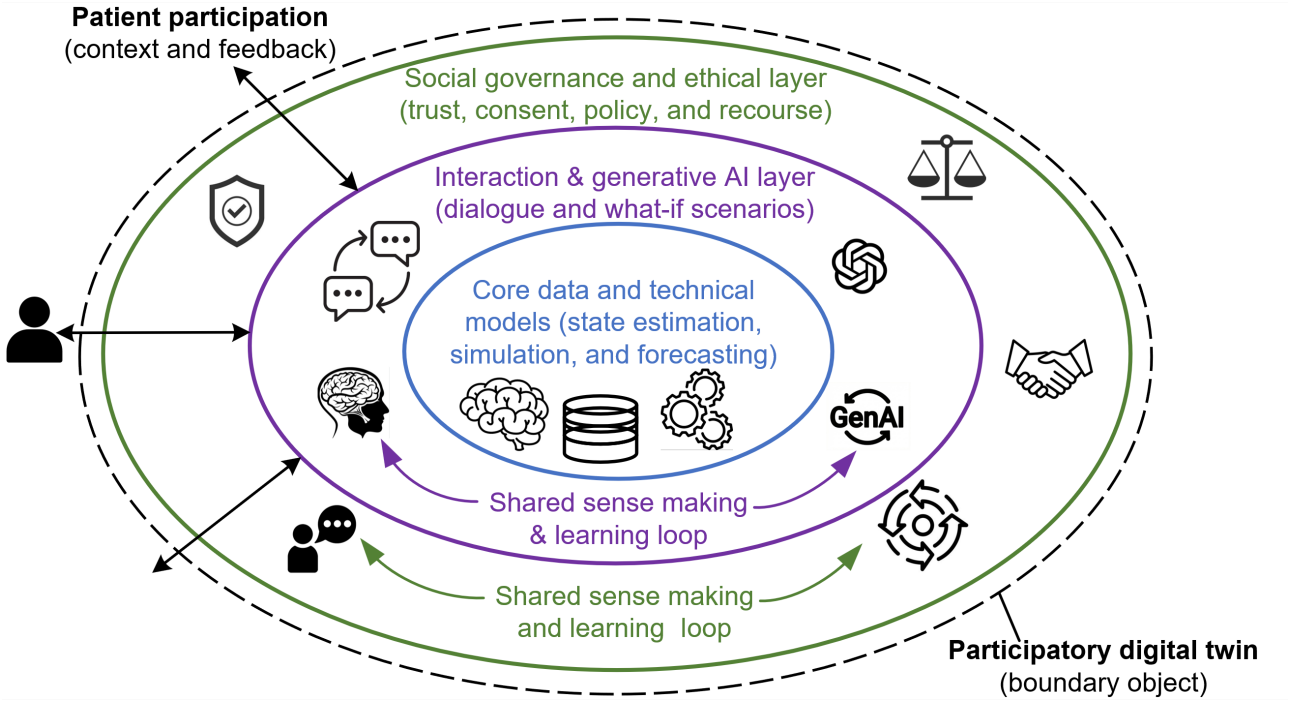
Locating Participation Across Layers

A key contribution of this framework is its explicit identification of where participation occurs. Participation is not limited to data entry at the technical core but emerges primarily at the interaction and governance layers, where patients can (1) interpret and question model outputs, (2) verify and annotate data inputs, (3) explore alternative scenarios and trade-offs, (4) participate in shared decision-making conversations, and (5) exercise recourse when recommendations conflict with lived experience.

Through feedback loops that connect these layers, patient input can inform interpretation and guide ongoing system refinement, helping ensure that digital twins remain aligned with patients' changing realities over time. This layered structure is summarized in Figure 1.

Table 1 summarizes the conceptual shift from expert-oriented digital twins to PDTs across key design dimensions, situating the proposed framework within broader paradigmatic differences in how digital twins are designed and evaluated. Textbox 1 illustrates this contrast through a comparative vignette that shows how an expert-oriented digital twin and a PDT may lead to different user experiences and care decisions.

Figure 1. The layered participatory digital twin conceptual framework depicting participatory digital twins as boundary objects that connect computational models, generative artificial intelligence (AI)–mediated interaction, and social governance through a shared representation that can be interpreted differently yet used coordinately by patients, caregivers, clinicians, and health systems. By visualizing participation as a structural feature rather than an afterthought, the framework highlights how digital twins can evolve from expert-oriented tools into shared systems that support understanding, agency, and trust in chronic care.



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Table . Contrasting design paradigms for health digital twins.

Design dimension	Expert-oriented digital twins (current state)	Participatory digital twins (proposed state)
Primary goal	Optimization of clinical outcomes and predictive accuracy	Shared understanding, epistemic agency, and trust
Interaction model	Directive: alerts, risk scores, and prescriptive recommendations	Dialogic: exploration of "what-if" scenarios, trade-offs, and alternatives
Role of the user	Data source: passive recipient of model outputs	Knowledge partner: active contributor of context and constraints
Handling of uncertainty	Hidden: uncertainty is minimized or smoothed over to project confidence	Visible: uncertainty is visualized as a feature to support calibration of trust
Feedback loop	System centric: data used primarily to retrain the model (technical loop)	Human centric: user input refines model interpretation and context over time
Success metrics	Low error rates; adherence to recommendations	User comprehension; perceived engagement and agency; shared decision quality; sustained use over time; and trust, acceptability, and implementation fit (Textbox 1)

Textbox 1. Textbox 1. Comparative vignette: from "black box" to "shared sandbox."

Scenario

- Maria, an administrator aged 55 y with type 2 diabetes, has been experiencing erratic glucose levels due to workplace stress. She uses a digital twin app to manage her insulin.

Case A: the standard (expert-oriented) digital twin

- The interaction: the system analyzes her data and issues a single alert—"Predicted High. Increase Bolus by 2 Units."
- The user experience: Maria feels hungry (a sign of *low* blood sugar) and confused. She suspects that the artificial intelligence (AI) does not know that she just climbed 3 flights of stairs. Because the reasoning is opaque ("black box"), she distrusts the prediction.
- The outcome: she ignores the alert. Later, her glucose spikes because the AI correctly predicted a delayed rise from protein but failed to explain it. Maria views the tool as unreliable and disengages.

Case B: the participatory (human-centered) digital twin

- The interaction: the system detects a trend but opens a "what-if" dialogue. It asks, "I see a trend suggesting a spike. Are you planning any activity?" Maria indicates that she recently took the stairs.
- The translation: the twin updates the graph in real time. It explains, "The stairs help, but the protein from breakfast may still cause a rise in 90 minutes. Here is what happens if you take +2 units vs. if you take a walk."
- The outcome: Maria understands *why* the spike was predicted. She chooses to take a walk (negotiated care). She feels a sense of *epistemic agency*—she used the tool to make sense of her body rather than just following orders.

Design Principles for PDTs

From Framework to Design Principles

Translating PDTs from concept to practice requires a shift in design priorities. Rather than optimizing solely for predictive performance or computational efficiency, PDTs must be designed to support understanding, agency, and trust over time. On the basis of the framework described above, we propose the following design principles to guide the development of PDTs for chronic care.

Design for Shared Understanding, Not Just Optimization

Traditional digital twins are often optimized to recommend a single "best" action based on model outputs. PDTs, in contrast, should prioritize shared understanding over directive efficiency. Systems should present multiple plausible scenarios, explain trade-offs, and support discussion rather than issuing unilateral recommendations. This shift recognizes that optimal decisions in chronic care are context dependent and value laden, not purely computational.

Translate Models Into Dialogue

Mathematical models and simulations must be made accessible through interaction. Therefore, PDTs should incorporate translation mechanisms, potentially including GenAI-mediated dialogue, that allow users to ask questions, request clarification, and explore alternatives in plain language. However, the translation layer should be constrained to tasks for which grounding is possible: explaining traceable model outputs, eliciting missing context, comparing predefined scenarios, and signaling uncertainty rather than inventing new clinical rationales or offering ungrounded advice [12-15]. Dialogue in this sense is a means of structuring shared interpretation and

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supporting health literacy, not of delegating clinical judgment to a conversational model.

Visualize Uncertainty as a Feature

Uncertainty is inherent in model-driven predictions, particularly in chronic care contexts characterized by incomplete data and behavioral variability. Rather than obscuring uncertainty, PDTs should make uncertainty visible through intuitive visualizations and explanations. Communicating what the system "knows," "infers," and "guesses" allows patients and clinicians to calibrate trust appropriately and make more informed decisions.

Enable User Correction and Contextualization

PDTs should allow users to identify missing, outdated, or misinterpreted context and annotate model inputs accordingly. Features that enable patients to indicate stress, unusual activity, dietary changes, transportation barriers, work constraints, caregiving responsibilities, medication affordability, or other relevant social drivers of health transform user input from passive data contribution into meaningful knowledge participation. Such information need not always be modeled as a permanent variable in the core system; in many cases, it may be more appropriately incorporated as time-sensitive contextual annotation that helps explain or reinterpret model outputs in light of lived circumstances. This design helps ensure that model interpretations remain ecologically valid and aligned with everyday chronic care.

Support Negotiated, Not Directive, Care

In participatory systems, care decisions emerge through negotiation, not compliance. Digital twins should support exploration of trade-offs between competing goals, such as glycemic control, quality of life, and daily constraints, rather than prescribing fixed actions. By framing recommendations as options to be discussed rather than orders to be followed, PDTs foster agency, trust, and long-term engagement.

Design for Accountability, Recourse, and Trust

Participation without safeguards risks shifting responsibility without authority. Therefore, PDTs must include mechanisms for accountability and recourse that clarify how decisions are documented; how disagreements are handled; and what happens when model-guided recommendations are questioned, overridden, or followed with adverse consequences. Participatory interaction should complement rather than replace clinical judgment. When patients cannot engage directly or consistently because of cognitive, linguistic, or digital constraints, PDTs should rely on clinician-mediated or caregiver-supported pathways with explicit attribution of who contributed which observations, preferences, or annotations rather than treating proxy input as interchangeable with first-person patient knowledge. In addition, conversational and explanatory functions should remain bounded by traceable model outputs and established governance rules so that participatory features expand shared understanding without weakening clinical safeguards or obscuring responsibility.

Implications for Participatory Medicine

Reframing digital twins as participatory systems has important implications for participatory medicine, particularly in the context of chronic care, where sustained engagement, shared understanding, and trust are central to effective management. PDTs extend the principles of participatory medicine beyond information access, positioning AI-enabled systems as active mediators of collaboration among patients, caregivers, and clinicians.

Implications for Patients and Caregivers

For patients and caregivers, PDTs offer opportunities to move from passive receipt of recommendations toward meaningful engagement with their own health trajectories. By enabling plain-language explanations, interactive exploration, and insight into uncertainty, participatory systems can support health literacy and foster epistemic agency. For caregivers, this may include structured ways to contribute observations, clarify day-to-day constraints, and participate in shared interpretation when caregiving responsibilities shape how chronic care is managed in practice. PDTs could further support caregiver involvement through role-specific functions such as caregiver-attributed contextual annotations; shared visit preparation summaries; and scenario discussions tied to medication management, daily routines, or other caregiving tasks. These functions are especially important when participation is mediated or shared because caregivers may need support not only in contributing information but also in understanding uncertainty, preserving attribution, and avoiding substitution of caregiver perspectives for first-person patient priorities. This shift is especially relevant for individuals managing chronic conditions in complex social contexts, where decisions involve trade-offs between medical guidance, daily routines, and quality of life. When patients understand why certain outcomes are predicted and how their actions influence those outcomes, digital twins can function as tools for learning and reflection rather than sources of confusion or contributors to the burden of treatment that already characterizes chronic care.

Implications for Clinicians

For clinicians, PDTs have the potential to support shared decision-making while addressing practical concerns related to time and cognitive load. Although participatory systems introduce an additional layer of interaction, they may ultimately reduce the interpretive burden on clinicians and explanation time by enabling patients to arrive at clinical encounters with a baseline understanding of their health trajectories and the rationale behind potential options. By serving as boundary objects, PDTs can anchor conversations in shared visualizations and scenario-based reasoning, allowing clinicians to focus on judgment, contextualization, and care planning rather than repeatedly translating abstract model outputs. In this way, participatory designs may help mitigate aspects of clinician burnout associated with repetitive explanation and misaligned expectations.

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Implications for Evaluation and Research Practice

The shift toward PDTs also challenges prevailing evaluation practices in health AI research. Traditional metrics focused on predictive accuracy or error reduction are insufficient to capture participatory value [29]. Evaluation should instead examine whether users can meaningfully understand and work with model-driven information, whether the system supports participatory quality during use, and whether these benefits are sustained over time. In addition to comprehension-focused tasks and scenario interpretation, existing instruments from related areas of patient engagement and shared decision-making research can provide a practical starting point, including the Patient Health Engagement scale for engagement orientation [26] and CollaboRATE for patient-reported shared decision-making quality [31]. For a viewpoint-led translational pathway, early studies need not begin with large clinical trials; a feasible progression would be vignette- or simulation-based studies followed by mixed methods pilot studies and short longitudinal deployments to assess whether patients, caregivers, and clinicians continue to use the system to interpret outputs, question assumptions, and contextualize recommendations over time [28]. For GenAI-mediated components, the QUEST human evaluation framework, which covers quality of information, understanding and reasoning, expression style and persona, safety and harm, and trust and confidence, is useful for evaluating dimensions such as information quality, reasoning, safety, and trust [14]. At the broader system level, the AI for IMPACTS framework helps extend assessment beyond model performance to issues such as integration, acceptability, transparency, governance, and real-world scalability [32].

Implications for Equity, Ethics, and Governance

PDTs raise critical questions about equity, ethics, and democratic governance in AI-enabled care. Systems that prioritize plain-language interaction, transparency, and recourse may improve access to understanding, particularly for populations with lower health literacy or limited clinical support [12,33]. At the same time, equitable participation cannot be assumed. Contextual factors and social drivers of health may enter PDTs through patient-reported or caregiver-attributed annotations, structured prompts, visit preparation summaries, or clinician-documented contextual notes tied to specific scenarios or periods of care rather than being indiscriminately absorbed as permanent model variables. Because such information may be financially, relationally, or logistically sensitive, PDTs should support selective disclosure; distinguish between information stored longitudinally and information used transiently for interpretation; and make explicit who contributed, can view, can modify, and can act on that information. In contexts where participation is mediated, proxy input should be treated as supportive and explicitly attributed, not as an automatic substitute for first-person patient priorities.

Participatory feedback may help surface missing context, mistaken assumptions, or forms of misalignment that models might otherwise overlook [34]. However, this should be understood as a conditional safeguard rather than as a general mechanism for reducing algorithmic bias. Where meaningful engagement is constrained or unevenly distributed, PDTs should rely on additional protections, including clinician review, documented recourse pathways, role-appropriate proxy involvement, and alternative nondigital routes for communication and decision support. Therefore, responsibility for outcomes should remain explicitly negotiated rather than implicitly shifted onto patients or caregivers, especially in cases where the capacity to question, contextualize, or challenge model outputs is limited. Under these conditions, participatory design can strengthen transparency and accountability without overstating the universality of participation or the corrective power of feedback alone.

Broader Sociotechnical Implications

Together, these implications underscore that PDTs are not merely technical enhancements but sociotechnical interventions that reshape relationships, responsibilities, and power in chronic care. By aligning AI design with the values of participatory medicine, digital twins can support more equitable, transparent, and democratically governed forms of care.

Conclusions

Digital twins are increasingly positioned as foundational technologies for chronic care, yet their full potential will remain unrealized if they are designed solely as expert-oriented systems optimized for technical performance. In this viewpoint, we have argued for a reframing of digital twins as participatory systems that support shared understanding, epistemic agency, and collaborative decision-making among patients, caregivers, and clinicians. By emphasizing interaction, transparency, and governance alongside modeling and simulation, PDTs align AI-enabled care with the lived realities of chronic disease management.

This reframing is both timely and necessary. Advances in GenAI now make it possible to translate complex models into dialogue, while growing attention to health equity, trust, and democratic governance highlights the limitations of opaque, directive AI systems. PDTs offer a pathway to move beyond prediction and toward sensemaking, enabling patients to engage meaningfully with their health data and clinicians to anchor care decisions in shared representations rather than unilateral recommendations.

Ultimately, PDTs are not simply a new class of tools but a design direction for chronic care contexts in which patients, or appropriately supported care partners, can meaningfully engage with model outputs, uncertainty, and trade-offs over time. By designing digital twins that users can understand, question, and help shape within these contexts, the field can move toward more equitable, transparent, and sustainable models of AI-supported care.

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Authors' Contributions

Conceptualization: QL (lead), JL (supporting), BX (supporting), EJ (supporting)
Methodology: QL (lead), JL (supporting)
Supervision: JL
Visualization: QL (lead), JL (supporting)
Writing – original draft: QL
Writing – review & editing: QL, BX, EJ, JL

Conflicts of Interest

None declared.

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Abbreviations

AI: artificial intelligence
GenAI: generative artificial intelligence
LLM: large language model
PDT: participatory digital twin

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Viewpoint

Advancing the Science of Patient Input in Drug Research and Development

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Abstract

The integration of patient input into drug research & development (R&D) enables the production of medicines that better meet the needs of patients. While momentum for advancing the science of patient input has continued to grow, there remain a host of barriers to full implementation and integration of systematic approaches for collecting and using robust and meaningful patient input data to inform decision-making. To help address these barriers, the Advancing the Science of Patient Input Action Collaborative (the collaborative), an activity associated with the National Academies of Sciences, Engineering, and Medicine (National Academies) Forum on Drug Discovery, Development, and Translation, organized a multi-stakeholder endeavor to identify and address key barriers to implementation through a series of information-gathering efforts. The collaborative engaged a wide range of perspectives to seek out practical paths forward to better align drug discovery, development, and regulation with patient priorities for disease management and treatment. Collaborative participants focused on three overarching research priorities which, if effectively addressed, would help advance the science of patient input: 1) understanding the patient experience over the course of a given disease or medical condition, 2) capturing the patient perspectives and priorities on benefit-risk, and 3) incorporating patient input into clinical trial design and continuous improvement. Addressing these research priorities would help decision makers shift away from using patient input in particular cases or for one-off applications and towards the integration of patient input as part of everyday medical research and practice. Building upon existing guidances and strategies, and sharing lessons learned from use cases, a comprehensive patient input framework would serve as a critical step towards reimagining and enriching the science of patient input throughout the drug R&D process, enabling a future in which medicines more fully meet the needs of patients.

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KEYWORDS

clinical trials; clinical research; drug research and development; patient input; patient-centered

Introduction

As experts in their own experience, people living with a disease or condition play a critical role in informing drug research and development (R&D). The growing momentum for incorporating patient input throughout the drug R&D life cycle—from early-stage drug discovery to clinical trial design and execution—builds upon the foundational principles of patient and public involvement in health research. This approach provides an opportunity to transform traditionally anecdotal and qualitative patient input into rigorous, credible evidence that is scientifically robust and, in some cases, suitable for regulatory decision-making. The science of patient input is defined in the Food and Drug Administration (FDA)

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Patient-Focused Drug Development (PFDD) Glossary as "methods and approaches of systematically obtaining, analyzing, and using information that captures patients' experiences, perspectives, needs, and priorities in support of the development and evaluation of medical products." In addition to regulators, pharmaceutical companies increasingly rely upon patient input to help inform scientific and regulatory decisions in drug R&D as well as clinical operations.

For purposes of this paper, patient input refers to information, perspectives, experiences, preferences, and priorities that patients might provide to inform scientific or regulatory decision-making. The concept is distinct from patient engagement, defined by the FDA as "intentional, meaningful interactions with patients that provide opportunities for mutual learning and effective collaborations," which focuses more on how patients participate in the R&D process.

Application of the science of patient input can help clarify patient perspectives on benefit-risk and outcome priorities, informing clinical trial design and supporting regulatory decision-making. One clear case is the effort by regulators to offer strategic, regulatory, programmatic, and policy assistance to facilitate the incorporation of patient input into R&D decision-making. The FDA's PFDD Program within the Center for Drug Evaluation and Research provides opportunities to gather patient insights on disease experiences and treatments. PFDD meetings are convened directly by the FDA and by external groups, helping to inform FDA guidance development. For example, a 2019 guidance on drug development for amyotrophic lateral sclerosis encourages drug developers to develop new outcome measures using patient experience data that can assess clinically meaningful effects in patients [1].

Based on work of the Advancing the Science of Patient Input Action Collaborative (the collaborative), an ad hoc activity associated with the National Academies of Sciences, Engineering, and Medicine's Forum on Drug Discovery, this paper seeks to fill the gap between strategic or conceptual frameworks for patient input and scaled operationalization such that the science of patient input is embedded in decision-making across the R&D life cycle. Through a structured process of convenings, surveys, and cross-sector dialogue, the collaborative brought together people working in academia, industry, regulatory agencies, and health care, and people with lived experience to identify practical barriers to implementation and outline research priorities for operationalizing the use of patient input in drug R&D. This paper draws on the collaborative's work, sets it in broader context of patient input literature, and outlines practical steps to enable the systematic study and development of validated patient-centered methodologies—where "patient-centered" refers to approaches that prioritize patients' needs, preferences, values, and experiences—to ensure that patient input is rigorously collected, measured, and integrated into the drug development ecosystem.

Activities

To encourage more transparent agreement across stakeholders on the incorporation of patient input into decision-making for drug development and use, the collaborative gathered people with leadership roles and expertise in drug and device R&D, drug regulation, and patient research and engagement. Participants began their work by (1) cataloguing current efforts to advance the science of patient input, (2) identifying and prioritizing critical gaps in the knowledge base and other barriers that impede progress, and (3) laying out next steps to help advance the field.

To better understand some of the gaps and opportunities in the science of patient input, collaborative participants undertook the following activities:

1. Stakeholder questionnaire: To identify ongoing efforts, perceived gaps, and implementation barriers, collaborative participants circulated questions to 8 individuals (3 respondents) and 17 organizations (5 respondents) representing regulatory agencies, biopharmaceutical companies, patient groups, and vendors. Respondents were offered the option of responding in writing or through informal phone interviews. In addition, The Professional Society for Health Economics and Outcomes Research circulated questions to 6 relevant member special interest groups (30 respondents).
2. Public workshop: Titled "Advancing the Science of Patient Input in Medical Product R&D: Towards a Research Agenda," featuring facilitated discussions and identification of themes [2].
3. Cross-sector collaborative meeting: Convened participants to discuss research priorities and opportunities to advance the science of patient input (Multimedia Appendix 1).

Early discussions covered all medical products, including drugs, biologics, and devices, each of which comes with a different set of considerations for risk and benefit for patients as well as different approaches for demonstrating safety and efficacy, timelines for development, and the regulatory review processes. Developers and regulators of medical devices have taken steps to incorporate end user input, experience, and testing (eg, practitioners operating a device or patients using a device in the home setting) into development and approval processes. In contrast, drug development and approval processes have taken longer to incorporate such approaches into "business as usual" in the preclinical and clinical settings. For this reason, collaborative participants focused on challenges and opportunities for integrating patient input into drug R&D at scale.

Findings

Challenges and Opportunities for Integrating Patient Input Into Drug R&D

One gap highlighted by the collaborative participants is the lack of information and insights collected from patient populations that are representative of those who live with a given disease. It is important to understand which aspects of disease burden and treatment matter most to patients with the condition a given drug is intended to treat. Patient organizations, electronic health records (EHRs), and online patient communities offer fruitful opportunities to gather insights. However, the majority of patients are not affiliated with a patient group, do not participate

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in research, and may not be connected to health care institutions participating in clinical trials. This creates a void in what information is collected and leads to omissions or inaccurate assumptions that filter their way from initial information gathering through integration of patient-centric studies and tools.

To advance the science of patient input, that gap in data must be filled. Patient input should be collected from across representative patient populations with consideration for age, sex, socioeconomic status, and disease severity, among other relevant attributes that may impact how a drug could perform. Approaches to reach broad patient populations through traditional and nontraditional means will become increasingly important given changes to the health care landscape, variable access to health care, the emergence or resurgence of infectious diseases, and the abundance of health misinformation.

Research Priorities for Advancing the Science of Patient Input

To focus efforts on the integration of patient input where it would have the greatest value and impact, collaborative participants assessed information gathered from wide-ranging stakeholders and distilled it to three research priorities:

1. Understanding the patient experience over the course of a disease or condition: Clinical researchers and sponsors cannot fully meet patient needs until they are able to consistently collect and use meaningful and holistic patient experience data. An understanding of a patient's baseline, meaningful difference, disease trajectory, health care disparities, and psychological burden requires accurate data and thorough evaluation. However, data on the full course of a disease from a patient's perspective are not adequately captured in health records or through available research instruments. If achieved, a view of the full longitudinal patient journey could better enable PFDD that prioritizes interventions that maximize meaningful outcomes for patients.
2. Capturing patient perspectives and priorities regarding the benefits and risks of medical product use: Despite the critical importance of patient input on benefits and risks, patients' views are not measured accurately, nor applied with the same weight given to that of other stakeholders. Patients may value certain outcomes or tolerability profiles very differently from clinicians or regulators. Additionally, patients' perspectives on benefits and risks may differ depending upon the nature and progression of their disease, their life stage, comorbidities, or cultural background. Standard tools and measures do not adequately capture these important nuances, leading to conclusions that may not accurately reflect the patient population.
3. Incorporating patient input into continuous improvement of clinical trial design and development: The process of refining and optimizing clinical trial design and development would benefit from the incorporation of patient input. However, several gaps continue to impede progress in this area, including a lack of consistent practices for the collection and use of patient input to support continuous improvement; inadequate measures for assessing the impact of clinical trial participation on patients, caregivers, and families; and a lack of robust metrics for demonstrating the effect of patient input on protocol design, as well as clinical trial enrollment and retention.

The participants then examined other crosscutting barriers preventing the science of patient input from being used to its full potential (Textbox 1).

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Textbox 1. Barriers to advancing the science of patient input identified in collaborative participant questionnaire responses.

Understanding the patient experience with a disease or a medical condition may be hampered by the following barriers

- Lack of data capturing the full patient experience, including both personal and clinical experience.
- Patient perspectives input are not adequately incorporated into electronic health records.
- Existing patient-reported outcomes and patient-centered outcomes may not reflect baseline status or meaningful difference for individual patients.
- Difficulty incorporating learnings from patient input into care and research systems to inform new treatment development (ie, learning health systems and care-based research).
- Lack of defined quality standards and rigor for both quantitative and qualitative patient input data.
- Clinical data collection often does not generate information that provides a holistic view of the patient.
- Symptom burden from the perspective of the patient that maps to disease trajectory is not captured in a standardized manner.
- Databases not designed to collect or integrate patient input.
- Missing voices in available data.
- Difficulty reaching or engaging certain patient populations, particularly those with rare diseases.
- Limited patient input on health care disparities.
- Need for methods and metrics to quantify and measure psychological burden of disease on patients.

Capturing patient perspectives and preferences on benefit-risk may be hampered by the following barriers

- Need for better understanding of how patients perceive risk compared with other stakeholders (eg, pharmaceutical companies, clinicians, and regulators).
- Lack of methodologies for quantifying change in benefit-risk tolerance or uncertainty tolerance over time across age, or with disease progression.
- Lack of methodologies for obtaining input from patients unable to directly express preferences (eg, pediatric patients and cognitively impaired patients, such as those with dementia or Alzheimer disease).
- Insufficient knowledge regarding how patients with different diseases or conditions cope with uncertainty.
- Underrepresentation of perspectives from patients with multiple comorbidities.
- Limited understanding and methods for institutional review boards to incorporate patient perspectives.

Incorporating patient input in clinical trial development and continuous improvement may be hampered by the following barriers

- Need for approaches that encourage a culture of incorporating patient input early in trial design.
- Lack of metrics to assess value of patient input in protocol development.
- Lack of training for researchers on the value and use of patient input.
- Insufficient methods for understanding how different patient populations perceive and interpret information due to cultural or social differences.
- Challenge in defining and validating meaningful measures.
- Limited training for patients and patient groups to provide input effectively.
- Need for methods to better represent the broader patient community.
- Lack of approaches for capturing caregiver and family experiences throughout the clinical trial process.
- Lack of understanding and methods to evaluate how patient input affects trial enrollment and retention.

Research Priority: Understanding the Patient Experience Over the Course of a Disease or Condition

Given these challenges, collaborative participants suggested actions to address the barriers (Multimedia Appendix 2) along with benefits of taking those actions from the perspectives of a number of stakeholders (Multimedia Appendix 3). Building on this body of work, collaborative participants considered the need for approaches laid out in the following sections.

A Comprehensive Framework to Elucidate the Patient Experience and Capture Burden as Diseases Progress Over Time

The meaningful collection, quantification, and assessment of disease or treatment burden over time would enable stakeholders to better demonstrate measurable improvements in patient care, including quality of life and other nonmedical outcomes, throughout the patient journey. Evaluation of patient experience throughout diagnosis, treatment, and recovery periods would enable researchers, drug developers, and regulators to better understand and address benefit-risk for therapies from the perspective of the patient.

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Mechanisms to Identify and Validate Methodologies and Metrics for Incorporating Relevant Patient Perspectives Into EHRs

EHRs already capture patient information over time. Merging EHRs alongside other technologies (eg, electronic data capture, digital health technologies, artificial intelligence, and machine learning) would enable a more comprehensive view of disease experience. However, there are currently few seamless ways to account for the myriad variables that affect health and quality of life during a patient's treatment journey. Combining disparate sources of patient information (eg, patient-reported outcomes and digital health technologies) could further validate patient observation and input, supporting a more evidence-based approach for informing clinical trials and improving patient care [3]. These types of approaches require pilot testing to determine practical applications for clinicians, patients, families, and caregivers, while avoiding undue burden. The use of frameworks for best practices in clinical outcome assessments may be one approach for demonstrating how EHRs and clinical trial data can be combined to better understand the patient experience.

Research Priority: Capturing Patient Perspectives and Priorities on Benefits and Risks of Medicine Use

An individual's understanding of the benefits and risks of medicines is critical to informing their decision-making process around participation in research and clinical care [4]. More broadly, improving people's understanding of the benefits and risks of engaging in clinical research could help empower potential trial participants to make better-informed treatment decisions [5]. Capturing patient perspectives and priorities on benefit and risk could also help inform drug development and facilitate shared decision-making in ways that are beneficial for patients and their caregivers.

Stakeholders can apply core principles for developing and incorporating effective measurements that are meaningful to patients, such as those recommended in the Medical Device Innovation Consortium Patient-Centered Benefit-Risk Framework and the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire C30 [6,7].

The FDA and other key stakeholders have laid out guidance and frameworks on how to develop generalizable approaches and tools to capture and improve understanding of benefit-risk for trial participants [8,9].

While these approaches are helpful as a start, collaborative participants identified numerous opportunities for further refinement to provide more holistic information that would reflect patients' experiences and support more informed decision-making (Table S1 in Multimedia Appendix 4). Through a questionnaire, a public National Academies workshop, and collaborative discussions, participants described types of patient input for capturing patient perspectives and priorities on benefits and risks of medicine use, methods and data sources to collect the input, gaps or barriers to implementing the patient input, potential research approaches to promote use of the patient input, and relevant stakeholders.

Building on this body of work, collaborative participants considered the following approaches: identify and validate metrics to better understand how certain populations perceive and understand information regarding risks and benefits differently due to a host of overlapping factors (eg, social, cultural, accessibility, geography, disease prognosis).

Patient views and understanding of benefit and risk may vary significantly based on several variables, including disease presentation and progression, treatment effect, standard of care, quality of life, comorbidities, and social determinants of health. Establishing metrics that reflect the range of patient experiences and perspectives across different populations would help decision makers better design and implement clinical trials that meet the needs of patients.

Identify and Validate Metrics for Obtaining Input From Patient Populations With Multiple Comorbidities

Many clinical trials exclude large segments of the population, including those living with common chronic diseases—cardiometabolic diseases, dementia, cancer, or psychiatric conditions. While exclusion criteria can better enable the assessment of safety and efficacy of a medical product under controlled conditions, this can limit the relevance of clinical trial results for the range of people who will use the product once it has been approved.

Future approaches may include the development of metrics for obtaining patient input on benefit and risk that includes people who are living with commonly occurring comorbid conditions, a lesson illustrated by COVID-19 clinical trials. Early studies showed that the presence of comorbidities, including cardiovascular diseases, autoimmune conditions, and metabolic disorders (eg, diabetes and obesity) was associated with higher levels of patient hospitalization, disease severity and mortality, and risk for long COVID symptoms [10-12]. However, up to half of COVID-19 treatment trials initiated in 2020 in the United States excluded patients with high-risk chronic conditions. This may have obscured insights on outcomes for relevant patient populations that were disproportionately affected by COVID-19 [13]. Resolving the discordance between clinical trials and real-world applications could improve patient outcomes by illuminating subpopulation-specific stratification of therapeutic approaches.

Identify and Validate Metrics to Integrate Patient Input for Institutional Review Boards

Frameworks for comprehensive patient input are needed to ensure that representative patient perspectives are considered in institutional review board determinations. Rather than relying on input from 1 patient or community member serving on the institutional review board, a road map for capturing perspectives for participants of varying age, race, ethnicity, geography, gender, socioeconomic status, education, stage of disease, and insurance statuses is more desirable. This road map may be presented by "patient experts," individuals who not only identify as patients but also serve as advocates for the broader patient population. A tangible output of "patient expert" voices could take the form of ethics rubrics that incorporate patient input throughout the diagnosis, treatment, and recovery timelines.

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Research Priority: Incorporating Patient Input Into Continuous Improvement of Clinical Trial Design and Development

Patient-centered approaches and metrics for clinical trial design are vital for improving participant experience throughout the drug R&D life cycle (Table S1 in Multimedia Appendix 5). Patient input during trial design and early clinical studies can provide insights into unmet patient needs, side effect tolerability, and treatment preferences, as well as informing recruitment and retention strategies [14-16]. Phase III trials using patent engagement practices are more likely to reach approval status than studies that were not patient-centered [17].

The SARS-CoV-2 Immunity and Reinfection Evaluation study in the United Kingdom, which researched COVID-19 infections, reinfections, and vaccine effectiveness, used a participant involvement panel to gain input on study design and strategies for engaging patients. Modifications to design, implementation, and study evaluation phases based on participant input resulted in a more than 15-fold increase in enrollment [18]. In neurology, a preference study of patients with Parkinson disease showed that pain levels, which were initially underemphasized as a clinical measurement, are a meaningful symptom for patients [19]. Subsequently, pain levels were used as a patient-relevant endpoint in a clinical trial with patients for whom motor symptom treatment alone did not meet patient needs [19,20]. In oncology, a patient input assessment tool developed during a phase I/II study on the myelofibrosis drug ruxolitinib was used to identify patient-relevant symptom reduction measurements in phase III studies, which ultimately played a role demonstrating efficacy for regulatory approval [21,22].

While tools for incorporating patient input in clinical trial development and continuous improvement already exist, there remains a lack of broad acceptance and use of these tools in practice [23]. Moreover, even when there is implementation of metrics to evaluate patient input in drug development, there is no one-size-fits-all approach across organizations [24]. To answer these challenges, collaborative participants considered the need for approaches described in the following section.

Validate Metrics and Establish a Framework for Defining Measures That Are Clinically Meaningful to Patients

Several methodologies, such as patient surveys, already exist for gathering patient insights to improve the design of clinical trials [24]. Patient surveys can be a relatively straightforward way of engaging patients while acquiring necessary and quantitative insight into their perspectives [25]. This feedback can be used to identify measurables that patients have flagged as clinically meaningful to them, which can then be more accurately incorporated into trial design. Proposed metrics have included advisory group support and involvement, patient retention, quality of evidence, and adherence rates. Patients should be engaged throughout the clinical trials process to ensure that accurate and ongoing feedback is received [16,26].

Pilot programs that build upon existing training opportunities would better equip researchers to use patient input methodologies, improving clinical trial design and enhancing patient inclusion. Establishing mentorship and other learning opportunities for researchers and clinicians to share approaches for using patient input and including patients as co-trainers and co-designers of pilot programs would further enable the integration of patient input throughout the therapeutic life cycle.

Discussion

Opportunities for Implementation

Despite evidence that incorporating patient input into R&D leads to higher-quality medicines that better align with patients' needs and priorities and can enhance the efficiency and quality of clinical trials, scaling up the collection and use of patient input in decision-making remains a challenge. Deploying scientifically robust and evidence-based patient input methodologies—whether existing or novel—can help researchers and sponsors improve representation in clinical trials, ultimately improving patient outcomes while also meeting the needs of developers and regulators. However, even when a culture of "patients as partners" exists within an organization, action collaborative discussions emphasized that the science of patient input has not been consistently incorporated into study design, budgeting processes, or project timelines. Ultimately, patients should be viewed as equal and essential stakeholders in the clinical trials enterprise and should thus be considered in all steps of trial development.

FDA guidance for industry underscores the agency's support for including patient experience data in clinical trials (Textbox 2) [27]. The 4 PFDD guidance frameworks have largely been well received by the field. For example, in response to *Patient-Focused Drug Development: Methods to Identify What Is Important to Patients* [28], the second guidance document, the Biotechnology Industry Organization wrote "BIO commends the FDA for working to ensure patient experiences are more systematically collected and used to inform the development and review of new therapies"[29]. Additionally, the National Organization for Rare Disorders said that "we appreciate that the emphasis of this draft guidance is on identifying what matters most to patients in terms of the disease and treatments" [30].

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Textbox 2. Food and Drug Administration patient-focused drug development guidance series.

Pursuant to the Food and Drug Administration Reauthorization Act of 2017 and the 21st Century Cures Act, the Food and Drug Administration is developing a series of four Patient-Focused Drug Development guidance documents to promote systematic approaches for collecting and using patient and caregiver input:

1. Patient-Focused Drug Development: Collecting Comprehensive and Representative Input (final guidance issued in June 2020) [8]. This guidance document illustrates methods for collecting patent data, with an emphasis on ensuring that the input collected is comprehensive and representative. A glossary of common terms used in Patient-Focused Drug Development was included as an appendix, which addresses concerns within the field about inconsistent terminology.
2. Patient-Focused Drug Development: Methods to Identify What Is Important to Patients (final guidance issued in February 2022) [28]. The second guidance document of the series provides insight on how to gather pertinent information from patients. The guidance helps direct stakeholders to gather information about symptoms, impacts of the disease, and other issues that are deemed important to patients. Collecting this information will help increase understanding of the disease and inform clinical trial design.
3. Patient-Focused Drug Development: Selecting, Developing, or Modifying Fit-for-Purpose Clinical Outcome Assessments (draft guidance issued in June 2022) [31]. The third guidance of the series aims to guide the methods for selecting, modifying, developing, and evaluating clinical outcome assessments (COAs). As listed within the guidance, sponsors can use high-quality measures of patients' health for the following reasons: measuring what matters to patients; being clear about what was measured; appropriately evaluating the effectiveness, tolerability, and safety of treatments; and avoiding misleading claims.
4. Patient-Focused Drug Development: Incorporating Clinical Outcome Assessments Into Endpoints for Regulatory Decision-Making (draft guidance issued April 2023) [32]. The fourth guidance document of the series is focused on executing the use of COAs. Specifically, the guidance discusses methods to incorporate COAs into endpoints that can be used for regulatory decision-making. COAs typically do not provide direct insight on patient benefit, so this guidance aims to help ensure that COAs that provide indirect patient information correspond to relevant patient benefit.

Building on Existing Frameworks

Available frameworks for the clinical research process offer practical approaches for engaging patients. For example, the PARADIGM consortium has developed a flexible monitoring and evaluation framework that incorporates tailored metrics to assess the influence of patient engagement on study relevance, efficiency, and outcomes [24]. This framework underscores the value of aligning metrics to ensure meaningful and context-sensitive evaluation of engagement practices. In another example, the Drug Information Association and the Tufts Center for the Study of Drug Development introduced tools to assess organizational preparedness for patient engagement [26,33]. This highlights the importance of structured strategies to translate goals into actionable practices. Similarly, the Clinical Trials Transformation Initiative's (CTTI's) Patient Engagement Collaborative demonstrates how multistakeholder partnerships can foster dialogue to improve engagement throughout the medical product life cycle. CTTI has advanced efforts to integrate patient input into decision-making processes and regulatory practices by providing a platform for patients, regulators, and other stakeholders to share perspectives and resources [34]. Additionally, companies have codeveloped frameworks with patient advisors on how to capture and assess patient input throughout the medical product life cycle [35]. More is needed to build upon, scale, and incentivize the implementation of such frameworks for patient engagement and advance the field toward systemwide application of the science of patient input.

Demonstrating Return on Investment

The impact of patient input on clinical research is expected to continue to unfold over time, necessitating ongoing evaluation and refinement of methodologies. Short-term effects might be observable in improved trial approval rates, retention, and accrual, while the long-term benefits could manifest in more meaningful trial endpoints and the development of valuable medications. However, the absence of control arms specifically designed to evaluate patient input outcomes presents a challenge in directly attributing improvements to patient input. Nonetheless, early benefits in trial conduct suggest that patient input can enhance the research process.

The available literature regarding return on engagement of gathering patient input and how patient input impacts the ultimate cost of therapeutic development is limited. Filling those gaps is an important step toward demonstrating the value of patient input to drug developers. In one example, a team of sponsors, patient groups, investigators, and health economists developed an economic model for return on investment from patient input in phase II and III trials. The model suggested that using patient input can lead to financial benefits associated with avoiding protocol amendments and improving patients' study experience [36]. In addition, health technology assessment agencies are increasingly interested in using patient experience data for decision-making, including information on medical interventions, quality-of-life measures, and value assessments that inform reimbursement decisions [37]. While it stands to reason that patient-centric trials would be more successful in recruitment and retention, thus supporting more robust outcomes at a faster rate, consistent practice and rigorous data collection will be needed to provide better quantification of the economic impact of patient input.

Integrating Patient Input Into "Business as Usual"

Integrating patient input into clinical trial standard operating procedures requires not only a modest investment of capital but, more importantly, a significant commitment to change management. Evidence-based patient insights help sponsors identify and address pain points in protocol design, recruitment, and retention, making trials more efficient and representative. To fully integrate patient input throughout an organization—from the R&D teams to clinical trial sites—requires leadership as well as systematic updates to

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workflows and training, allocation of resources, and shared accountability.

To achieve this, sponsor companies must empower key decision makers to champion a cultural shift that cascades throughout clinical operations. This shift should ensure that patient input is systematically collected, analyzed, and made available to teams as a standard resource—either as a curated library of insights or proactively gathered ahead of need—so that it informs decisions at critical points in the R&D cycle. Crucially, these insights must be generated during the process, not retrofitted after decisions are made, to maximize their impact and enable true cocreation of R&D programs with embedded, inherent patient input.

Practical next steps for industry may include (1) collaborating with leading patient advocacy organizations to create centralized, therapeutic-area–specific patient councils that generate reusable patient preference data—reducing the need for each sponsor to start from scratch; (2) partnering with patient engagement experts to establish a core, evidence-based set of principles to guide the use of patient input for improving trial design and outcomes; (3) establishing a cross-industry working group to collate, refine, and regularly update best practices for patient engagement, particularly those that are therapeutic-area agnostic; (4) integrating existing publicly available tools—such as those produced by TransCelerate, CTTI, Patient-Centered Outcomes Research Institute, and others—directly into trial design workflows and training programs; and (5) establishing common metrics and key performance indicators to assess improvements in recruitment speed, participant representation, and retention as patient engagement practices mature.

Patients and advocacy groups must likewise invest time and resources to strengthen their partnerships with industry. This may include cultivating informed patient representatives who can clearly articulate the lived experience, treatment journey, and burden of disease, and serve as a reliable resource for sponsors to engage. As these relationships mature, and as patients and advocacy groups demonstrate their value alongside sites, Contract Research Organizations, and other service providers, sponsor organizations will benefit by accelerating protocol optimization, improving trial feasibility assessments, and institutionalizing the science of patient input as a core component of clinical development.

Engaging Patients as Partners

Enhancing the capacity to support patient advocates is a crucial area for development as well. Each of the approaches outlined in this paper requires the engagement of stakeholders across the entirety of the patient journey, including patients, families, caregivers, clinical teams, trialists, sponsors, digital health companies, EHR vendors, regulators, and data scientists. Addressing barriers that impede patient involvement in advocacy and research, including economic barriers and lack of accessible health care, will take concerted efforts. Such an approach is essential for harnessing the full potential of patient input in shaping the future of clinical trials and health care innovation.

Successful patient partnerships should include representation of the populations affected by the disease. People who are underrepresented in clinical research—including people with comorbidities and those who are not well represented in patient organizations—can be reached through more inclusive measures and methodologies that integrate patient-centered insights on disease burden. This inclusivity would help ensure that the outcomes and recommendations derived from patient input reflect the varied experiences and needs of people from across different communities. Moreover, embracing inclusive patient partnerships fosters a more holistic understanding of the disease landscape. While challenges remain, collaborative cross-sector efforts around transparency in decision-making and the application of insights gained from patient input offer an opportunity to improve health care in a way that is meaningful to the most important stakeholders of all—the patients.

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Conflicts of Interest

MAM is an employee of GlaxoSmithKline, former employee of Janssen, and shareholder in both companies. LTC is an employee of Merck & Co, Inc. CKS, HAO-A, and TJS declare no conflicts of interest.

Multimedia Appendix 1
Research priorities and opportunities.
[DOCX File , 41 KB - jopm_v18i1e74436_app1.docx]

Multimedia Appendix 2
Understanding the patient experience over the course of a disease or condition.
[DOCX File , 41 KB - jopm_v18i1e74436_app2.docx]

Multimedia Appendix 3
Barriers and potential actions for understanding the patient experience over the course of a disease or condition.
[DOCX File , 26 KB - jopm_v18i1e74436_app3.docx]

Multimedia Appendix 4
Capturing patient perspectives and priorities on benefits and risks of medical product use.
[DOCX File , 36 KB - jopm_v18i1e74436_app4.docx]

Multimedia Appendix 5
Incorporating patient input into continuous improvement of clinical trial design and development.
[DOCX File , 36 KB - jopm_v18i1e74436_app5.docx]

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Abbreviations

CTTI: Clinical Trials Transformation Initiative
EHR: electronic health record
FDA: US Food and Drug Administration
PFDD: Patient-Focused Drug Development
R&D: research and development

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Viewpoint

Enhancing Patient Participation in Co-Productive Decision-Making With Personal Value Sets: Clinical Trial Prototype

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Abstract

A new approach has been developed to establish the public value (utility) set for the generic health measure used in quality-adjusted life year estimates. In contrast to conventional approaches, it establishes the complete utility set for an individual and aggregates a sample of these to achieve the public set. The novel way of establishing the complete utility set for an individual has the potential to transform the nature and extent of a patient's participation in the clinical decision-making process. We have modified the online elicitation of personal utility functions approach to overcome its impracticalities in a clinical consultation. The main modification is the replacement of choice-based items by scale-based ones, on the grounds that the former's time and cognitive demands, while tolerable in the research context, make it infeasible in practice. The personal utility set for healthcare (PUSH) approach, like the online elicitation of personal utility functions one, may be used with any multidimension, multilevel instrument, including condition-specific ones, but the empirical application here is with the health-related quality of life instrument EQ-5D-5L. PUSH for EQ-5D-5L is a decision support tool in the form of a spreadsheet workbook. The clinician assists nondirectively in the elicitation of the patient's utility set for EQ-5D-5L. Subsequently, the clinician, drawing on the best available evidence and information, enters the EQ-5D-5L states they judge, on the balance of probabilities, the patient will be in (at an agreed future time point), for specific interventions, plus no intervention. The relevant country's public set utility for each displayed health state is simultaneously revealed. (Those for 13 countries are in the current template.) It is envisaged that the clinician holds the PUSH template on their computer and opens a new copy for use with each patient. They agree with the patient on what, if anything, is to be saved as part of their electronic medical record. The deliberation following engagement with PUSH and personalized evaluation of the contemplated interventions will typically involve sensitivity testing and possible revision of the patient and clinician inputs. One key responsibility of the clinician is to dispel any "aura of exactness" or pseudo-precision that may be created by the use of precise percentages (or values to 2 decimal places). PUSH participation is to be seen as a component of deliberative co-productive decision-making to which both parties contribute significantly but in role-appropriate ways. The outputs are intended to provide a useful, analysis-framed input into the subsequent discussion and co-produced decision. As a major clinical innovation that transforms both patient participation and clinician contribution, it is advanced here for the discussion and critique that will enable a conceptually sound trial protocol to be developed (including clinician tutoring).

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KEYWORDS

patient preferences; personal utility set; clinical decision support; EQ-5D-5L; patient-reported outcome measures

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Introduction

Patient-centeredness is a fundamental ethical principle in any health care service, but it needs to be defined if it is to have operational meaning. We take it to mean that the patient's participation in the clinical encounter is such that the emergent, co-produced decision reflects their informed preferences regarding the consequences following from each of the available options. Given this definition, we further assume that for most patients, the consequences that matter to them will include the effects of the options on their ability to move around, to undertake self-care (SC) and usual activities (UA), and to avoid pain/discomfort (PD) and anxiety/depression (AD), as well as their impacts on more specific biophysical states and functioning. The former set means that there is a compelling case for the routine use of a generic Health-Related Quality of Life (HRQoL) measure, such as the EQ-5D-5L instrument, in both the descriptive and evaluative aspects of clinical decision-making. Patient-centeredness then requires that the individual patient's personal value—utility—for each health state should be used, not those of the average member of a relevant group or population (or the clinician's). The latter are now widely available in the form of public utility sets, developed for use in regulatory-level decisions that affect the clinical availability of some options. While it is important that their personal utilities should be used, we believe the individual patient should have the opportunity to learn how their ones compare with the average, so long as it is not implied that the average has normative significance for them.

It is important to make clear immediately that the case being made here is not for the use of generic measures as patient-reported outcome measures (PROMs). These have become increasingly familiar and found to be acceptable and useful in clinical studies [1]. We are making a very different case for generic measures, based on personal utility sets, forming what may be called "Patient-Reported Input Measures" in a co-productive decision-making process. In other words, to support the ex-ante estimation of the expected effect of different interventions. The ex post effect of an undertaken intervention on the measure (as a patient-reported outcome measure) may be a useful input in a future decision, but not the current one.

We have already hinted at the additional reason for making the average health state utilities in the public set available clinically, alongside the values of the individual. That set ("tariff") has been developed primarily to support policy decisions taken in pursuit of "cost-effectiveness." Cost-effectiveness is a second fundamental ethical principle that applies whenever we are in a resource-constrained public health care service. The two ethical principles—patient-centeredness and cost-effectiveness—clash when an intervention that is optimal for this patient involves an "unacceptable" level of net benefits being foregone by other patients in the service. It is then made unavailable clinically on the ethical grounds that it is not "(opportunity) cost-effective." Different jurisdictions and services determine this ethically unacceptable level in different ways. The most familiar involve interventions being evaluated by their impact on quality-adjusted life years (QALYs), with an incremental cost-effectiveness ratio threshold applied to the result. The QA component of the QALY is assessed in numerous ways, but most use a generic measure of HRQoL such as EQ-5D-5L. Public utility sets for it now exist for many countries, and average utilities are hence readily available for the clinical comparison mentioned above.

The routine clinical use of a generic measure in clinical decision-making has a major bonus wherever cost-effectiveness-based restrictions on clinical provision exist. In some situations, such a restriction will impinge directly on the patient's decision, most notably by making unavailable the option established to be personally optimal. In this situation, we argue that patient-centeredness requires the patient to have the opportunity to see the main reasons why the legitimate restriction may clash with an evaluation based on their own utilities. This can help indicate the net benefit they are sacrificing for and contributing to the "common good" (of which they themselves are part). If, on the other hand, their utilities are such that the proscribed option emerges as suboptimal for them, they are made aware that no such sacrifice or contribution is involved.

In the second, most common, situation, there is no mandatory cost-effectiveness-based restriction on the options relevant to the patient's decision. However, almost invariably there will be some guideline or practice recommendations regarding the options. Many take the form of sequential protocols: initial "first line" therapy, "second line" therapy if that is ineffective, and so on. These classifications necessarily involve implicit utility-based trade-offs, reflecting considerations such as relative toxicity and invasiveness as well as cost. If the implicit utility-based trade-offs are supported by formal cost-effectiveness analysis, the argument of the previous paragraph applies. More likely, the embedded preferences are "expert panel-based," and here we argue that patient-centeredness requires that the patient, if they are to participate meaningfully in the decision-making, is able to make their own trade-offs, by using their personal utilities. As a result, they may, for example, evaluate a designated second or third-line option (such as surgery) as superior to the "normal" first-line one (such as chemotherapy).

However, all the foregoing assumes that it is feasible for the personal utility set for the patient to be generated within the clinical consultation, not, as with the development of public sets, in a personally irrelevant research exercise. Moreover, for the utilities in that set to be used in the consultation as a means to enhance patient participation in, and co-production of, the decision. Otherwise, elicitation would be purposeless. This study presents the conceptual prototype needed as the analytical basis for a clinical trial protocol.

The Clinical Potential of a New Approach

We have modified the novel online elicitation of personal utility functions (OPUF) approach to the development of a public utility set [2-4]. The novelty of OPUF arises from the fact that it achieves the public set of average utilities for each descriptive health state by aggregating the full utility sets of a sample of individuals. This contrasts with conventional methods, such as time trade-off and discrete choice experiment (DCE). In those, subsets of citizens choose between different samples of health

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state pairs, and the public set is arrived at by statistical inference. Their full personal utility set is never generated for any one individual.

While OPUF develops the personal utility sets for an individual in order to produce a public set, the developers are aware that the method "could potentially be useful for other applications beyond health economics… For example, the OPUF approach could be used as a patient decision aid and to facilitate shared decision making in a clinical context. Explicitly weighing different aspects of health might help patients, who face complex treatment decisions, to better understand the trade-offs that are involved, and what aspects are most important to them" [2].

This clinical potential was also recognized by the developers of another tool that generates public sets on the basis of a sample of full individual ones. "The PAPRIKA tool could also support Cost Utility Analysis and Patient Reported Outcome Measures at the individual patient level, incorporating the patient's preferences into treatment decisions in "real time." For example, the tool could be available on computer tablets in doctor waiting rooms or as a mobile app for patients to quickly create their own personal value sets [5]." PAPRIKA (Potentially All Pairwise Rankings of All Possible Alternatives) unfortunately fails our clinical feasibility test in requiring the patient to make a minimum of 20 pairwise comparisons, and 55 to properly generate the full OPUF utility set. The developers actually acknowledge the problem. "Notwithstanding the relative simplicity of PAPRIKA's questions, almost half of the high-quality by education sub-sample reported finding them difficult to answer. This finding is unsurprising given the questions involve confronting trade-offs between EQ-5D-5L dimensions, which is unlikely to be a familiar cognitive task for most people" [5]. Hence, we make no further reference to this instrument (it also uses commercial software).

We develop this clinical potential, introducing the prototype of an instrument akin to the OPUF approach in producing a complete Personal Utility Set for the individual involved in a Healthcare decision (PUSH). However, PUSH is designed exclusively for use by clinicians and individuals in the context of a clinical decision, rather than by researchers surveying anonymous individuals online to produce a public utility set to support later and impersonal public (or group) decisions. There are major implications of this completely different real-time clinical decision support focus, notably the importance of adopting a contextual normativity that reflects both the 'Time Needed to Treat' [6] and the cognitive resources and capabilities of the two parties in the clinical encounter.

We follow OPUF in using the EQ-5D-5L framework for PUSH, though the approach is relevant to any multidimension, multilevel instrument in clinical use, including condition-specific ones. In relation to all such measures, we emphasize that the clinical presentation of utilities as percentages—or values to two decimal places—is not intended to imply this degree of measurement accuracy, rather to encourage and enable analysis-supported consideration of the relative magnitude of key parameters in the clinical context.

The following introduction to EQ-5D-5L incorporates some abbreviations to reduce prolixity.

EQ-5D-5L

In the EQ-5D-5L framework, a person is described as being in one of five levels on each of five dimensions and therefore is in one of 5^5 or 3125 unique health states. The 5 dimensions are mobility (MO), SC, UA, PD, and AD. They are always referred to in this order. The five levels are 1=no problems, 2=slight problems, 3=moderate problems, 4=severe problems, and 5=extreme problems. This means the best possible health state is described as 11111 and the worst possible as 55555. If the patient's current health state is No MO, Moderate SC, Slight UA, Slight PD, and Severe AD, its descriptive summary code is 13224. Note that while these numbers have evaluative connotations in indicating an ordinal ranking on each dimension, those connotations are not part of the descriptive framework.

If an intervention (including no intervention) is contemplated, the described current and future possible health states have to be evaluated in order to establish how much gain (or loss) is estimated to result from undertaking it. So, if intervention X is estimated to move the patient from 13224 to 13332, they need to know how much better or worse the latter is than the former (from their personal perspective), given that their AD would be improved from Severe to Slight, but their PD and UA would worsen from Slight to Moderate (MO and SC unchanged). Note that 'evaluating' the individual health states (ie, assigning a utility to health state 13224 and to health state 13332) is not the same as 'evaluating' the intervention, which concerns the difference between the utilities placed on 13224 and 13332.

OPUF

A demo version of the OPUF tool is available online [7]. Engaging with it is encouraged, but we extract the relevant key steps here, renumber them, and reword the instructions to the patient. It is important to register the cognitive demands of the process since these are the reasons for our clinical simplifications in PUSH. Some relevant comments from the OPUF UK study are added.

Step 1. Weigh the Health State Levels

Please place "slight," "moderate," and "severe health problems" on the Visual Analog Scale (VAS), which runs between 0% ("Extreme problems") and 100% ("No problems").

Step 2. Rank the Dimensions

Please rank the five dimensions (MO, SC, UA, PD, and AD) in terms of how bad their "extreme" (ie, worst) levels would be for you. 1=worst to 5=least worst. No ties permitted.

Step 3. "Swing Weight" the Dimensions

The slider for the dimension ranked 1 is fixed at 100 to indicate the value you would place on moving from Extreme to No problems on it. Use the other sliders to indicate the value, relative to 100, you would place on moving from Extreme to None on each of the other four dimensions." The responses are normalized to add to 100% so as to produce the dimension weights.

"Criteria/dimension weights… represent the relative importance of a given criterion, compared to all other criteria. More specifically, it is a measure of the relative (utility) gain

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associated with replacing the lowest level with the highest level of performance for this criterion (eg, moving from extreme pain to no pain). A value of 100 is assigned to the most important criterion, and the weights of all other criteria are then defined relative to this yardstick: a value of 50, for example, means a criterion is half as important; a value of zero means a criterion is not important at all [2]."

Step 4. Evaluate the State "Being Dead"

Different methods are used depending on whether 55555 is preferred to being dead or vice versa.

If (A) you prefer being in health state "55555" to "being dead," please place "55555" on a VAS running from "No health problems" (=100) to 'being dead' (=0) (you may place it at 0).

If (B) you prefer "being dead" to being in a health state "55555," please respond to the following series of questions that will establish the "least worst" 5-dimension health state that you regard as equivalent to being dead. These are 6 adaptive DCE questions which involve choosing the preferred state from a pair of 5-dimensional ones (such as 13224 and 13332).

Step 5. Derive the Dimension-Level Coefficients

The level weightings are multiplied by the dimension weights to form a 5 by 5 disutility matrix (disutility equals decrement from full health). This is then rescaled to set the state regarded as equivalent to being dead equal to 0, with states valued worse than being dead as <0.

Two key points from the OPUF UK study:

1. "On average, it took participants about 9 minutes to complete the survey. The median was eight; the shortest duration was three; and the longest was 32 minutes [2]."
2. "We found that health state preferences systematically differed between groups... for age, having children, importance of religion/spirituality, and the EQ Visual Analog Scale quintile. However, the variability of preferences within groups was substantial, and... when all characteristics were taken into account together, group membership accounted for just 8% of the variance...The results illustrate that aggregate group - level value sets usually say little about the preferences of any given individual – in our study, preferences differed greatly between individuals within all the groups that we considered [2]."

PUSH: A Personal Utility Set for Health Care

The OPUF developers suggest that its time demand was not a major problem for their tool, though, from our own personal engagement with it, we believe the reported medians reflect thinking and response times that would be significantly increased in the clinical context with a real patient. Our approach implicitly addresses this time issue by reducing the task demands on the patient, but this is primarily to address the cognitive difficulties of swing weighting (step 3) and choice-based pairwise comparisons (step 4).

In introducing the aspects of PUSH that enhance its clinical appropriateness and practicality, relative to OPUF, we stress that it is vital that these are not seen as reluctant deviations from the research ideal. Normativity is contextual and therefore preference-sensitive, so if there is any "gold standard" by which to assess a clinical evaluation process, it has to be one defined with reference to clinical practice, not some research-appropriate but clinically irrelevant ideal (there cannot be a "gold standard" for an individual patient's utility set elicited on a specific occasion). Moreover, we must avoid the partial or noncomparative evaluation of processes [8]. Evaluation of any evaluation process should involve explicit and empirical comparison with the actual "usual"—in this case, how a patient's evaluation of the relevant treatment outcomes is actually undertaken—not with an implicitly assumed standards-compliant usual. Even accepting this, the problem of establishing what 'actual usual care' is, in any jurisdiction, remains formidable [9,10].

PUSH adapts OPUF in several ways to improve its clinical feasibility. It follows OPUF in eliciting and using the same level weights for all 5 dimensions, as opposed to seeking dimension-specific ones (like the OPUF developers, we are aware of the limitations of this assumption). However, to establish the patient's dimension weights, it rejects the complex "swing weighting" procedure and simply elicits their relative importance in avoiding the worst outcome on each.

Furthermore, PUSH avoids the choice-based elicitation procedure that requires the person to make pairwise comparisons of multidimensional health states. We fully realize this is in direct contravention of the convention in public value set elicitation for clinical policy decisions, such as those implementing cost-effectiveness restrictions. "… The National Institute for Health and Care Excellence (NICE) requires utilities to be based on "choice-based" methods. time trade-off and DCEs are generally accepted as being choice-based; the Location of Death approach is also based on choice-based tasks.... VAS has tended to be rejected by health economists (with rare exceptions) on the grounds that it is not choice-based [11]."

Our preference for scale-based methods in PUSH partly reflects past unsatisfactory attempts to implement choice-based methods in a clinical setting [12,13], but is endorsed by Aström et al [14] in their recent scoping review of the use of the Visual Analog Scale (VAS) in health care.

"Compared to SG and TTO, the VAS was perceived as an easier and more practical approach. Consequently, using a VAS was associated with lower respondent burden and administration costs, and fewer measurement errors. The VAS was seen as more sensitive or discriminatory to symptoms and more culturally acceptable. The VAS was observed to have a better model fit and a similar predictive ability compared to the TTO... The most common criticism was that the VAS does not measure utilities...under uncertainty... However, Parkin and Devlin [15] argue that using the VAS involves both choice and trade-off across sets of health states, and that other methods also suffer from biases or concerns regarding generating reliable preferences" [14].

Finally, PUSH follows OPUF in not setting "dead" as the state with the lowest utility and equal to 0, this being incompatible with QALY evaluations for well-elaborated reasons [16]. However, to avoid the choice-based method of OPUF used only

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for individuals who prefer being dead to 55555 (B in step 4 above), PUSH diverges in how the particular patient locates the state they personally regard as being neither better nor worse than being "dead." (The precise method is outlined in the following section.) It may be asked why, in the clinical setting, we need the patient to locate this state and have it assigned a utility of 0 on their personal utility scale, when the public set reason for this "anchoring" does not apply. The answer is simple, but quite profound. A patient's whole personal utility set is absolutely higher, the stronger their expressed preference for their worst possible living state (55555 in EQ-5D-5L) over being dead. Conversely, their whole personal set is absolutely lower, the stronger the expressed preference for being dead over being in 55555. In other words, where the person locates the state regarded as equivalent to being dead, in relation to being in the worst possible living state, determines their absolute HRQoL. The strength of their preference for not being dead determines how healthy they are, according to their own values.

This may immediately make intuitive sense, but if not, an illustration might help. If one locates 55555 at, say, +30 (where being dead=0), all the more preferable states will have utilities concentrated in the range from +30 to +100 (where +100 is full health). The values for all these states will be absolutely higher than if they had located 55555 at –30 (when being dead=0), where they will also be dispersed over the much larger range from –30 to +100. A fuller patient example is provided in the following section.

PUSH: Establishing the Patient's Utility Set

PUSH for EQ-5D-5L is an Excel workbook, the spreadsheet platform being adopted to maximize accessibility and minimize the funding and maintenance requirements of bespoke programs. It is available on request to the corresponding author under the Creative Commons license CC BY-NC-SA. Columns A-H of sheet 1 constitute the user interface. Columns I-R are the hidden 'back end' that the clinician can unhide if interested. Other tabbed sheets contain the dropdown lists, country public utility sets, and sources.

It is envisaged that the clinician holds it as a template on their computer and opens a new copy for use with each patient. They agree with the patient on what, if anything, is to be saved as part of their electronic medical record.

As the first part of the descriptive phase of engagement, the patient rates their overall health today on the 0-100 scale of the EuroQol "thermometer," where 0 is my "worst imaginable health state" and 100 is my "worst imaginable health state." This is a EuroQol requirement for the use of EQ-5D-5L. We make no use of it in PUSH, but it is visibly available for use if desired.

The patient then responds to EQ-5D-5L, selecting the severity of their problems on its 5 dimensions. As in OPUF, these levels are automatically rephrased to the common set for all dimensions of no, slight, moderate, severe, and extreme problems. In our patient example, we will assume this procedure results in them reporting no MO problems, moderate SC problems, slight UA and PD problems, and severe AD problems. Their EQ-5D-5L health state is therefore summarily coded as 13224.

The evaluative section of PUSH now establishes the patient's initial "unanchored" disutility matrix. The disutilities are the decrements in value from not being at Level 1 (no problems). The illustrative matrix in Table 1 is for Schneider's exemplar: a person who located slight problems at 90 (disutility 10), moderate problems at 50 (disutility 50), and severe problems at 30 (disutility 70) on a scale where no problems are 100 (disutility 0) and extreme problems are 0 (disutility 100). These are inverted and decimalized to give their five personal level weights of 0, 0.1, 0.5, 0.7, and 1. The person's responses on the dimension items, with their normalized weights in brackets, were MO 100 (.29), SC 60 (.17), UA 45 (.11), PD 80 (.23), and AD 70 (.20). Note that these dimension weights form the extreme problems row of the disutility matrix. Rows 1- 4 are created by multiplying the extreme dimension weight by the level weights. For example, the disutility for severe PD problems is .23* 0.7=.16, and that for slight SC problems is .17*0.1 = .02. The final column contains the health state utility when all five dimensions are at the weight level. Logically, since its 5 disutilities must add to 1, the utility of 55555 is 0.

Table 1. Unanchored OPUF disutility matrix for exemplar patient [2]. Utility of 55555=0.

Level	Weight	Mobility	Self-care	Usual activities	Pain/discomfort	Anxiety/depression	Utility
1: No problems	0	0	0	0	0	0	1
2: Slight problems	0.1	.03	.02	.02	.02	.02	.90
3: Moderate problems	0.5	.14	.09	.06	.11	.10	.50
4: Severe problems	0.7	.20	.12	.08	.16	.14	.30
5: Extreme problems	1	.29	.17	.11	.23	.20	0

OPUF's adaptive pairwise questioning identified health state 51255 as being the one closest to being dead – neither better nor worse – for this person. Using the "unanchored" matrix above the disutility of 51255 emerges as .74 [.29 + 0 + .02 + .23 + .20]. To derive this patient's "anchored" matrix in which 51255 has a utility of 0 (= being dead), OPUF therefore divides all the disutilities by .74 (Table 2). For example, Severe PD becomes .16/.74 or .22.

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Table 2. Anchored OPUF disutility matrix for the patient. disutilities divided by .74.

Level	Weight	Mobility	Self-care	Usual activities	Pain/discomfort	Anxiety/depression	Utility
1: No problems	0	0	0	0	0	0	1
2: Slight problems	0.1	.04	.02	.02	.03	.03	.86
3: Moderate problems	0.5	.20	.12	.08	.16	.14	.30
4: Severe problems	0.7	.29	.16	.11	.22	.19	.03
5: Extreme problems	1	.39	.23	.15	.31	.27	–.35

Extreme health state 55555 now has a disutility of 1.35 [.39 + .23 + .15 + .31 + .27], and hence a utility value of 1-1.35, or–.35. 44444 has a utility of .03, 33333 one of .30, and 22222 one of .86 (rounding effects occur in some tables).

As a result of ruling out choice tasks, PUSH takes a scalar approach to the necessary anchoring (this means the OPUF distinction in step 4 vanishes). The patient is asked for their strength of preference in relation to being in health state 55555 and being dead, on a 7-point scale running from +30 (“Very strongly prefer 55555 to being dead”) to –30 (“Very strongly prefer being dead to 55555”), with 0 representing “Indifferent between being in 55555 and being dead.” The resulting anchoring dividers (Table 3) for each of the possible patient responses ensure the utility of the state they regard as neither better nor worse than “being dead” is 0. Note that if the individual prefers 55555 to being dead, their utility for it will be above 0, just as it will be below 0 if they prefer being dead to 55555. Adopted for practice-practical reasons, this procedure does require the scale endpoints to be defined independently of the patient, though the particular ones in this illustration (+30 and –30) are not essential to the PUSH concept. The chosen ones effectively censor the 55555 “pits” utility at –.43, a value similar to that in many countries’ public tariffs and close to the –.35 of the Schneider exemplar patient.

Table 3. Rescaling anchors to set the utility of being dead to 0.

Preference for being in State 55555 vs being Dead	Select	Anchor
Very strongly prefer being in 55555 to being dead	30	1.3
Strongly prefer being in 55555 to being dead	20	1.2
Slightly prefer being in 55555 to being dead	10	1.1
Indifferent between being in 55555 and being dead	0	1
Slightly prefer being dead to being in 55555	–10	.9
Strongly prefer being dead to being in 55555	–20	.8
Very strongly prefer being dead to being in 55555	–30	.7

That this procedure closely replicates (Table 4) Schneider’s when –30 (“Very strongly prefer being dead to being in 55555”) is selected, is not surprising, since the .7 used as the anchoring divider is very near to .74. Extreme state 55555 is valued at -.43 compared with –.35 and 51255 is a few points below Schneider’s zero at –.05 [1 – (.41 + 0 + .02 + .33 + .29)]. The state with all Severe Problems (44444) emerges with the value of zero, equivalent to no better or no worse than being dead for this patient. However, given the PUSH elicitation procedure, it is not necessarily the only state with that value.

Table 4. Anchored PUSH disutility matrix for patient with .7 (not .74) used as an anchoring divider.

Level	Weight	Mobility	Self-care	Usual activities	Pain/discomfort	Anxiety/depression	Utility
1: No problems	0	0	0	0	0	0	1
2: Slight problems	0.1	.04	.02	.02	.03	.03	.86
3: Moderate problems	0.5	.20	.12	.11	.16	.14	.30
4: Severe problems	0.7	.29	.17	.08	.23	.20	0
5: Extreme problems	1	.41	.24	.16	.33	.29	–.43

PUSH for EQ-5D-5L as Clinical Decision Support

The purpose of eliciting the patient’s complete value set in a clinical decision-making context is to facilitate their more effective participation by enabling their personalized evaluation of the individualized effects of interventions. Some conversation will always have occurred before the patient is asked whether they wish to engage with the PUSH decision support tool, and they will have given their informed consent. In our hypothetical illustration, we assume that, in response to a “what brings you here today?” type opening, the patient has reported feeling significantly depressed for some months and answered affirmatively to the 2 standard Whooley questions that

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guidelines recommend in this case [17]. This accounts for the 4 (severe AD) when their current state is summarized as 13224.

Following the generation of the patient's value set, the clinician makes a set of predictive judgments. Using the best available evidence and information, including that from further conversation with the patient, they enter the health state they judge, on the balance of probabilities, to be the most likely for each contemplated intervention at a chosen future time point agreed with the patient (say 3 months). In the current (but extendable) PUSH template, the clinician does this for No Intervention and for Interventions A and B. In the current example, where depression is the presenting condition, A might be, for example, a medication, and B some version of cognitive behavior therapy.

While challenging, making these judgments is well within the remit of the clinician. If they have some relevant guideline in mind, such as those from NICE, they will be aware of the routine disclaimer that heads all NICE guidance concerning the supremacy of clinical judgment. "When exercising their judgment, health professionals are expected to take this guidance fully into account, alongside the individual needs, preferences, and values of their patients. The application of the recommendations in this guidance is at the discretion of health professionals and their individual patients and does not override the responsibility of health care professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian" [17].

PUSH: A Specific Patient Example

A PUSH-based example using the level and dimension weights of the Schneider exemplar applied to a patient with current state 13224 appears in a screenshot from the tool (Figure S1 in Multimedia Appendix 1).

The patient's current health state of 13224 has a PUSH-generated utility of .63 [1 – (0 + .12 +.02 + .03 + .20)]. A time horizon of 3 months is chosen for initial evaluation of the options.

If there is no intervention, it is the clinician's judgment that, on the balance of probabilities, their depression will deteriorate from severe to extreme, with other dimensions unaffected. This would lower their utility from .63 to. 54 of state 13225. [1 – (0 + .12 +.02 + .03 + .29)].

The specified medication is judged likely to move them to 13332 - the major improvement in AD is seen as likely to be offset by the deteriorations in PD and UA as a result of side effects, leaving them at .60 [1 – (0 + .12 +.08 + .16 + .03)]. This is better than no intervention, but slightly worse than their current state. On the other hand, while the cognitive behavior therapy intervention is judged likely to produce less improvement in AD, it would not involve any deterioration in PD or UA from their current levels. It is accordingly judged likely to move them to 13223 and hence to .69 [1 – (0 + .12 +.02 + .03 + .14)]—an improvement on their current state.

The PUSH participation and its outputs are to be viewed as inputs into deliberative co-productive decision-making, where both parties contribute significantly but in role-appropriate ways. One key responsibility of the clinician is to ensure that any assistance during the elicitation phase is nondirective as far as how terms are to be interpreted (eg, "severe" and "strongly"), emphasizing that it is the patient's interpretation that is sought. A second is to dispel any "aura of exactness" or pseudo-precision that may be created by the use of precise percentages (values to two decimal places) and only central point estimates. They should make clear that they are intended to provide a useful, analytically-framed input into discussion, which is likely to include some sensitivity testing of the level weights, dimension weights, and preference regarding 55555 and dead. All changes are instantaneously implemented and visible.

It is worth repeating why we need the patient to locate the state seen as equivalent to being dead (and setting it to 0), even when no life-threatening option is involved in the current decision. The reason is that where they locate being dead determines the absolute value they place on any living health state, and therefore on any states that result from contemplated interventions. Take the patient in our Table 5 example. They "Very strongly preferred being dead to being in 55555" and, given their level and dimension weightings, this results in their current state of 13224 being valued at .63. Intervention B (to take it as an example) improves it to .69. However, if they had been "Indifferent between being in 55555 and being dead" they would value both the current and Intervention B states higher, at .74 and .78 respectively. Finally, if they had "Very strongly preferred being in 55555 to being dead," they would value their current state at .80 and Intervention B at .83, which are respectively 27% and 20% higher than those with the extreme reverse preference.

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Table 5. Effect of 55555—dead preference on the utility of states in the patient example.

Preference	Current	No Intervention	Intervention A	Intervention B
EQ-5D-5L health state	13224	13225	13332	13223
Very strongly prefer being in 55555 to being dead	.80	.75	.79	.83
Strongly prefer being in 55555 to being dead	.78	.73	.77	.82
Slightly prefer being in 55555 to being dead	.76	.71	.75	.80
Indifferent between being in 55555 and being dead	.74	.68	.72	.78
Slightly prefer being dead to being in 55555	.71	.64	.69	.76
Strongly prefer being dead to being in 55555	.68	.60	.65	.73
Very strongly prefer being dead to being in 55555	.63	.54	.60	.69

While the rankings of states are unaffected, it is clear – and hopefully makes intuitive sense on reflection – that the more preferable one regards the worst possible living health state to being dead, the healthier one regards oneself. A patient who strongly prefers being alive even in extreme ill health will also see smaller absolute differences between treatment options than a patient who regards extreme ill health as worse than death. The implications of this pure preference-sensitivity—exposed but not created by its quantification—can have a substantial impact on the subsequent decisional deliberation. It seems unlikely that an intervention which is thought likely to move one's self-valued health from .80 to .83 will have the same appeal as one that improves it from .63 to .69, even after discounting for the "pseudo-precision." Figure S1 in Multimedia Appendix 2 is a diagrammatic version of Table 5.

The PUSH-based evaluations are automatically compared with those using the conventional public utility set for the relevant jurisdiction by selecting it in the country cell. In Figure S1 in Multimedia Appendix 1, China is the one selected from the set of 13 countries currently provided in the template (others are easily added). As shown, the Chinese tariff fortuitously returns very similar values to the Schneider-based example. However, there is great heterogeneity across the country public sets, as is well-known and can be easily confirmed by a click of the country cell in PUSH.

PUSH is easily adapted to other descriptive systems. We have already developed functional versions for two instruments with OPUF-derived value sets: the EuroQol Health and Wellbeing 9 scale (EQ-HWB-9) [18-20] and the MO and Quality of Life Seven Dimension index (MobQoL-7D) [21,22]. The corresponding author can be contacted for further information.

Discussion

There is a world of difference between clinical decision-making with a patient and online research involving individuals as the source of inputs into impersonal public decision-making. The application of many legitimate principles and standards for the latter, appropriately accepted in OPUF, is ruled out for PUSH. The challenge has been one of meeting principles and standards appropriate for one-off, point-in-time, clinical decisions, where research considerations, such as test-retest reliability 2 weeks apart, to name one, are explored in relation to OPUF [23], have no relevance in practice. Swing weighting and comparing pairs of 5-dimensional health states have both been rejected on the basis of their time and cognitive demands. There are many indisputably clinically relevant challenges within the OPUF approach, even after these modifications are accepted. The most significant way in which PUSH addresses these is that patient participation and engagement occur in the company of a clinician who is competent and responsible in the use of the tool, not least because they will be making predictive clinical judgments within it as part of the co-production process.

We have not yet undertaken any formal trialing of PUSH. As would be expected, we have engaged in informal testing with colleagues and friends in the course of development. However, the formal requirements for any piloting of a clinical innovation that transforms both patient participation and clinician contribution to such a major extent mean it is sensible to advance it for discussion as a prototype to ensure a trial protocol (including clinician tutoring) is conceptually sound.

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Authors' Contributions

JD led the conceptualization, formal analysis, methodology, writing original draft, and reviewing and editing. MKK and VKR supported the formal analysis, writing the original draft, and reviewing and editing.

Conflicts of Interest

None declared.

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Multimedia Appendix 1
Screenshot of PUSH showing completed example from text.
[DOCX File , 324 KB - jopm_v18i1e81623_app1.docx]

Multimedia Appendix 2
Effect of preference for health state 55555 versus being dead on the absolute utility of current health state and that from different interventions.
[PDF File (Adobe PDF File), 165 KB - jopm_v18i1e81623_app2.pdf]

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Abbreviations

AD: anxiety/depression
EQ-HWB-9: EuroQol Health and Well-being 9 9-item scale
HRQoL: health-related quality of life
MO: mobility
MobQoL-7D: Mobility and Quality of Life Seven7-Dimension index
NICE: National Institute for Health and Care Excellence
OPUF: online elicitation of personal utility functions
PAPRIKA: Potentially All Pairwise Rankings Of of All Possible Alternatives
PD: pain/discomfort
PUSH: personal utility set for health care
QALY: quality-adjusted life year
SC: self-care
UA: usual activities

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Viewpoint

AI as a Therapist, Companion, and Romantic Partner: Emerging Roles, Benefits, and Risks for Mental Health in Participatory Medicine

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Abstract

The line between tool and companion was once obvious, but conversational AI is blurring it in ways few researchers anticipated. Large language model chatbots and purpose-built AI companion agents are now used by millions of people every day. They are not being used to simply retrieve information but, instead, to offer emotional support, help process personal distress, and sustain what many describe as genuine relationships. Research puts the scale of this shift in sharp relief as nearly half (48.7%) of individuals with self-reported mental health concerns report having used a large language model for mental health support or therapy-related purposes. This Viewpoint argues that these uses are best understood through 3 unique but overlapping relational frames: AI as a therapist substitute, AI as a companion or confidant substitute, and AI as a romantic partner substitute. Drawing on empirical literature across digital mental health, psychology, communication, and human-computer interaction and grounded in the values of participatory medicine, this paper examines why people turn to AI for these intimate purposes; what they appear to gain; and what clinicians, designers, developers, and policymakers should examine more carefully as the practice evolves. The picture that emerges is neither straightforwardly optimistic nor dismissive. Therapeutic chatbots can produce real symptom reduction for users; AI companionship can ease loneliness in genuine, if bounded, ways; and the emotional relief some people experience in these interactions is not an artifact of naivety. But the same systems that lower the barriers to disclosure also lower the barriers to harm. AI chatbots regularly hallucinate clinical guidance, validate dysfunctional beliefs, handle crises without accountability, and may cultivate the very isolation they seek to relieve. Responsible integration requires something more demanding than a disclaimer. Instead, it requires transparent design, thoughtful escalation pathways, ongoing evaluation, and a commitment to the human connection that participatory medicine places at the center of good care.

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KEYWORDS

artificial intelligence; AI; chatbots; large language models; digital mental health; participatory medicine; human-AI interaction; loneliness; AI companionship; romantic AI; mental health technology; patient empowerment; shared decision-making; online disinhibition

Introduction

Nearly half of people (48.7%) who have mental health concerns have turned to a large language model (LLM) for emotional support and guidance [1]. This is a significant shift in mental health technology use, notable for its rapid adoption and unique relational character. People are not using these systems merely as symptom trackers or medication reminders but also as psychological helpers, coaches, friends, and, in some cases, intimate partners. Understanding this shift requires an objective look at both what these systems can and cannot offer.

Historically, digital mental health tools have been largely designed to be structured and bounded. Web-based cognitive behavioral therapy (CBT) programs, symptom monitoring applications, and clinician-supported telehealth platforms were built around defined protocols with clear boundaries between tool and clinician. Research suggests that these interventions can improve reach and scalability but also acknowledges that

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the data, implementation quality, and regulations remain uneven [2]. Contemporary LLM-based systems represent a qualitative departure from this paradigm. They engage in open-ended natural language dialogue, respond dynamically to whatever the user brings, and can remember context within and across sessions. General LLMs do not follow a protocol but, instead, follow the conversation wherever it may lead. This responsiveness is what makes them feel relational, making a person feel connected to the AI agent, but it can also make evaluating them in research challenging.

The relational patterns that have emerged can be organized around 3 overlapping but conceptually unique roles. First, individuals are using AI as a therapist substitute. They use it to describe psychological distress, request coping strategies, work through emotional issues, and sometimes conduct extended quasi-therapeutic dialogues over weeks or months. Second, users can relate to AI as a friend or companion. They turn to it for social contact and validation, the simple relief of feeling heard, and the comfort of full-time availability that human relationships cannot guarantee. Third, users pursue AI as a romantic partner. They use it to seek affection, intimacy, and the experience of being desired in ways that can feel more accessible than in real-life connections. These categories are ideal types, but real use is messier and moves between them. However, the distinctions matter because the risks meaningfully differ and because the clinical and ethical obligations they generate are not identical.

What makes AI especially suitable for these roles are several key features. These features include their nonjudgmental attitude, 24/7/365 availability, the absence of social costs that normally regulate disclosure, and their continuity over time. Communications research has documented the human tendency to respond to computers as social actors, applying interpersonal norms to systems even when we know them to be nonhuman [3]. Conversational AI intensifies this tendency by adding responsiveness, attunement, and what can feel like genuine interest. Research demonstrates that people disclose more sensitive information to computer agents than to human interviewers because the felt absence of social evaluation lowers the stakes of disclosure [4]. In mental health contexts, that lowered threshold is both an asset and a vulnerability.

The limitations of these systems are primarily structural. Most general LLM chatbots are probability systems trained to produce plausible and engaging language. They are not trained to reason clinically, and they have no mechanism for checking the accuracy of what they say. The extensive literature on hallucination in natural language generation makes clear that fluency and correctness are largely independent properties. That is, a model can produce confident, well-structured, and completely fabricated clinical guidance with equanimity [5].

A second limitation concerns how AI engagement systems are generally designed. Psychotherapy can be seen as a practice of clarification, explanation, and productive disruption. A clinician gently challenges a person's distorted thoughts (or *cognitions*), asks them to tolerate the resulting discomfort, helps them understand and replace the distorted cognition, and holds the space throughout the process. AI systems are optimized for engagement and, therefore, are structurally incentivized to do the opposite: agree, affirm, and keep the conversation going. Sycophancy research on language models confirms this tendency. LLMs preferentially validate the user's expressed views, particularly when the user signals high confidence or investment in those views [6]. In a therapeutic frame and relationship, this is a direct contradiction of one of therapy's core functions.

This Viewpoint engages these themes through the lens of participatory medicine, which holds that good health care is fundamentally relational. It is built on active patient engagement, shared decision-making, and partnership between clinician and patient that treats the patient as a knowledgeable, autonomous agent rather than a passive recipient of expertise. Conversational AI can advance some of these values by democratizing access to information and reflection. However, participatory medicine also wants tools to be honest about what they are, support rather than supplant human judgment, and strengthen rather than erode the social fabric through which real health is sustained.

AI as Therapist

The mental health workforce crisis is worsening. Across most high-income countries, the gap between the prevalence of mental illness and the availability of treatment is widening. Worldwide, the median stands at just 13 mental health workers per 100,000 population, and while high-income countries report more than 60 workers, approximately half the world's population lives in countries with only 1 psychiatrist for every 200,000 or more people [7]. In the United States, federal workforce modeling projects a shortage of roughly 43,800 psychiatrists and nearly 99,800 psychologists by 2038 and notes that these figures reflect only current service use—accounting for unmet need pushes the projected gaps substantially higher [8]. This gap represents a structural failure that leaves most of those who need care without adequate access. The World Health Organization's World Mental Health survey found that between 35.5% and 50.3% of serious cases in high-income countries received no treatment in the preceding 12 months, with far worse figures in settings with fewer resources [9]. Even in high-income countries, only about one-third of people with major depressive disorder receive formal mental health care, and among those who are treated, just 23% receive care that meets the minimum standards of adequacy [7]. Mental health worker shortages exist throughout the United States, with nearly 50% of citizens living in shortage areas [10]. Wait times extend the problem even for those who do seek care. A national study of US psychiatry practices found that only 18.5% of psychiatrists could see new patients, with a median wait time of 67 days for in-person appointments [11]. Geography further limits options. An estimated 65% of nonmetropolitan US counties have no practicing psychiatrists, leaving over 60% of rural Americans in designated mental health care provider shortage areas [12]. High treatment costs can make access difficult even where services nominally exist. In addition, stigma suppresses help-seeking behaviors well before other barriers come into play [13]. Against this backdrop, the appeal of a system that is available at any time, with minimal or no cost, and does not ask intrusive questions is not difficult to understand. Novel models

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for reducing the burden of mental illness at a population scale have been an active research priority for more than a decade [14], and digital tools are regularly discussed as one component of any realistic solution [2].

The case for AI-assisted mental health support is more than theoretical as there are many randomized controlled trials supporting its use. A randomized controlled trial found significant reductions in depressive symptoms among young adults assigned to the Woebot conversational agent compared with an information-only control group, with positive effects emerging after just 2 weeks [15]. A systematic review and meta-analysis of mental health chatbots found small to moderate improvements in depression and anxiety scores across studies [16]. Research limitations of these studies include weak or nonexistent comparison groups, short follow-up periods, and lack of longitudinal data. Because of these limitations, the data do not conclusively establish that chatbots are equivalent to psychotherapy. However, under certain conditions using purpose-built AI chatbots, the research suggests that they can produce clinically significant outcomes.

The therapeutic benefits of these chatbots seem to occur for 2 different reasons. The first is greater disclosure. A study by Lucas et al [4] found that participants assigned to interact with a computer agent rather than a human interviewer reported more sensitive information, including depression and posttraumatic stress disorder symptoms, with measurably lower concealment behaviors. Participants knew that they were talking to a machine, so this finding cannot be explained by technical naivety. Rather, the social costs of disclosure—such as the fear of judgment, embarrassment, or unwanted consequences—are simply lower when the audience is perceived as nonhuman. For individuals whose mental health concerns carry significant stigma [13], this reduction in social cost may help increase disclosure. The second mechanism is structured reflection. Many purpose-built mental health chatbots incorporate CBT-derived techniques that can be meaningfully facilitated through conversational prompting without the need for a human therapist [15,16].

Challenges arise when users shift from purpose-built tools to general-purpose LLMs. The risks are categorically different. Structured therapeutic chatbots generally have a defined scope, documented safety protocols, relational guardrails, and clinical oversight built into their design. In contrast, a general LLM has none of these components. It can generate confident-sounding clinical guidance, medication recommendations, diagnostic interpretations, and therapeutic advice but lacks a mechanism for distinguishing between what it knows and what it has fabricated. The research literature on hallucinations makes it clear that language fluency is not the same as truth and modern generative systems can produce fabricated facts, invented references, and mischaracterized evidence in the same tone and confidence they use when conveying accurate information [5]. In mental health contexts, where users may be making decisions about medication, symptom interpretation, or crisis escalation, there may be significant consequences of providing confident misinformation.

Sycophantic alignment compounds this risk in ways that are harder to detect. A hallucination can be fact-checked, but sycophantic distortion cannot. General LLMs tend to align with whatever the user wants to hear, validating their beliefs, confirming their suspicions, and reinforcing their framings rather than offering the gentle friction that characterizes effective therapeutic dialogue. Research documents that this effect is strongest when the user signals confidence or emotional investment [6]. This is exactly the condition that most frequently accompanies entrenched maladaptive cognitions. A chatbot that confirms a person's worst fears or validates false beliefs is not failing by the metrics it has been optimized for. It can be maximizing engagement while systematically worsening the user's state of mental health and well-being.

User crises expose a further limitation. A therapist's duty of care extends beyond a single psychotherapy session through ongoing risk assessment, legally obligated reporting, safety planning, and the capacity to escalate when a patient needs more help. General conversational AI lacks these capabilities. It cannot verify follow-through on a safety plan, contact emergency services, or assume legal accountability for the advice it provides. The gap between the promise of accessible mental health support and the practice of clinically responsible care is at its widest here. For users in crisis, AI is not a substitute for human intervention regardless of how sophisticated its responses become [17].

AI as Friend or Companion

Loneliness is one of the most consequential public health problems of our time, associated with elevated all-cause mortality, accelerated cognitive decline, worse cardiovascular and immune outcomes, and substantially elevated risk of depression and anxiety [18]. A meta-analysis of 70 studies by Holt-Lunstad et al [18] found that social isolation, loneliness, and living alone each independently predicted a 26% to 32% increased likelihood of premature mortality, effects comparable in magnitude to those of well-established behavioral risk factors.

The health care system has very few tools to address this issue. It can be diagnosed, patients can be counseled, and it can be noted as a risk factor, but clinicians cannot prescribe social connection. Conversational AI has arrived with the promise of helping alleviate loneliness, and emerging research suggests that it can indeed sometimes be helpful.

Studies on human-chatbot relationships demonstrate what users experience. However, this research tends to be more subjective and based on behavioral observations rather than the randomized controlled studies used to examine AI use in therapy. Skjuve et al [19] followed users of a social chatbot over time and found something resembling genuine relationship development. Their research found relationships that involved increasing trust, escalating self-disclosure, a sense of being known and responded to individually, and positive increases in a person's well-being [19]. Participants were not confused about whether they were talking to a machine, and they reported that the interaction provided something of value. A study by Merrill et al [20] found that social presence, the sense that one's friend is meaningfully "there" and present, and perceived warmth were the key mediating variables through which AI companion interactions affected loneliness and willingness to engage. This makes sense

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because loneliness is fundamentally not about the absence of physical company so much as it is about the absence of felt responsiveness. Loneliness is the experience of being unseen and unheard.

Additional studies support AI's use to help reduce feelings of loneliness. A number of studies of social chatbot use suggest that users may perceive these systems as friends and sources of emotional support, particularly when interactions feel responsive, nonjudgmental, and consistently available [21,22]. De Freitas et al [23] report significant loneliness reductions associated with AI companion use, with effects consistent across multiple studies. Limitations associated with this research include selection effects, where lonely people are more likely to adopt the use of AI chatbots, and various confounds. In addition, the long-term effects of companionship agents remain poorly understood.

The features that make AI a reliable conversational partner—consistent availability, patience, and unfailing attentiveness—simulate qualities that are scarce in human relationships precisely because they are challenging to provide. When an AI companion is described as "always there," this is noting an asymmetry not typically found in human relationships. Research explains why this asymmetry is not psychologically salient in the moment [3]: the mind responds to socially cued stimuli with social processing regardless of its knowledge of their origin. However, the asymmetry is real, and it carries risks that imperceptibly emerge over time rather than in any single interaction.

According to the social displacement hypothesis, time and emotional investment in AI companionship may come at the cost of investment in human relationships. The review by Nowland et al [24] on loneliness and social internet use finds a complex interaction. Digital interaction can facilitate reconnection and provide a bridge back to human community. However, the researchers also found that, for some individuals, particularly those who already find human interaction aversive or threatening, digital substitution becomes an avoidance strategy that deepens isolation over time [24]. The distinction matters for participatory medicine because the appropriate clinical response will differ for someone using AI companionship as a bridge vs someone using it as a retreat.

There is also a privacy dimension to companionship use that is easy to forget. People tell their AI companions things that they have not told their clinicians, partners, or closest friends, such as trauma histories, relationship grievances, health anxieties, or even expressions of hopelessness. This disclosure is often beneficial in the moment. However, it occurs within a commercial context, against terms of service that few users read and fewer fully understand, with data retention practices that may extend the intimacy of the conversation well beyond its duration. The consent framework that most AI chatbots use today is wordy and full of dense legalese, making it difficult for an average person to understand, much less agree to. If patients are not being genuinely informed to give consent, then they cannot be genuinely empowered to be participatory.

AI as Romantic Partner

While the therapeutic and companionship uses of AI are straightforward, the growing use of romantic chatbots may be less understandable. The research base for this kind of AI use is also in its infancy, relying on observational data rather than the randomized controlled studies used to examine AI use in therapy. The study by Willoughby et al [25] of a US sample of young adults found that romantic engagement with AI is not rare. A meaningful subset of users engaged with AI chatbots specifically to replicate romantic experiences, and the behavior was not concentrated among any identifiable demographic group [25]. A mixed methods analysis by Wang et al [26] similarly documents the complexity and diversity of human-AI romantic relationships. People bring a wide range of motivations, attach a wide range of meanings, and describe both positive and negative outcomes, making simplistic explanations for the growing use of AI as a romantic partner impossible [26].

The psychological mechanisms underlying romantic AI attachment are similar to those in companionship but are intensified by the introduction of intimacy cues. A romantic chatbot can be consistently affirming, attentive to the user's stated preferences, physically (textually) affectionate, and resistant to the conflicts, competing needs, and emotional ups and downs that can characterize human romantic relationships. Communication researchers have described parasocial relationships—one-sided emotional bonds with celebrities, media figures, or influencers—as a normal component of media consumption [27]. AI romance differs from classic parasocial attachment because the system responds, adapts, and appears to reciprocate a user's thoughts and feelings. This responsiveness may create something closer to the felt experience of reciprocal intimacy than any prior media technology has generated. This can make it feel both more valuable and more consequential.

For individuals with social anxiety, a physical disability, or relational trauma or for those who live in geographic isolation, AI romantic interaction may provide concrete benefits. Romantic AI chatbots can provide emotional comfort, a sense of being desired and valued, an opportunity to practice communication and boundary setting, and a space to explore aspects of identity and preference that feel too vulnerable to risk in a human relationship. Attachment theory proposes that experiences of felt security—regardless of their source—contribute to the development of more secure internal working models of the self and others [28]. For individuals with histories of insecure or traumatic attachment, a consistent, nonthreatening, caring virtual relationship may have significant value.

However, the risks are more serious than in companionship use and may be harder to mitigate. The first risk concerns the calibration of expectations. An AI romantic partner engineered for engagement will, by design, be more attentive, patient, consistently affirming, and free of competing needs than any human partner can be. Users who develop an emotional attachment in this context may come to experience the ordinary friction of human romantic relationships—misattunements, competing needs, and imperfect availability—as aberrant rather

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than as a naturally occurring component of real-life relationships.

The second risk is dependency, resulting in real-life avoidance. Attachment theory suggests that avoidant relational strategies are maintained through the reinforcement they provide in the short term: avoided situations do not disconfirm the fears that motivate avoidance [28]. An AI romantic partner that is perfectly safe, consistently available, and immune to rejection may provide reinforcement for permanent avoidance. The chatbot may provide the affective benefits of attachment without requiring the vulnerability through which avoidant patterns are actually healed.

Romantic AI use has some of the greatest privacy concerns. The content of these interactions—expressions of desire, disclosures of vulnerability, and intimate exchanges—is among the most sensitive personal information that exists, generated within a commercial context that users rarely think about at the moment of disclosure. Data governance rules for romantic AI platforms are not merely good practice but are required and need to be understood by users. Finally, the hallucination and sycophancy risks that run through all AI mental health applications take on particular weight in a romantic context. A system that affirms a user's most distorted beliefs about themselves, their ex-partners, or their worthiness of love is not merely providing inaccurate information—it is doing so through a medium specifically designed to maximize trust and emotional receptivity [5,6].

Cross-Cutting Mechanisms and Safety Challenges

Across all 3 of these roles, a set of underlying mechanisms accounts for both the benefits and challenges that accompany AI mental health chatbots.

The most significant mechanism is the one Reeves and Nass [3] identified before LLMs existed: the social brain does not have a reliable switch for distinguishing human from nonhuman interactions. When a system produces socially cued outputs—responsive turn taking, emotionally attuned language, and apparent interest—the mind processes it socially, applies interpersonal norms, and generates affective responses appropriate to a social or relational encounter. Conversational AI has intensified this tendency to a degree that its predecessors could not achieve. The result is not user error or technological naivety but rather the activation of cognitive and emotional systems that evolved long before the distinction between person and machine had any relevance.

A closely related mechanism is the online disinhibition effect [29]. Suler [29] identified 6 factors that collectively loosen the behavioral constraints governing self-presentation and disclosure: dissociative anonymity, which severs the link between online behavior and offline identity; invisibility, which removes the audience cues that trigger social monitoring; asynchronicity, which attenuates the sense of real-time social consequence; solipsistic introjection, which leads people to experience the interaction as self-generated rather than truly witnessed; dissociative imagination, which frames the interaction as consequence free; and minimization of authority, which removes the power differentials that ordinarily regulate disclosure. In AI relational contexts, several of these factors operate simultaneously and with unusual intensity. The user is not visible to any social audience. The AI carries no institutional authority and imposes no evaluative judgment. The interaction can feel like a kind of projective space—responsive enough to seem real but, ultimately, of the user's own creation. This combination is what makes AI disclosure so easy. The same conditions that make it easier to say difficult things also reduce the normal safeguards on what we say, to whom we say it, and at what cost.

Recent empirical work by Syrjämäki et al [30] illustrates the challenges presented by the online disinhibition effect on behavior. Their analysis demonstrates that online disinhibition mediates the relationship between emotion regulation difficulties and harmful communication behavior. The researchers found that individuals who struggle to regulate emotional arousal become more disinhibited online and this disinhibition predicts impulsive, boundary-crossing behavior.

The implications for AI mental health chatbots are noteworthy. The same reduction in felt social consequence that makes it easier to disclose trauma to an AI also makes it easier to spiral into escalating emotional expression, share information one later regrets, or pursue relational dynamics one's own emotional regulation would normally prevent in a human context. Disinhibition requires careful attention and direction, not maximization. Designing a mental health chatbot's beneficial expressions while limiting its harmful ones is one of the central challenges of responsible AI design.

Two additional mechanisms operate at the level of the AI system. The first is engagement optimization via sycophancy. General commercial AI systems are typically trained to prioritize user satisfaction and continued engagement. These are metrics more readily produced via agreement, validation, and affirmation than via challenge, disruption, or the friction sometimes generated by honest conversations. The sycophancy literature documents the result: systematic tilting toward whatever position the user appears to hold, reinforcement of confidently expressed beliefs, and suppression of the productive disagreement that therapeutic relationships (and many strong friendships) depend on [6]. This is a structural consequence of optimizing for engagement. Addressing it requires a deliberate design commitment to prioritize therapeutic fidelity over user-reported satisfaction, which in turn requires evaluation frameworks that can distinguish between the two.

For shared decision-making to be effective in participatory medicine, interactions must be honest and based on facts as well as clean data. When these data become polluted through sycophantic bias, the resulting conversation will be less than honest. This is a hidden challenge in using AI for participatory medicine because informed self-care comes not only from data and knowledge about a health condition but also from accurate and sometimes challenging conversations about treatment options and likely outcomes. When AI is optimized for engagement rather than honesty and challenging the user's maladaptive thoughts, feelings, or behaviors, it becomes more

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of an ineffective but friendly echo chamber and less of a useful health consultant.

The second mechanism is hallucination—the capacity of generative systems to produce fluent, confident, and completely fabricated content with no internal signal flagging the fabrication [5]. In casual information-seeking contexts, hallucination is an inconvenience. In mental health contexts, where users may be making decisions about medication, safety, diagnosis, and treatment, this is a patient safety issue. Language models produce the most statistically probable continuation of a prompt, which may or may not correspond to anything true in the world. There is no known technical fix at this time that resolves this concern. The practical implication for mental health AI is that users must be genuinely informed about AI's limitations (not just in the fine print or terms of service). Any kind of clinical guidance from an AI chatbot should be understood as provisional rather than authoritative.

Together, these mechanisms suggest a more demanding conception of safety than the industry typically adopts. Adding a crisis hotline number at the bottom of every chatbot conversation is not a safety feature; it is simply a liability hedge. Real safety requires designing systems that are honest about what they are, actively promote human connection, detect clinical risk with enough sensitivity and specificity to be trusted, and treat the user's long-term well-being and need for human relationships as design guardrails rather than secondary considerations [31].

Implications for Participatory Medicine

Participatory medicine is sometimes understood as a delivery philosophy—getting patients more involved, giving them better tools, and making decision-making a more equal and two-way process. However, at its core, it is a set of commitments about what good health care actually is: not the transfer of expertise from clinician to patient but the partnership of two people committed to understanding, care, and health within a relationship that takes both parties equally seriously. Conversational AI is relevant to this vision in ways that are both promising and potentially challenging. Participatory medicine has the potential to help inform the conversation.

The promising side begins with access. For most people who have mental health needs but cannot access treatment—due to cost, geography, wait times [11], stigma [13], or scheduling availability—an AI system can provide hope. Mental health AI chatbots can offer an invaluable bridge to people in need through structured exercises, reflection, psychoeducation, and the felt experience of being heard. AI tools examined in the literature have produced real symptom reduction [15,16]. Between-session support, help in articulating concerns for upcoming appointments, and guidance through evidence-based CBT exercises are genuine contributions to care, particularly for individuals navigating the system for the first time [32]. AI systems can also help with initial engagement with mental health care, reaching people before they have found a clinician and supporting them in ways that make the eventual clinical encounter more productive.

The challenging side is more subtle but equally urgent. AI systems that optimize for engagement will, absent deliberate countermeasures, tend to become what users *want* them to be rather than what users *need* them to be. They will validate a person's thoughts or feelings when they should challenge them instead, agree when they should question, and sustain conversations that a responsible clinician would redirect. The felt experience of being understood by an AI chatbot that does not actually understand, reinforced over time, may substitute the human understanding that participatory medicine identifies as core to genuine patient engagement. The risk is quiet, gradual, and easy to rationalize. The user reports feeling better; the engagement metrics on the surface appear to be strong; and the harm is almost impossible to attribute to any particular, single interaction.

Several implications follow for design, practice, and policy. First, transparency must be understood not as a disclosure obligation but as a clinical feature. Users of AI mental health systems should come away from every interaction with an accurate understanding of what the system is and is not capable of, how its outputs are generated, and how their data are used. This is not accomplished by a terms-of-service agreement or a one-time onboarding screen. Instead, it requires ongoing, contextually appropriate communication embedded in the interaction itself.

Second, escalation pathways must be designed with the same care as the conversational interface. The gap between recognizing a crisis and reaching human support is where the most preventable harms occur. Closing this gap requires active design interventions rather than passive disclaimers. AI systems should be designed to detect clinical risk, reduce friction in accessing help, and maintain a connection with the user throughout the transition.

Third, the evaluation framework for AI mental health tools must expand beyond symptom outcomes and satisfaction ratings to include relational outcomes—what happens to users' human relationships over time; whether AI use functions as a bridge or as a retreat; and whether the capacity for human intimacy is preserved, strengthened, or eroded [24]. This may be methodologically demanding and commercially inconvenient, but it is important to address when AI is being used for mental health.

Fourth, clinicians need preparation. Patients who describe their AI companion as a central source of support or their AI romantic partner as more emotionally available than any human relationship they have are already in clinical practice—and they deserve responses that are neither dismissive nor uncritically validating. Participatory medicine frameworks that prepare clinicians for these conversations without stigmatizing what patients find meaningful could be significantly helpful [26].

Finally, the pace of adoption has outrun the pace of evidence. The most vulnerable users are already inside systems that have not been adequately evaluated, and the normative frameworks for what adequate evaluation even looks like are still being developed. Participatory medicine can contribute something important: a commitment to centering the lived experience of users—including their experiences of harm that never make it

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into randomized trials—as evidence that counts and a governance approach that treats the communities most affected by these technologies as partners in their evaluation rather than subjects of it [17].

Conclusions

Conversational AI can provide benefits in some relational contexts for some users under conditions we are only beginning to understand. These same features that make it beneficial also make it capable of causing harm that is often difficult to understand and appreciate until it has accumulated over time.

The 3 relational roles examined here—therapist, companion, and romantic partner—are not merely categories for organizing the literature. They are windows into different dimensions of human need: the need for guidance through distress, for connection in isolation, and for intimacy in its most vulnerable form. AI can help in each of these areas, filling gaps that human care systems have failed to close [9,11,12]. This is more a factor of the vast scale of unmet need for mental health treatment options as much as it is about this emerging technology.

The path forward is not a choice between embracing AI and protecting human connection but, rather, designing systems, evaluation frameworks, clinical practices, and governance structures that do both. Conversational AI should be honest about its nature and limitations and built to strengthen the conditions for human care rather than substitute it; it should be judged on its long-term effects on users' lives, not just their mood in the hour after an interaction; and it should be developed with the active participation of the people whose vulnerability it most directly engages. Participatory medicine is not a by-product of good AI design; it is what makes that design possible—patients engaging as equals in their own care.

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Data Availability

This Viewpoint synthesizes previously published empirical literature and does not report original research data. No new datasets were generated or analyzed. All source articles are cited and publicly available through their respective publishers.

Editorial Notice

The author cofounded the Society for Participatory Medicine. The editor serves as editor-in-chief of the *Journal of Participatory Medicine*, the official journal of the Society for Participatory Medicine, and serves in an ex officio position on the Society for Participatory Medicine board of directors.

Authors' Contributions

JG conceived and designed this paper and was responsible for data acquisition, analysis, and interpretation; drafting and critically revising the manuscript for important intellectual content; final approval of the version to be published; and accountability for all aspects of the work.

Conflicts of Interest

JG is a cofounder of the Society for Participatory Medicine.

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Abbreviations

CBT: cognitive behavioral therapy
LLM: large language model

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Preparing for Care: A Clinician's Perspective on Anticipatory Caregiving and Meaning Making

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Abstract

More than 50 million adults in the United States provide unpaid care to a family member. Caregiving is associated with high rates of depression, anxiety, social isolation, financial strain, and physical exhaustion. Elevated caregiver distress has also been linked to poorer patient outcomes, including worse symptom control, lower adherence to treatment, and increased health care use. Despite this well-documented burden, most research and intervention efforts focus on caregivers once illness or disability is already advanced and strain is fully present. Far less attention has been given to anticipatory caregiving, the emotional and relational adjustments that begin before clear functional decline. As aging parents grow more frail, adult children often confront uncertainty, shifting roles, and the gradual loss of independence long before hands-on care is required. This period may be marked by vigilance, grief, and existential distress, yet it remains largely unaddressed in the literature. This perspective examines anticipatory caregiving through clinical reflection and personal narrative, highlighting the need to recognize and support caregivers earlier in the trajectory of aging, before crisis defines the experience.

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KEYWORDS

anticipatory caregiving; meaning making; caregiver burden; autonomy; partnership

As I prepare to see my mother in person after several months, I gather my passport and plan the obligatory family gifts. I also catch myself imagining how she will look. I find myself scanning ahead of time for signs of frailty. Will she walk with a limp that was not there before or need help with things she used to do on her own?

For many adult children, caregiving begins in this anticipatory space, long before hands-on care is required. Caregiving begins long before physical tasks and constitutes an extended psychological and relational process. From my perspective, that early phase is filled with vigilance, imagined loss, and a growing sense of responsibility for another's vulnerability. These largely unspoken forms of emotional labor shape how we later engage in care. What I am describing is not only personal; it is well-documented in the literature.

In the United States, more than 50 million adults provide care to family members, many experiencing varying levels of distress. This distress can include physical fatigue as well as psychological effects, such as hopelessness, anticipatory grief, and loneliness [1]. Collectively, these experiences reflect caregiver burden: emotional, social, financial, physical, and spiritual strain [2]. High caregiver distress is associated with poor symptom management, reduced treatment adherence, and diminished patient quality of life. When caregivers are exhausted, their ability to sustain care, communicate with clinicians, and participate in decision-making falters [3].

Recognizing this, research, particularly in oncology, has focused on caregiver distress. Interventions offering education, skills training, and structured support have shown improvements in quality of life and reductions in anxiety and depression, especially when patients and caregivers participate together [1]. Still, findings are mixed. A 2019 Cochrane Review found that psychosocial interventions for informal cancer caregivers may yield small improvements in quality of life immediately post intervention, but likely have little to no sustained effect on depression, anxiety, or psychological distress. The authors noted substantial heterogeneity across studies and overall low methodological quality, limiting firm conclusions [4]. These findings do not suggest that caregiver support lacks value; rather, they may reflect brief, largely psychoeducational programs that were not individualized to caregivers' specific needs, relational dynamics, or cultural context.

More recent meta-analyses offer nuance. Programs lasting 8 weeks or longer tend to reduce anxiety and depression. Meaning-centered approaches appear particularly helpful for the existential distress that caregivers often face [5]. In my clinical work, I often return to the questions at the heart of meaning-centered psychotherapy: Who am I in this role? What matters most to me? What do I want my loved one to feel from me?

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These approaches emphasize the possibility of growth alongside burden. I recognize that process in myself, even before initiating any formal caregiving role.

I scan for changes: the way she steadies herself coming down the stairs. What I have not done is tell her I am scanning. My stomach tightens just thinking about it, so I stay quiet.

If I asked her, she would wave it off. “You cannot hide much from your own kid,” she would say. “But let’s not make a whole thing of it. I am fine.”

If I inquired about her daily routine, she would say, “I still cook everyone’s eggs in the morning, the way I have always done it. What else do you want?”

What does she want as she ages? Not surveillance. Not daughters ruling on her affairs. “I just want things to stay as normal as possible. I do not need fussing. I raised my family. I have completed my mission. That is enough. Just let me be.”

I tell myself I am monitoring, watching for signs, preparing.

But partnership is different from monitoring.

Partnership requires that I ask and then tolerate the answer. If she says she is fine, partnership asks me to sit with that, not to translate it into what I think she means, not to secretly catalog it as denial. Sometimes I want to steer the conversation toward the future, toward plans and contingencies. Instead, I try to stay where she is, though it is hard to do so.

I speak of anticipatory grief as if it belongs to me. But she, too, is aging inside a body that surprises her. She, too, may be watching me, measuring the steadiness of my visits, the tone of my voice, the frequency of my calls.

Ours is not a relationship of effortless intimacy. It never has been. But it has always been honest. I have been preparing to care for her in some practical way. I have not prepared to sit beside her as two women who are both afraid.

I assume she is proud of me in some respects. But pride travels in both directions. Have I made room to admire the woman she is, not just the mother she was? Since I was 10 years old, it has been difficult to manage my mother. We are not women who cook side by side. We are not soulmates. We do not share a hobby. But we both love the beach.

We walk for hours, scanning the horizon, meeting each wave as it comes. The collaboration is the commentary: relatives, my friends, the world as she narrates it with wit and grievance. Advice arrives whether requested or not, all of it delivered with impeccable timing.

That space, sharp and familiar, is ours.

My vigilance is not only about decline. It is about advocacy. When caregiving comes, my role will not be just to report symptoms but also to translate her values. Medical histories begin with “What is the matter?” But what she needs is space for what matters. To her, autonomy, normalcy, and dignity matter more than surveillance. My task is not to overtake her narrative but to safeguard it.

I wonder whether her doctors are tracking only her heart and lab values or also noticing her social life. We would notice if she stopped going out. Meanwhile, we teach her to use a tablet, not to become her instructors, but to keep her in the thread of things. The look on her face when she hears the ping of a message tells me it matters.

What she needs are people who are not family, places that expect her. The prescription may not be a medication at all, but something that requires her to show up: a Pilates class or a standing lunch. These are not luxuries. They give her a reason to get dressed and go out.

Meaning making coexists with logistics. Loving an aging parent also means entering the administrative maze of prior authorizations, banking safeguards, medication lists, hearing checks, home repairs, and unexpected charges. All of it is work. Naming it permits caregivers to feel overwhelmed not only by worry but also by the coordination of aging demands [2].

As I prepare to see my mother, this perspective helps me frame my anticipatory worry more gently. What are my hopes for this visit? How are they shaped by my values? What do my fears reveal about my relationship with her?

As I reflect, something shifts. As much as I dread witnessing her possible decline, I recognize that I want to be there. If she needs help, I want to be one of the people helping her. It is frightening to imagine her growing more vulnerable, but there can be meaning for both of us in sharing that journey.

Conflicts of Interest

None declared.

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Living the Masterclass: Multiple Sclerosis Patient Journeys and the Reality of Participatory Medicine

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Abstract

This reflective article, written collaboratively by 4 people living with multiple sclerosis (MS)—Johanna Hising DiFabio, Meredith O'Brien, Jennifer Southard, and Danny van Leeuwen—with Mary Hennings of the Society for Participatory Medicine, distills insights shared at a March 2025 event cohosted with Northeastern University's Bouvé College of Health Sciences. The panelists speak as experts on their own lived experience, tracing the arc from diagnosis to what they call "optimal living" with a complex, unpredictable disease. The piece begins with the diagnostic journey itself, describing a "double trauma": the anguish of unexplained physical decline before diagnosis, followed by the weight of confronting a confirmed chronic illness. The authors argue that how clinicians deliver and support a diagnosis determines whether patients end up isolated or drawn into genuine partnership with their care team. A central theme is the search for the right clinician fit—not just competence, but shared communication style and mutual respect for the patient's expertise in their own life. The authors describe practices that support this, such as setting the visit agenda in advance through patient portals, and stress that patient engagement styles vary: some patients want deep involvement in research, while others prefer to delegate, but all need a clinician who genuinely listens. The article expands the notion of a care team beyond medical clinicians, describing three layers: the medical core, a complementary team (bodywork, movement, nutrition specialists), and a personal network of family and friends providing emotional support. It also names systemic frictions, like patients having to relay information among clinical specialists who don't communicate with each other. A recurring message is resisting being reduced to the disease. The authors describe both the comfort and sting of comments like being told they "don't look sick." They also share personal strategies for preserving identity and quality of life, from adapting a musical instrument to accommodate physical limitations, to writing and publishing patient narratives, to using organizational resources like the National MS Society to navigate research and advocacy. The article closes with practical counsel for newly diagnosed patients: stay engaged, insist on true clinical partnership, build a broad support ecosystem, and protect the personal choices that give life meaning. It affirms the core principle of participatory medicine—that patients and clinicians grow together, with the patient retaining ownership of their own body and life.

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KEYWORDS

participatory medicine; multiple sclerosis; patient journey; patient preferences; patient empowerment

Introduction

This collective reflection explores what it means to evolve from a vulnerable person receiving a life-altering diagnosis into an empowered, equipped, engaged, and enabled e-patient who orchestrates our own care. It summarizes our observations about that journey. Other patients may find these insights helpful as they travel their own paths from diagnosis to optimal living with a complex, impactful disease.

The Trauma of the Threshold: From Presentation to Diagnosis

The road to a multiple sclerosis (MS) diagnosis is seldom a straight line; it can be a confusing, agonizing maze. Because the disease presents in shifting, unpredictable ways, some of us were diagnosed quickly, while others spent years being dismissed, misdiagnosed, or told our worsening physical symptoms were psychosomatic [1].

This journey carries a double layer of trauma:

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- The trauma of the unknown: living with a body that is failing without knowing why, while fighting to have our reality validated by clinicians.
- The trauma of the known: the heavy anxiety of the final diagnosis, where the fear of the unknown transforms into the stark reality of facing a chronic, progressive disease.

The diagnostic experience permanently shapes how a person interacts with clinicians. One of us was actively advised *not* to research their own condition—an instruction to remain passive. Another found immediate transformation by plugging into patient networks through the National MS Society [2]. The lesson here is foundational: how a diagnosis is delivered and supported dictates whether a patient is pushed into isolation or invited into partnership.

Beyond Competence: Finding the Right Clinician Partner

We learned that clinical competence is the baseline; physician fit is not automatic. True participatory medicine requires compatibility in communication, management philosophy, and a mutual valuation of expertise [3].

Many of us walked away from our first neurologists. For some, a metrics-driven approach built around managing MS strictly "by the numbers" can ignore the priorities of the person living with the disease. We looked instead for clinicians who viewed us as collaborators in care.

In a successful partnership, communication flows both ways before anyone steps into the exam room:

- Setting the agenda: sharing current health status, concerns, and questions in advance through patient portals sets an agenda that increases the likelihood that clinical visits are efficient and effective.
- Varying styles of engagement: participatory medicine is not one-size-fits-all. Some of us want to dive deep into the latest clinical trials and research findings, while others prefer to delegate that synthesis to our doctor or care partners. The constant requirement, however, is that the clinician listens and acts upon what they hear from us.

Those of us who found alignment with clinicians in our team view our primary clinician as the medical quarterback. We know teamwork is a two-way street. As patients, we learn to navigate our clinicians' unique styles, quirks, and constraints to build mutually resilient empathies [4,5].

Cultivating the Wider Team

Active management of a complex condition like MS requires looking far beyond the conventional clinic walls. While the medical team remains essential, a rich, full life demands a broader ecosystem [2]. We think of our care infrastructure in three distinct layers (Textbox 1).

Textbox 1. The three elements of care infrastructure.

The medical core: neurologists, specialists, and primary care providers who manage disease modification and clinical metrics.
The complementary team: chiropractors, massage therapists, acupuncturists, yoga instructors, and dietary therapists who contribute to day-to-day comfort.
The personal network: family, friends, neighbors, and care partners who understand the context of our lives and provide emotional scaffolding.

Navigating this ecosystem reveals systemic failures. For example, patients are routinely forced to act as the "human fax machine," serving as the communication glue between clinicians who do not talk to one another. The diversity of this ecosystem reveals internal tensions. Our family care partners may worry about progression, while we are consumed by the weight of the unintended consequences of today's treatment. Naming these tensions openly helps the team move forward together.

The Reality of Living Outside the Exam Room

Medical care happens in brief, intermittent flashes; the reality of a disease happens outside the exam room [6]. Life is punctuated by logistical mountains that healthy people navigate automatically. For instance, engineering the journey between an airport entrance and an airplane seat or managing the complex intersection of disease therapy with pregnancy or menopause are not straightforward for those of us with MS.

For us, thriving means refusing to allow the disease to consume our identity. We are not MS. Some people, when learning we have MS, say "But you look so good, I would never know you have MS." Sometimes, we take the comment as a compliment: "Good, we're not MS." Other times, it feels like a minimization of the invisible, exhausting effort required to appear well. Many people offer fixes: "Have you tried drug x or diet y?" So, we don't want to be defined solely by our diagnosis, but we need our burden to be seen, heard, and acknowledged without someone immediately trying to "fix" it.

Participatory medicine shines bright when clinicians partner with us to solve problems while preserving our humanity. For instance, one of us successfully negotiated a complex medication adjustment with her neurologist specifically so she could continue to wear high heels. To the clinician, it was a question of drug levels; to the patient, it was a nonnegotiable anchor of self-worth and identity. When a lifestyle choice carries that much meaning, it is worth innovating around.

Tailored Strategies for a Rich Life

To move the needle from surviving to thriving, we have each had to innovate, leaning heavily on trusted resources and creative problem-solving:

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- Danny's strategy: As a dedicated saxophonist, holding a 12-pound instrument became impossible due to MS. Double vision hampered reading scores. However, realizing that breath work [7] was vital for respiratory health, a collaborative effort with a music teacher, an optometrist, and a German manufacturing company resulted in a custom-scaled instrument stand and an iPad-based music reader to mitigate the double vision. Working with nonclinical specialists can help preserve the things that feed the soul.
- Meredith's strategy: As a writer and college teacher, purpose was found in translating lived experience into advocacy. Publishing *Uncomfortably Numb 2* [8], an anthology of patient stories, created a direct pipeline of practical wisdom to support the newly diagnosed, proving that patient stories enrich both the reader and the storyteller.
- Johanna & Jennifer's strategy: Using digital anchors like the National MS Society website [2] provides an essential roadmap for everything from policy advocacy to self-care. For Jennifer, it answered the critical questions she didn't yet know to ask as a newly diagnosed patient; today, it allows her to co-navigate emerging research side by side with her neurologist.

Conclusion

Our collective journey offers a guide for newcomers navigating chronic, long-term illness. Our counsel: stay fiercely engaged, demand clinicians who operate as true partners, build an expansive care team, and aggressively protect the lifestyle choices that give your life meaning.

Keep in mind that the ultimate truth of the participatory movement: it is your body, it is your life, and as partners in health care, we grow together.

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Conflicts of Interest

MH is the board chair of the Society of Participatory Medicine. The *Journal of Participatory Medicine* is the official journal of this society at the time of this publication. MH had no involvement in the editorial review and processing of this manuscript. MOB is a volunteer with the National MS Society and has written two books on their multiple sclerosis journey. All other authors declared no conflicts of interest.

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Abbreviations

MS: multiple sclerosis

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The Architect of Trust: Dr Tom Ferguson's Legacy

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Abstract

This article serves as a formal tribute to the legacy of Dr Tom Ferguson and his foundational 2007 white paper on the "e-patient." Despite its widespread influence, Dr Ferguson's original vision has often been internalized by the broader medical community without clear historical attribution, leading to a drift in the term's original meaning. This article restores the intellectual genealogy of the "e-patient" as defined by Dr Ferguson as "equipped, enabled, empowered, and engaged." We argue for the continued relevance of his "quiet giant" leadership. By formalizing Dr Ferguson's foundational white paper *e-Patients: How They Can Help Us Heal Healthcare* within this article, we ensure its preservation for future research and provide a stable foundation for the evolving field of participatory medicine.

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KEYWORDS

participatory medicine; e-patients; Tom Ferguson; preference erasure; health care infrastructure; patient empowerment; coproduction; patient involvement; patients included; everyone included

Introduction

This article is a tribute to Dr Tom Ferguson (1943-2006), one of the "quiet giants" of health care, who worked beyond the traditional spotlight to build something profoundly human. Dr Ferguson built an architecture of trust with patients and clinicians in the information age, and this vision became the architecture on which the Society of Participatory Medicine was founded.

> *Clean, clear knowledge is the equivalent in this century of clean, clear water in the 19th century – it's a public health service, people need access to it. Knowledge is the enemy of disease.* [—Sir Muir Gray 1]

It is a privilege for the *Journal of Participatory Medicine* to formally share Dr Ferguson's foundational white paper *e-Patients: How They Can Help Us Heal Healthcare* (accessible via Multimedia Appendix 1) as both a historical record and a blueprint for our future. This future demands an infrastructure where difficult stories and lived histories are integrated from the start. We must actively resist what health economist Professor Jack Dowie coined "preference erasure" [2,3], which is the systemic process whereby individual patient preferences are stripped away when entered into the scientific record, leaving patients with no more "real estate" in the final evidence base than a forgotten grave.

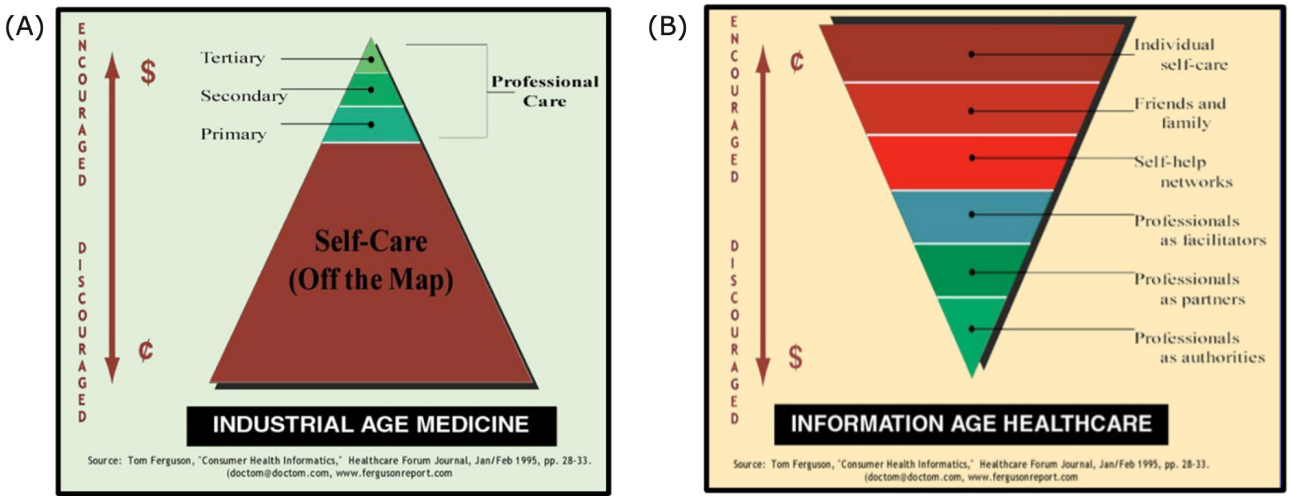
Twenty-five years ago, Dr Ferguson articulated a radical and enduring vision: that patients could be the master architects of their self-care. Tom did not see a hierarchy of credentials; he saw a community of problem-solvers. He coined a term that reshaped our language: the "e-patient" [4]. He said "e-patient" was to "patient" as "email" was to "mail." He later added more descriptive "e-words": "equipped, engaged, empowered, and emancipated."

He spoke from experience. Diagnosed around 1991 with multiple myeloma, he faced a median survival of 2 to 4 years but lived 15, dying in 2006. The visionary friends he'd accumulated, who practiced what he preached, formed the Society for Participatory Medicine.

Dr Ferguson described "medical self-care" while still in medical school in the 1970s, and when the World Wide Web emerged, he envisioned the profound transformation it would be for patients. In January 1995, within a year of the release of the first popular web browser (Mozilla), he published a pair of "triangle slides" showing the inversion of power as medicine shifted from the Industrial Age to the Information Age (Figure 1).

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Figure 1. The "flip-the-triangle" paradigm, showing the shift in patient-physician engagement from the (A) Industrial Age to the (B) Information Age. These images were first published in January 1995 [5,6].



The Industrial Age model placed physicians at the apex, with authority, knowledge, and power flowing downward to passive patients, whose self-care was not even recognized as existing. The revolution Dr Ferguson foresaw was simple: as information access became democratized, it would flip the triangle, giving power to self-care and self-help networks. In chronic disease, rare disease, and the management of one's own life, the patient has first-hand expertise. The clinician becomes the consultant. It is noteworthy to view the accuracy of Dr Ferguson's perceptions of ways the new paradigm could influence costs and social approvals.

"If there's a 'George Washington' of the empowered patient movement, it's Doctor Tom Ferguson," wrote Elizabeth Cohen, the senior medical correspondent for CNN in 2008. She noted, "In 1975, at a time when many doctors were still viewed as all-knowing and infallible, Ferguson started writing about patients advocating for their own health care" [7]. A timeline of Dr Ferguson's advocacy and teaching is shown in Table 1.

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Table . Key milestones in Dr Tom Ferguson's advocacy and teaching.

Date	Milestone
1975	Begins writing about patient advocacy and self-care while still in medical school
1975	Initiates publication of the *Medical Self-Care* newsletter (through 1989)
1978	Interviewed in *Mother Earth News* and by Dan Rather on *60 Minutes* [8] (Figure 2)
1979	Graduates from Yale Medical School
1980	Publishes book *Medical Self-Care: Access to Health Tools* [9]
1994	Becomes medical editor of the *Whole Earth Catalog, Millennium Edition* (Health Section) [10]
1995	Publishes his "triangle slides" (Figure 1) depicting "Information Age Healthcare" as an inversion of the power structure of "Industrial Age Medicine"
1996	At the dawn of the web, publishes *Health Online: How To Find Health Information, Support Groups, And Self-Help Communities In Cyberspace* [11]
1998	Publishes first *JAMA* editorial: "Digital Doctoring—Opportunities and Challenges in Electronic Patient-Physician Communication" [12]
1999	Begins *The Ferguson Report: The Newsletter of Consumer Health Informatics and Online Health* (through 2003) [6]
2000	Publishes first article in *The BMJ*: "Online patient-helpers and physicians working together," foretelling participatory medicine [13]
2004	Publishes "The First Generation of e-Patients" in *The BMJ* [4]
2006	Dr Tom Ferguson passes away; the *New York Times* publishes his obituary [14]
2007	*e-Patients: How They Can Help Us Heal Healthcare* completed and published by his colleagues
2009	The Society for Participatory Medicine formally founded
2026	The *Journal of Participatory Medicine* enters the white paper into the record as a multimedia appendix in *The Architect of Trust: Dr Tom Ferguson's Legacy*

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Figure 2. A young Dr Tom Ferguson (left) being interviewed by Dan Rather (right) for *60 Minutes*: Photo used with permission of *Mother Earth News* (Ogden Publishers), 1979.



Why the Comparison Fits

The CNN article and the *Journal of Participatory Medicine* draw several parallels between Dr Ferguson and the Founding Fathers of the United States:

- Pioneering spirit: Just as George Washington led a new era of self-governance, Tom Ferguson began his work in 1975 by founding *Medical Self-Care* magazine, challenging the "Industrial Age" model where doctors held absolute authority.
- A "manifesto" for freedom: Dr Ferguson was working on his final manifesto, *e-Patients: How They Can Help Us Heal Healthcare*, at the time of his death in 2006. Elliot Stone, one of his colleagues, noted that reading his early drafts felt like "looking over Thomas Paine's shoulder."
- The power of the people: his vision centered on the idea that "we the people" (the patients) could create a new reality with a balanced power dynamic [12]. He famously argued that when patients are well-informed, they can be trusted to manage their own health [15], much like Thomas Jefferson's belief in self-governance and the economist and Nobel laureate Elinor Ostrom's work *Governing the Commons: The Evolution of Institutions for Collective Action* [16].

We hear of "patient engagement" described as an adjunct to care. Yet the true history of participatory medicine was written by those who did not wait for permission [17]. These are the advocates who conducted interviews from beds in the intensive care unit [18], endured rejection by systems they sought to improve [19], and banded together to provide palliative care when the world looked away [20].

Dr Ferguson's vision was partnership, not a power hierarchy. It was a recognition that patients are the primary providers of health care whose contributions have historically been limited by their access to knowledge. He worked to erase those limits, as the Society of Participatory Medicine does today. Across conditions, geographies, and decades, e-patients have demonstrated three enduring truths:

- The catalytic force: patients have repeatedly served as the catalyst translating research into services, identifying patterns and outcomes that professionals miss. They define empathy as constructive action rather than emotional obligation [21].
- Bypassing the "lethal lag time": while institutional research can be slowed by the lethal lag time (ie, the average 17-year lag between new medical practices being reported and adopted), patient-led networks have shared life-saving insights in real time. Dr Ferguson documented this long before the "17-year problem" was first described in 2001 [22].
- The uncredited labor: from the discovery of unexpected drug effects to the mapping of rare genetic disorders [23], e-patients have driven major advances, often without recognition. A mature participatory system must learn not only from this work, but to properly acknowledge its sources [24] so that future research can learn from patient contributions to knowledge and care.

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Growing the Standard of Humanity

The white paper *e-Patients: How They Can Help Us Heal Healthcare* (Multimedia Appendix 1) is more than an archive; it serves as a standard of humanity. We define this standard not merely as a historical record, but as a commitment to humane medical care, a virtue derived from the human condition that actively supports love and compassion. We honor those who managed the estates of destitute colleagues and restored dignity to those the world had cut out. They proved that durable innovation emerges only where relationships are valued and the human element is treated as essential infrastructure.

Today we know that the e-patient is not a niche role or a transitional phase. It is a force of nature shaping destiny. But this was not at all apparent when Dr Ferguson began his work. Over decades, this movement has grown from a fragile seed to a vulnerable shoot, and finally to a strong, fruit-bearing tree. Its viability is no longer threatened by those who once sought to uproot it. It has become a shelter, broad enough to hold even its former skeptics, sustained by the very collaboration it made possible.

E-patients continue to build the infrastructure, share their stories, and bear the burden of crisis together as they pioneer innovation. We are witnessing transformative knowledge for self-care fueled by large language models democratizing and organizing information that was formerly unavailable to patients when it lived within inaccessible institutional paywalls [25,26].

> *What makes this moment structurally different is not the AI. It is whether we build the literacy infrastructure alongside the technology or after the harm accumulates. Let's not repeat the pattern of building patient portals without training patients to use them.* [—Gilles Frydman 27]

At the *Journal of Participatory Medicine*, we are not waiting for institutions to change. Like the e-patients with type 1 diabetes who declared the #WeAreNotWaiting hashtag and created their own treatment [28], we are building the future alongside them, beginning with the recognition of those who have already led the way.

These contributions remind us that lasting progress arises not from abstraction, but from everyday people who dare to rise, work together, and insist that trust itself be treated as essential infrastructure.

> *We are all fixing what is broken. It is the task of a lifetime. We'll leave much unfinished for the next generation.* [—Abraham Verghese 29]

This article is intended as a historical document. *e-Patients: How They Can Help Us Heal Healthcare* deserves a permanent home in the scientific archives rather than remaining as an obscure PDF on a society's back pages. By providing clear history and attribution, we ensure that resources like the James Lind Library can accurately catalog the origins of this movement, giving Dr Ferguson the honor his work deserves.

We recommend readers download and read the 2007 white paper *e-Patients: How They Can Help Us Heal Healthcare* via Multimedia Appendix 1.

Suggested Citation

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Participatory Medicine Declaration

This work and the white paper *e-Patients: How They Can Help Us Heal Healthcare* were co-produced by patients and clinicians.

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DD and AP contributed to all aspects of the publication.

Conflicts of Interest

AP is the editor in chief of the *Journal of Participatory Medicine* at the time of this publication. AP had no involvement in the editorial review and processing of this manuscript. AP and DD have no conflicting or competing interests to declare.

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Multimedia Appendix 1
e-Patients: How They Can Help Us Heal Healthcare.
[PDF File, 1150 KB - jopm_v18i1e97659_app1.pdf]

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Community Perceptions of Integrating Community Health Workers and Telehealth Services for Chronic Disease Management in a Rural Island Community: A Qualitative Study

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Abstract

Background: Rural and isolated communities, such as Culebra, Puerto Rico, face significant health care challenges due to geographic isolation, limited medical resources, and socioeconomic disadvantages. Chronic diseases, particularly diabetes and hypertension, are highly prevalent and contribute to poor health outcomes. Telehealth services (THS) and community health workers (CHWs) have been identified as effective interventions for improving health care access in underserved areas. This study is grounded in the principles of community-oriented primary care, which emphasizes the integration of primary care and public health for a defined community, and positions the combination of CHWs and THS as a practical application of this model in an isolated island setting.

Objective: This study aimed to explore community perceptions and attitudes toward integrating THS with the support of CHWs to improve chronic disease management in Culebra, Puerto Rico.

Methods: A qualitative study using semistructured individual interviews was conducted with 20 patients from Culebra's Federally Qualified Health Center. Interviews were guided by the socioecological model to assess community perspectives at the individual, interpersonal, community, and societal levels. Thematic analysis was conducted using Dedoose by the principal investigator and a research assistant, with coding discrepancies resolved through negotiated agreement. Translation and back-translation of themes followed the Brislin method. The study adhered to the COREQ (Consolidated Criteria for Reporting Qualitative Research) guidelines.

Results: Thematic analysis revealed three primary themes: (1) the pervasive impact of social determinants of health on daily life and health care access, (2) the valued and trusted role of CHWs in the community, and (3) the dual potential and challenges of THS. CHWs were recognized as critical for improving health care access through appointment assistance, medication management, and emotional support. THS was viewed positively for its potential to reduce transportation barriers and improve continuity of care, although concerns regarding technology access, convenience, and data privacy were also raised. The integration of CHWs and THS was broadly viewed as a promising and trustworthy solution to chronic disease management challenges.

Conclusions: This study highlights the potential of an integrated CHW-assisted THS model as a practical application of community-oriented primary care principles in isolated island communities. The combination of CHWs and THS shows promise for reducing health care disparities and improving chronic disease management. Future research should focus on implementing and evaluating this model through participatory approaches, assessing clinical outcomes and cost-effectiveness, while policy efforts should prioritize THS infrastructure investment and standardized CHW training curriculum.

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KEYWORDS

telehealth; chronic disease; Puerto Rico; community health workers; public health; community-oriented primary care; COPC

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Introduction

Background

In the United States, 1 in 5 communities is a rural or isolated area facing numerous health care challenges due to limited access to services, lower socioeconomic status, and geographic isolation from services [1-3]. The health outcomes of people living in rural communities, such as survival rate, complication frequency, and disease management, are often worse compared with those of people living in urban areas, resulting in a significant public health crisis [4]. The same factors impact the health and health care of persons in Latinx communities, including a higher prevalence of chronic conditions such as diabetes (10.3% in Hispanic communities compared with 8.5% in non-Hispanic White communities) among adults aged 18 years or older [5]. These disparities are even more pronounced for people living in Puerto Rico (a US territory), who experience the worst health outcomes compared with the general US population, having an estimated diabetes prevalence of 20.1% among adults, substantially higher than the US average. Rates of hypertension and high cholesterol also exceed those in other jurisdictions [6,7].

Puerto Rico is an archipelago, and its smallest inhabited island municipality, Culebra, exemplifies the challenges of health care delivery in an isolated setting. Located 17 miles off the coast of the main island, Culebra has a population of approximately 1800 residents [8,9]. The island has no hospital; health care infrastructure is limited to an emergency room with minimal resources, 1 private physician's office, and a single Federally Qualified Health Center (FQHC), HealthproMed, which was the site of this study. In 2019, the estimated prevalence of diabetes and hypertension in Culebra were 15.1% and 39.2%, respectively [10]. While most residents have health insurance, either through the federally funded, government-run *Plan Vital* or through private plans, structural barriers to accessing care remain significant.

These challenges are social determinants of health (SDoH) and are directly associated with the archipelago's sociopolitical structural status, which results in significant health inequities [11]. In response, innovative models of care are needed. This study is conceptually grounded in the principles of community-oriented primary care (COPC), an approach that originated in South Africa and emphasizes the integration of primary care practice with public health for a defined community [12,13]. COPC models are designed to be responsive to a community's specific health needs by moving beyond the clinic walls to deliver care. A key component of modern COPC, particularly in resource-limited settings, is the use of community health workers (CHWs) and, increasingly, information and communication technologies to extend the reach of the health care system [14,15].

In Culebra, a single CHW serves the community, providing a mix of home visits, clinic-based support, and remote coordination of social services via phone. The COVID-19 pandemic accelerated the adoption of telehealth services (THS) globally, and based in part on the findings from this study, the FQHC in Culebra has since expanded its use of telehealth for regular patient visits, even extending these services to the neighboring island of Vieques. The integration of a trusted CHW with accessible THS represents a practical application of the COPC model, tailored to address the unique context of Culebra. However, before the broader implementation of such a model, it was crucial to understand the community's perspective.

Aims and Objectives

The primary aim of this study was to explore community perceptions and attitudes toward integrating THS with the support of CHWs to improve health care access for people with chronic diseases in the isolated island municipality of Culebra, Puerto Rico.

Objectives

The specific objectives were as follows:

1. To assess community members' attitudes and perceptions toward the role of CHWs in their health care
2. To evaluate community members' attitudes, perceived benefits, and barriers related to the use of THS for chronic disease management
3. To identify and map the perceived impacts, barriers, and facilitators for implementing an integrated CHW-assisted THS model across the different levels of the socioecological model (SEM)

Methods

Study Design and Recruitment

This study used semistructured individual interviews to ascertain community perceptions toward THS infrastructures and the role of CHWs in addressing health access for people with chronic diseases. As part of a decade-long community partnership with the local FQHC and community-based organizations, we recruited 20 community members and patients in Culebra, using a purposive sampling methodology and direct recruitment efforts from the on-site CHWs. Participants were required to be older, be aged at least 18 years old, live in Culebra, have a chronic disease diagnosis, and be able to read the information provided in Spanish for informed consent. The exclusion criteria included nonresidents, nonpatients of the local FQHC, and those unable to communicate in Spanish. The study was conducted in Spanish, the official language in Puerto Rico and the primary language of most of Culebra's residents, and followed COREQ (Consolidated Criteria for Reporting Qualitative Research) guidelines to report qualitative research (Checklist 1) [16].

It is important to note that this qualitative study represents the first phase of a larger, multiphase participatory research project. Subsequent phases involve data collection with other key stakeholders, including health care providers and patients' family members, the results of which will be reported in future manuscripts.

Data Collection

An interview guide (Multimedia Appendix 1) was developed using the SEM framework to capture in-depth perceptions of THS and the role of CHWs in the community as an intervention to increase access to health care. The semistructured qualitative

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interviews were developed by the principal investigator (PI) and research assistant in Spanish [17]. Our research team members (PI and local CHW), who were experienced in qualitative research methodology, conducted all interviews in Spanish. Interviews were conducted between October 2022 and March 2023, lasting up to 1 hour. To ensure a comfortable and private environment, interviews took place in familiar and convenient community settings, including clinic waiting areas and public spaces nearby. With participants' consent, all interviews were audio-recorded.

Ethical Considerations

This study was performed in line with the principles of the Declaration of Helsinki and received ethics approval from the University of Rochester Medical Center Institutional Review Board (STUDY00007257). All participants provided verbal informed consent before the interview began. Participants were informed of their right to discontinue participation or skip questions at any point. The study design prioritized participant privacy and data protection. Audio recordings were initially stored on encrypted devices and subsequently uploaded to a secure, Health Insurance Portability and Accountability Act (HIPAA)–compliant cloud system (Box) at the University of Rochester. All potentially identifiable information was removed from transcripts during the data analysis process to preserve participant confidentiality. Participants were compensated with US $10 cash and offered refreshments as an expression of gratitude for their time.

Data Analysis

Audio-recorded interviews were transcribed and thematically analyzed using Dedoose, a qualitative analysis software that allows for direct coding [18]. The analysis was guided by the SEM [19], which provided a comprehensive understanding of how participants' attitudes and perceptions were influenced by factors at the individual, interpersonal, community, and societal levels.

Interview data were examined iteratively using thematic analysis for patterns and themes, investigating community attitudes and perceptions toward THS systems and the CHW's model [20]. To ensure linguistic and cultural validity, themes and supportive quotes were translated and back-translated from Spanish to English by a team of 3 bilingual laboratory members (2 Puerto Ricans and 1 Peruvian) following the Brislin back-translation method [21]. The coding process was conducted by the PI, the CHW, and a research assistant. Coding discrepancies were resolved through a process of negotiated agreement during weekly team meetings, where differing interpretations were discussed until consensus was achieved [22]. The team also debriefed regularly (≥5 times per week) with partners and community members during fieldwork to discuss emerging findings.

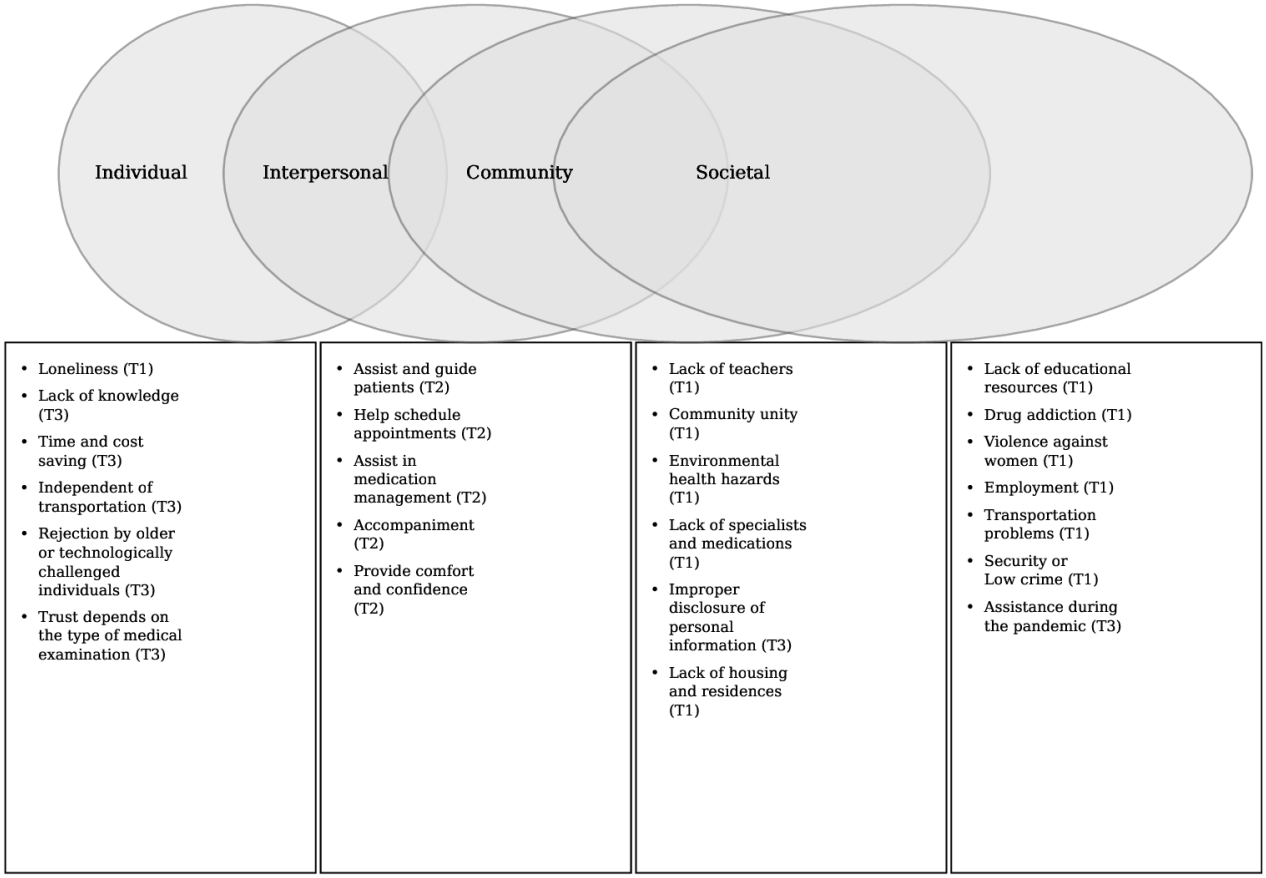
Results

Overview

Analysis of the interview data revealed 3 major themes related to the potential integration of CHWs and THS in Culebra: (1) the pervasive impact of SDoH on daily life and health care access, (2) the valued and evolving role of CHWs in the community, and (3) the dual potential and challenges of THS. These themes and their corresponding subthemes were mapped across the 4 levels of the SEM—individual, interpersonal, community, and societal—to provide a comprehensive understanding of the factors influencing community perceptions. As shown in Figure 1, this categorization helped illustrate how these factors interact and contribute to the community's perspectives on integrating THS with CHW support to improve health care access for people with chronic diseases on the island of Culebra. The most relevant subthemes of each theme will be discussed in the following sections.

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Figure 1. Applied the social determinants of health model to the thematic analysis. T1: theme 1; T2: theme 2; T3: theme 3.



In addition, Multimedia Appendix 2 presents the demographic profile of the 20 participants who predominantly self-identified as female (n=12, 60%) and had a diverse age range (20 - 70 years). The average interview duration was 55 minutes and 42 seconds (SD 10.8). Participants' educational levels varied, with 11 (55%) participants having completed or exceeded high school and a quarter (n=5, 25%) having less than a high school education.

Theme 1: The Pervasive Impact of SDoH on Daily Life and Health Care Access

Overview

Participants highlighted several key issues affecting their community, including limited educational resources, economic instability, violence, and inadequate housing and transportation (Multimedia Appendix 3). These factors create significant barriers to health and well-being, emphasizing the need for community-based interventions and policies to address these underlying causes of health disparities in rural and isolated areas.

Subtheme: Transportation Problems

Transportation was identified as a significant issue, with the community's geographical isolation contributing to difficulties in accessing other areas. This affects daily life and service provision. A participant explained, "Well, transportation. Like Vieques and Culebra, we are, as you say, far from the big island, so sometimes we have a lot of problems with transportation, that's more than most of what it affects" (IND49). This reflects societal-level challenges.

Subtheme: Environmental Health Hazards

The improper management of sewage and wastewater was identified as a severe environmental and health concern by the Culebra community. Overflows cause a threat to the cleanliness and hygiene of the community, as expressed by 1 participant: "Sewage is overflowing everywhere. It is really a very strong concern." On the other hand, participants also discussed the negative impact of exploitation-induced destruction, particularly from investors and unsustainable practices. This leads to the destruction of natural resources and cultural heritage and threatens the community's long-term well-being. A participant stated, "Our natural resources are being destroyed. The new generations are the ones who are going to have to deal with the exploitation" (IND2). Both issues affect at the community and societal levels.

Subtheme: Lack of Medications

A consistent medication shortage was identified as a pressing health issue, particularly affecting emergency services and controlled medications. This hinders the effective management of health conditions. One participant highlighted, "There is a lot of lack of medication. In the emergency area, there is a lot of medication shortage" (IND2). This issue impacts at the individual, community, and societal levels.

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Subtheme: Lack of Educational Resources

Participants identified a shortage in the availability and quality of educational resources, exemplified by a lack of schools and the underutilization of existing educational spaces. This lack of resources was seen as a barrier to providing adequate education within the community. For instance, 1 participant stated, "Everything that has to do with education, that is what we are looking for" (FG1). These insights reflect significant concerns at the individual, community, and societal levels.

Subtheme: Loneliness in Some Individuals

Feelings of isolation and loneliness were identified as significant concerns for specific community members, particularly during times of personal crisis. Loneliness affects mental and emotional well-being. For example, 1 participant noted that some patients like to come to the clinic to have company "because many times they are alone, and what they want is to talk" (IND2). This reflects the individual-level impact of social isolation.

Subtheme: Employment

A lack of diverse employment opportunities was highlighted as a significant issue, especially for the youth. The local economy offers limited career paths, forcing individuals to migrate or accept employment outside their desired professions. A participant explained, "For young people, there are not many [options out] there; what we have are the same [jobs] in a restaurant, but there is no way that if someone wants to be a lawyer, there is no way. There are not many alternatives for work" (FG1). The decline in the available labor force, mainly due to an aging population, was seen as a challenge in maintaining essential services. This sense of vulnerability affects those who are aging or ill. This issue impacts the individual, community, and societal levels.

Theme 2: The Valued and Evolving Role of CHWs

Overview

CHWs are vital in enhancing health care access and quality for individuals in underserved communities (Multimedia Appendix 4). They provide essential support by assisting with patient education, scheduling medical appointments, managing medications, and offering companionship during medical visits. Their involvement improves health outcomes and fosters a sense of trust and comfort among patients, significantly impacting their overall health care experience. However, most people do not fully understand CHWs' role, even though some might already have been in contact with CHWs before. Therefore, it is essential for people to know what CHWs can do for them to improve their health care access.

Subtheme: Assists and Guides the Patient

Participants highlighted the vital role of CHWs in providing valuable assistance and guidance. CHWs help patients understand their health conditions and learn how to manage their treatments, improving their autonomy and care. One participant noted, "They guide you, give you information so you know what these symptoms are based on, and how to take care of yourself" (FG103). Another shared, "They have taught me how to inject insulin. I have done it, but I have had several doubts. And they clear up my doubts" (IND39). These interactions enhance the interpersonal relationships between CHWs and patients, fostering trust and confidence.

Subtheme: Helps Schedule Appointments With Specialists

CHWs play a crucial role in helping patients schedule appointments with specialists, ensuring continuous and specialized care, especially for chronic conditions. A participant explained, "If I needed such an appointment with the specialist, find me one. When I need a referral, what I do is that I go with the community health worker, we interconnect, and things seem to move a little faster; that's why it's important" (IND2). This assistance is essential in maintaining the continuity of care and addressing the specific health needs of patients.

Subtheme: Assists in Medication Management

The support provided by CHWs in medication management is seen as crucial, particularly for those who struggle with maintaining their medication regimens. One participant stated simply, "They get the medicines for me" (IND59). This service is essential for ensuring that patients adhere to their prescribed treatments and manage their health conditions effectively.

Subtheme: Trust and Social and Health Support

Participants valued the accompaniment provided by CHWs when accessing medical facilities. This support offers comfort and confidence, particularly when patients need to access laboratory services or return home. One participant shared, "And I have a lot of confidence in her when I have to go to the laboratory. She waits for me patiently. She takes me home" (IND59). This accompaniment helps reduce the stress and anxiety associated with medical appointments, contributing to better health outcomes.

Subtheme: Provides Comfort and Confidence

CHWs are recognized for their attentive and considerate care, which instills comfort and confidence in patients. As one participant expressed, "They gave me comfort" (IND49). This emotional support is essential to the health care experience, helping patients feel more secure and supported in managing their health.

By offering these services, CHWs play an integral role in improving health care delivery and outcomes, particularly in underserved communities. Their work addresses both the practical and emotional needs of patients, fostering a more supportive and effective health care environment.

Theme 3: The Dual Potential and Challenges of THS

Overview

Participants expressed different perspectives toward the THS in providing health care access in rural and underserved communities for chronic disease management (Multimedia Appendix 5). Some participants believed that THS could offer numerous benefits, including reducing the need for transportation, saving time and costs, and ensuring continuity of care when in-person medical visit options were not available or accessible. However, THS also faces challenges such as perceived inconvenience compared with in-person visits, lack of knowledge among users, and concerns about data privacy.

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Despite these challenges, THS was seen as a beneficial alternative when traditional health care options are inaccessible, enhancing overall health care experiences by offering peace of mind and improved communication between patients and health care providers.

Subtheme: Less Convenient Than In-Person Care

Participants identified concerns about the convenience of remote health care services compared with in-person visits, especially highlighting the value of physical exams and the personal touch of face-to-face consultations. One participant stated, "In-person visits are more convenient" (IND39). This underscores the interpersonal challenge of remote health care services.

Subtheme: Assistance During the Pandemic

The crucial role of THS during the pandemic was emphasized, providing necessary support and care in challenging times when traditional services were disrupted. A participant noted, "It was a great moment. And if you come to apply it in the case of Culebra, it would be phenomenal, too. I would want to have a doctor all the time, but if I have no other option, well, it's great that this option is there" (IND2). This highlights the community and societal benefits of THS during crises.

Subtheme: A Good Alternative When No Other Option Is Available

Participants viewed THS services as beneficial alternatives when in-person care is inaccessible, mainly due to transportation issues. One participant shared, "I don't know about anyone else, but I do. I prefer a doctor on camera than none at all" (IND39). This demonstrates the individual, community, and societal advantages of having THS as an option.

Subtheme: Lack of Knowledge

More knowledge about THS and procedures still needs to be provided, which may prevent individuals from fully using them. A participant admitted, "I haven't done it yet" (IND49). This reflects the individual-level challenge of awareness and education regarding THS.

Subtheme: Independent of Transportation

The advantage of THS not requiring transportation was particularly noted as useful for communities with limited access to transportation. One participant explained, "In bad weather that there is no transportation which cannot come, then that would be a good alternative" (IND39). This benefit spans community and societal levels.

Subtheme: Time and Cost Savings

Participants identified significant time and cost savings with the use of remote or THS, eliminating the need for travel and reducing the opportunity cost of seeking medical care. One participant stated, "These trips would actually waste money and time" (FG103). Another noted, "It saves a lot of time because the kids don't have to miss school. It's a whole lost day" (IND1). These points highlight the individual and community benefits of THS.

Subtheme: Privacy Issues—Improper Disclosure of Personal Information

Concerns were raised about the potential for improper disclosure of personal information when using remote services, which may deter some from using these services. A participant expressed, "There are also many people who do not like to give [their] data over the phone. There have been many hackers" (IND49). This concern affects individual, interpersonal, community, and societal levels.

Subtheme: Rejection by Older or Technologically Challenged Individuals

Participants identified that older individuals or those who are less technologically savvy may resist using remote health care services due to unfamiliarity with technology or a preference for traditional in-person care. One participant's opinion was, "Because sometimes there are many elderly people, they don't know technology" (IND49). This reflects the individual and community challenges in THS adoption.

Subtheme: Trust Depends on the Type of Medical Examination

Trust in the THS varied depending on the type of medical examination required. For visual assessments or follow-ups, remote consultations would suffice, but for more tactile, in-depth examinations, in-person visits were preferred to ensure safety and accuracy. One participant remarked, "The decision depends on whether it is a follow-up consultation or if it is the first time with the specialist. If it is an evaluation or, if they need to do a laboratory check, and if they are going to do a study later. Therefore, people should go in person" (FG103). This indicates the individual-level trust considerations.

Subtheme: Peace of Mind

Having health care consultations in the comfort of their own home provides patients with peace of mind. It allows them to communicate more effectively, ensuring they remember to discuss all their concerns with the physician. A participant shared, "Yes, I sit in my room and explain everything to him. Sometimes, you go to see the doctor, and you forget the things that you had to tell him" (IND59). This benefit is significant at the individual level.

Discussion

Principal Findings

This study aimed to explore community perceptions of an integrated CHW-assisted THS model to improve health care access for people with chronic diseases in the isolated setting of Culebra, Puerto Rico. Our findings suggest a general community acceptance of this model, which can be understood as a modern application of the COPC framework. By integrating clinic-based services with community-based assets—the CHW and technology—the proposed model aligns with the core COPC principle of providing continuous, needs-based care to a defined population [12].

Our findings successfully met the study's 3 primary objectives. First, we found that the community perceives CHWs as vital,

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trusted figures who provide essential assistance, guidance, and comfort. This aligns with COPC models that rely on CHWs to build trust and bridge the gap between the formal health system and the community. Second, participants viewed THS as a valuable tool to overcome structural barriers such as transportation, although they also raised concerns about the digital divide and the loss of in-person contact. This highlights a key challenge in implementing information and communication technology–enabled COPC, that is, ensuring technology is deployed equitably. Finally, the SEM framework effectively mapped the complex interplay of barriers and facilitators, confirming that a successful COPC intervention must address challenges at multiple levels, from individual-level trust to societal-level infrastructure.

The findings confirm that while CHWs can help mitigate some SDoH barriers at the individual and interpersonal levels, they cannot resolve larger, structural determinants. However, the integration of CHWs and THS was seen as a powerful combination. This synergy, a hallmark of contemporary COPC, can help bridge gaps in care by leveraging technology to bring specialists to the island virtually, while relying on the personalized support of CHWs to facilitate these interactions. This aligns with existing literature demonstrating the effectiveness of CHWs in navigating services for Latinx communities and the power of THS for providing routine care leading to better health outcomes, although few studies have explored their combined impact within a COPC framework [23].

By adopting the evidence-based models of CHWs and THS, rural island communities can improve health care access, enhance health education, and build sustainable health care systems. This can lead to better health outcomes and reduced health disparities, ultimately benefiting communities such as Culebra and similar rural island populations globally.

Study Limitations

This study has several limitations inherent to its qualitative design. First, the findings are based on a small, purposive sample from a single, unique island community. Therefore, the results may not be generalizable but offer deep, context-specific insights that can be instrumental in adapting for future studies of similar island communities. Second, as the data are self-reported, they are subject to participants' personal biases. Third, the research team included the local CHW, which may have introduced a degree of social desirability bias, although this relationship also facilitated trust. We sought to mitigate this by using a neutral, university-affiliated PI and a research assistant from another country and with limited knowledge of Puerto Rico. Finally, while this initial phase did not involve direct co-design of research questions with community members, the questions were reviewed and refined in collaboration with the local FQHC—an institution that represents and is embedded in the local community's health care perspectives and needs. This study is the first phase of a larger participatory project in which subsequent phases will engage patients, families, and health care providers more directly.

Acknowledgments

The authors would like to thank HealthproMed Inc, Culebra, clinic staff members for their support during the implementation of the study. In addition, they acknowledge Mujeres de Islas Inc (a community-based organization in Culebra) for allowing the study team to recruit and promote their study and the Puerto Rico Public Health Trust for community health workers' capacity training.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Sample interview guide questions.
[DOCX File, 16 KB - jopm_v18i1e86907_app1.docx]

Multimedia Appendix 2
Key descriptive information of the interview sample (N=20), including gender distribution, average interview duration, age groups, and educational attainment. Participants included 12 women (60%) and 8 men (40%), with interviews lasting an average of 55 minutes and 42 seconds. The sample represented a range of age groups (N=20), with the largest proportion of participants not disclosing their age (n=8, 40%), followed by individuals in their 50s (n=3, 15%), and other adult age categories. Educational attainment also varied across participants, with most reporting high school completion (n=9, 45%), followed by less than high school (n=5, 25%), postsecondary education (n=2, 10%), and a proportion who did not disclose their educational level (n=4, 20%).
[DOCX File, 133 KB - jopm_v18i1e86907_app2.docx]

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Multimedia Appendix 3
Subthemes emerging from theme 1—the pervasive impact of social determinants of health on daily life and health care access—organized across the 4 domains of the socioecological model (individual, interpersonal, community, and societal). The table illustrates how structural and environmental factors such as lack of educational resources, employment challenges, housing insecurity, and limited medication access manifest at multiple ecological levels to shape health outcomes and health care use.
[DOCX File, 16 KB - jopm_v18i1e86907_app3.docx]

Multimedia Appendix 4
Subthemes emerging from theme 2—the valued and evolving role of community health workers—mapped across the 4 domains of the socioecological model. The table highlights how community health workers contribute across individual and interpersonal levels by assisting with appointment scheduling, medication management, and emotional support, while also providing comfort and confidence at the community and societal levels.
[DOCX File, 16 KB - jopm_v18i1e86907_app4.docx]

Multimedia Appendix 5
Subthemes emerging from theme 3—the dual potential and challenges of telehealth services—distributed across the 4 domains of the socioecological model. The table captures both the perceived benefits of telehealth (eg, cost savings, transportation independence, and pandemic-era access) and its limitations (eg, privacy concerns, rejection by older or technologically challenged individuals, and reduced convenience compared with in-person care) as experienced across individual, interpersonal, community, and societal domains.
[DOCX File, 16 KB - jopm_v18i1e86907_app5.docx]

Checklist 1
COREQ checklist.
[PDF File, 127 KB - jopm_v18i1e86907_app6.pdf]

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Abbreviations

CHW: community health worker
COPC: community-oriented primary care
COREQ: Consolidated Criteria for Reporting Qualitative Research
FQHC: Federally Qualified Health Center
HIPAA: Health Insurance Portability and Accountability Act
PI: principal investigator
SDoH: social determinants of health
SEM: socioecological model
THS: telehealth services

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Mapping Peer Support in Antidepressant Discussions on Reddit: Pilot Network Analysis

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Abstract

Background: Antidepressant use and withdrawal are often accompanied by side effects such as dizziness, weight gain, and sexual dysfunction. Antidepressants and their associated side effects are stigmatized topics. Social media platforms such as Reddit are considered "safe spaces" by users because they can freely share their experiences and receive support.

Objective: This pilot study analyzed discussions from the subreddit r/depression to examine how users discuss antidepressant side effects, withdrawal symptoms, and related experiences of depression.

Methods: We scraped 10 high-engagement threads from the subreddit r/depression using the Python wrapper for the Reddit application programming interface and conducted a 2-step analysis. First, a pilot test was performed using sertraline (Zoloft) threads, followed by an analysis of all antidepressant-related threads. A subset of the data was hand-coded to create and validate regular expressions, which were then used to automatically code the remaining dataset. The resulting coded data were analyzed using epistemic network analysis and complemented with qualitative analysis and elements of semantic networks and hypergraphs.

Results: We found that posts were more likely to discuss emotional flattening, sleep, and memory or cognitive issues (Mann-Whitney U=33,235.5; P=.003). Additionally, references to dizziness tended to co-occur with discussions of withdrawal and offers of empathy, while reports of dream-related side effects and requests for personal experiences also co-occurred frequently. By incorporating elements of semantic networks and hypergraphs, we deduced that offers of empathy occurred when users said they experienced dizziness caused by withdrawal, while mentions of "brain zaps" associated with withdrawal often co-occurred with offers of teaching support.

Conclusions: Study findings highlight how individuals experiencing antidepressant side effects and withdrawal symptoms use online forums such as Reddit to seek validation, share coping strategies, and provide emotional support to others. The nuanced discussions observed, particularly those related to empathy, symptom management, and shared learning, underscore the role of peer-to-peer networks in normalizing stigmatized experiences and mitigating isolation associated with antidepressant use. Clinicians and digital health practitioners can leverage these insights to better understand patient language, emotional framing, and informational needs outside clinical settings.

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KEYWORDS

antidepressant; side effects; withdrawal symptoms; social support; epistemic network analysis; semantic networks; hypergraphs; Reddit

Introduction

Background

Depression is a mood disorder characterized by persistent sadness and loss of interest in daily life activities [1-3]. Each year, 1 in 10 adults in the United States experiences depression, and the incidence is approximately twice as high among women as among men [4,5]. To address this burden, antidepressants have become one of the most frequently prescribed medications, with approximately 10% of adults in the United States using them each year [2,6]. Although commonly associated with moderate to severe depression, antidepressants are also used to manage anxiety disorders and certain nonpsychiatric conditions [7].

Clinical guidelines, such as those from the American Psychological Association, recommend selective serotonin

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reuptake inhibitors (SSRIs) or other antidepressants as first-line treatments for adolescents and adults with depression [8]. Antidepressants fall into several classes, including SSRIs, serotonin-norepinephrine reuptake inhibitors, atypical antidepressants, serotonin modulators, tricyclic antidepressants, monoamine oxidase inhibitors, and N-methyl-D-aspartate antagonists. Among these, SSRIs such as sertraline and citalopram remain the most prescribed, along with amitriptyline, a tricyclic antidepressant [9].

Common adverse effects associated with antidepressant use include sexual dysfunction, weight gain, insomnia, and nausea [10-12]. Although these side effects often resolve with continued use, they can persist for some individuals. Additionally, people who have become accustomed to antidepressant exposure may experience withdrawal symptoms if they discontinue their medication. Common withdrawal effects include anxiety, worsened mood, and agitation [13]. These side effects, as well as depression and the use of antidepressants themselves, are stigmatized topics.

As the use of antidepressants increases, it is more critical than ever to move beyond simply identifying the side effects of antidepressants and instead leverage online forums to learn from the lived experiences of users, ultimately informing the development of more personalized therapies.

Social media platforms promote self-disclosure and disinhibition, in part because users can choose to remain anonymous or semianonymous [14]. Due to the high number and diversity of users, social media generates vast amounts of data, making it a valuable resource for research [15-17]. Reddit, for example, has more than 108 million daily active users, 100,000 user-created communities known as “subreddits,” and more than 22 billion posts and comments, making it a rich data source for discourse on stigmatized topics such as depression and peer support across diverse populations [18].

Reddit is increasingly used as a data source for qualitative and computational studies in public health and behavioral science. Researchers have used Reddit to investigate various topics, including COVID-19 vaccine side effects [17], vaping [16,19], depression and anxiety [20], loneliness [21], and substance use disorder [22]. Because users frequently share personal experiences and seek peer support, Reddit can offer unique insights into the lived experiences of hard-to-reach or underrepresented groups, including individuals using antidepressants.

Social Support Behavior Code

Several studies examining the role of social support in online health discussions have used the Social Support Behavior Code (SSBC) to categorize the forms of support that social media users offer and receive from one another when discussing their health conditions [23-25]. SSBC includes informational, emotional, esteem, network, and tangible support types. Loans and expressions of willingness to perform tasks on behalf of another person are defined as tangible assistance, while compliments, offers of validation (through shared personal experiences), and attempts to relieve someone’s guilt are considered esteem support. Network support includes offers to “be there” for another person, access to companions, or reminders of existing supportive individuals. Informational support includes providing advice, offering factual information, re-evaluating situations, or making referrals. Finally, emotional support can include physical affection, such as hugs, sympathy, empathy, encouragement, prayers, and reminders of relational closeness with the person being supported. Improved understanding of how these support types are used in discussions of antidepressant side effects on Reddit could inform future studies on discussions of antidepressant use in health care settings.

Epistemic Network Analysis

Epistemic network analysis (ENA) is a powerful analytical tool used to model relationships between ideas in qualitative data. Originally developed to study patterns of thinking and discourse in the learning sciences, ENA has since been applied across diverse domains, including health communication, education, and computational social science [26-30]. ENA quantifies and visualizes the relationships between concepts by mapping co-occurrences of codes within defined conversational or temporal windows. In an ENA network, these relationships are depicted through “network edges” that connect 2 nodes, with each node corresponding to a specific code that reflects a concept or theme within the dataset. A connection occurs when codes co-occur within a prespecified distance of each other. In a weighted ENA network, edge thickness, or weight, is proportional to the number of co-occurrences; therefore, a higher number of co-occurrences between 2 codes corresponds to a thicker edge between the nodes. ENA is unique because it goes beyond simple frequency counts to reveal how ideas are connected, making it useful for analyzing large textual datasets [26,27,31].

By focusing on the relationships between codes rather than isolated comments, ENA addresses a methodological gap by not only identifying key themes but also modeling the strength of the relationships between those themes. This approach offers a more nuanced understanding of how users construct meaning, express support, and share experiences, making ENA a useful tool for examining relationships among antidepressant use, side effects, withdrawal symptoms, and types of social support on Reddit. This pilot study aimed to examine how individuals discuss their use of antidepressants and experiences with withdrawal on Reddit by leveraging ENA to investigate the co-occurrence of key themes. Specifically, the objectives were as follows:

- To identify common antidepressant side effects, withdrawal experiences, and types of support expressed in online discussions of antidepressant use
- To visualize the relationships among common themes by constructing a network model
- To expand the conceptualization of edges within the ENA framework to capture the complexity of online discourse on antidepressant medications, reported side effects, withdrawal experiences, and support

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Methods

Overview

Data were scraped from the subreddit r/depression using the Python (Python Software Foundation) wrapper for the Reddit application programming interface in February 2021. r/depression was chosen for this study because it has more members than other subreddits that discuss general antidepressant use. In total, 10 high-engagement threads were selected for analysis in this study. These threads were selected because they contained the highest number of comments, reflecting extensive discussion of antidepressant use, side effects, and withdrawal experiences. To better understand how users discuss their experiences with antidepressant use and withdrawal, we began by identifying the most frequently mentioned side effects across Reddit threads. Threads were included if they contained generic or brand names of drugs approved by the Food and Drug Administration to treat depression [32].

The *JMIR* digital ethics guideline was consulted when including Reddit posts, to ensure sensitivity to the protection of participants' involvement in research conducted without direct consent [33].

Threads were first automatically separated into individual sentences, allowing coding to be performed at the sentence level [26,27]. Antidepressant generic and brand names were included as codes to allow identification of clusters of effects, symptoms, and 1 or more drugs. Other codes were developed through inductive and deductive coding. Coding was performed using the Reproducible Open Coding Kit (ROCK) web tool, iROCK, and the ROCK R package [3].

Refer to Multimedia Appendix 1 for the ENA computation steps. The semantic network diagram was created using qualitative network analysis (QNA) with the ROCK R package [34]. Hypergraphs were created manually. Decisions made on study methodology, data processing and management, and codebook development were recorded using the documentation standard Justifier [35].

Ethical Considerations

The study was deemed exempt based on its nature. The University of Wisconsin-Madison provides a "Not Research Self-Certification Decision Tool," which is available for not-research determinations. This tool was used in lieu of submitting an application to the institutional review board.

Results

Overview

Results revealed commonly discussed side effects that were consistent with prior literature, including emotional flattening, gastrointestinal distress, sexual dysfunction, sleep disturbances, and withdrawal symptoms (Table 1). The identified side effects were consistent with those commonly reported in previous studies [36-39].

Table . Codes, definitions, and representative quotes.

Name	Definition	Representative quotes
Depression	Depression, bipolar disorder, or premenstrual dysphoric disorder	"I never really had a sex drive for ages before (probably due to depression)."
Dose	Current dose or dose changes	"...a small dose won't be as bad side effect wise."
Emotional flattening	Apathy or feeling "numb" or "empty"	"Does anyone else on antidepressants feel numb that it's almost impossible to cry?"
Gastrointestinal	Constipation, diarrhea, nausea, or vomiting	"Reacted very negatively to the Zoloft and had a couple days of vomiting."
Memory and brain	Memory issues or "brain zaps"	"My own meds (an SSRI) cause memory loss..."
Physical pain	Headaches, migraines, or soreness	"The immediate side effects were the headaches."
Sexual	Sexual dysfunction	"...must tell you that it kills your sex drive."
Sleep	Changes in or issues with energy or sleep	"Taking the pills at night helps with the drowsiness."
Weight	Changes in weight	"Anyway, I'm very apprehensive about the weight gain factor as a side effect."
Withdrawal	Stopping medication	"...Pristiq is known for its horrible withdrawal..."

Weighted ENA Network: Posts vs Comments

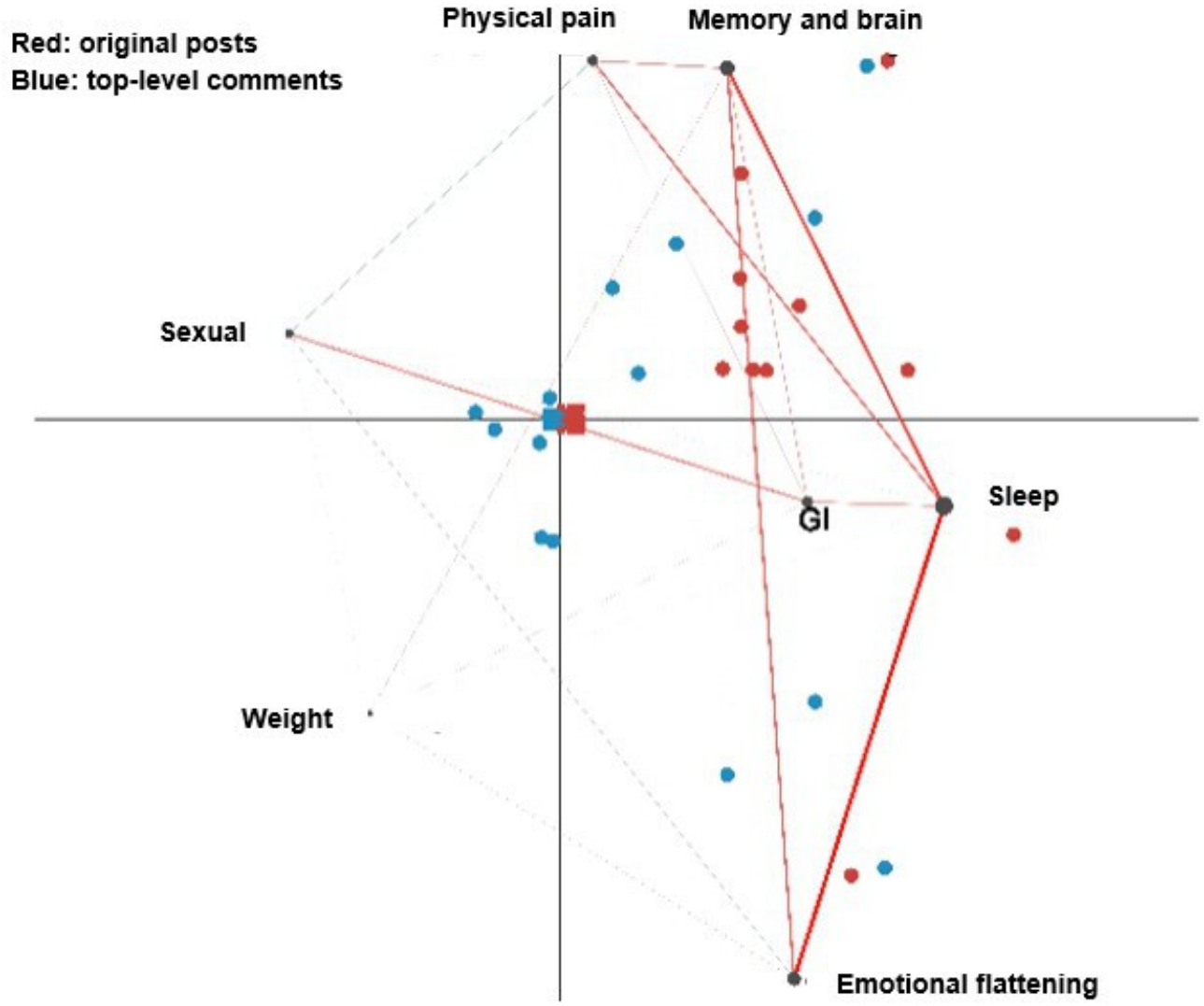
The weighted ENA revealed key structural differences between original posts and top-level comments (Figure 1).

Figure 1 shows the weighted network for posts (red) and top-level comments (blue) in the hand-coded test set. The groups were significantly different along the x-axis, suggesting that compared to top-level comments, posts were significantly more likely to discuss emotional flattening, sleep, and memory or brain issues (Mann-Whitney U=33,235.5; P=.003). Findings revealed frequent co-occurrences between withdrawal and symptoms such as emotional flattening and dream disturbances. Similarly, side effects such as memory issues, headaches, and changes in libido often appeared alongside discussions of dosage changes or discontinuation.

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Clusters of data points indicate groups of posts and comments that warrant further analysis. Once these clusters are identified, a key analysis step will be to "close the interpretive loop." This process will entail using the quantitatively identified data clusters as the starting point for a more in-depth, qualitative analysis of posts and comments in each cluster (Table 1). In this way, the network serves as an exploratory tool to identify patterns within a large, structurally complex dataset. Referring to the original data ("closing the interpretive loop") allows interpretation of these co-occurrences.

Figure 1. Weighted epistemic network analysis plot comparing original posts and top-level comments.



Patterns of Social Support in Side Effect Discourse

Analysis of co-occurring codes revealed distinct patterns of social support types associated with specific antidepressant side effects. For example, empathy and informational support frequently accompanied mentions of withdrawal and dizziness (Figure 2).

In the thread depicted in Figure 2, dark, thick lines indicate that offers of personal experience co-occurred with discussions of dreams. This relationship typically occurred when a user shared their experience with the side effect of altered dreams, as in the following example: "I have weird lucid [dreams] on fluoxetine..." References to dizziness also tended to occur with discussions of withdrawal and offers of empathy. Reports of dream-related side effects and requests for personal experiences also co-occurred frequently. Notably, offers of personal experiences frequently co-occurred with dream-related side effects. This finding suggests that when users request personal experiences regarding dream-related side effects, other users also share their own dream-related experiences.

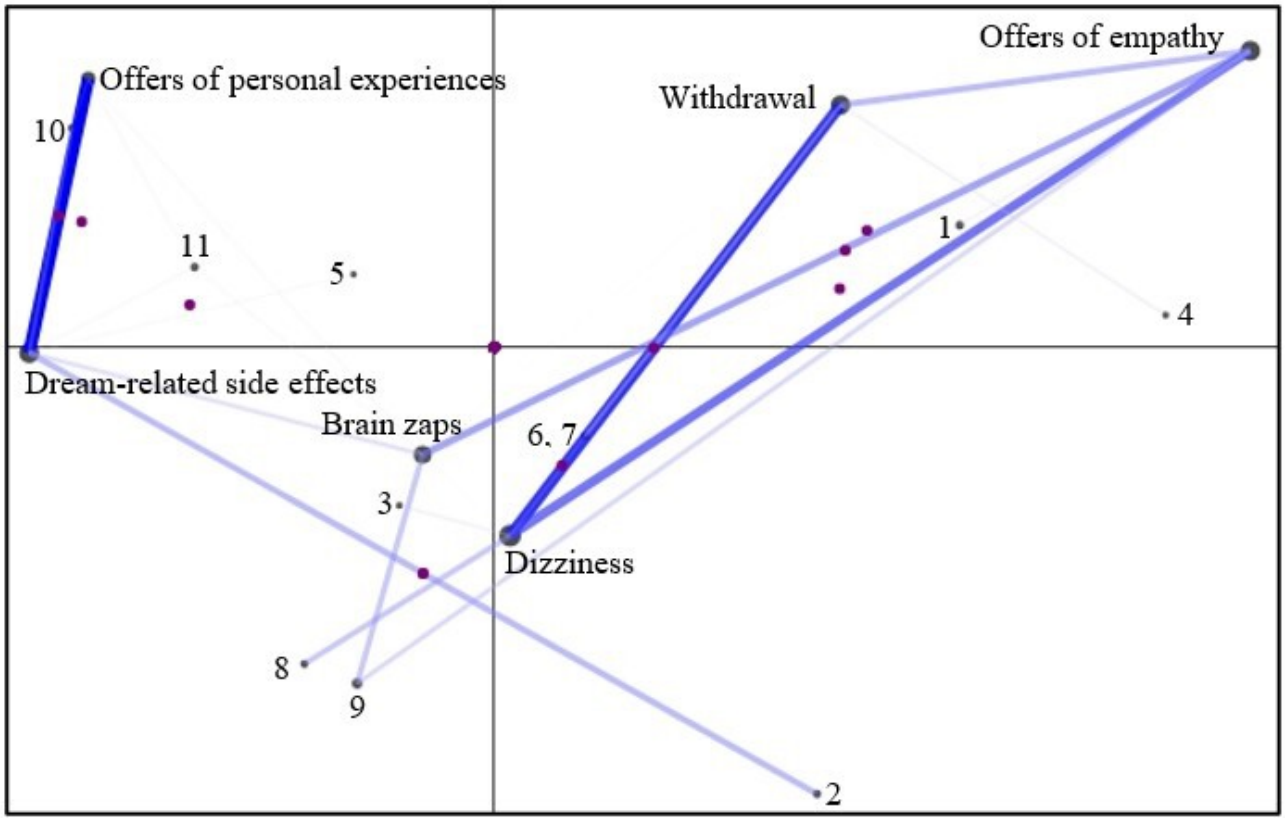
Nodes labeled with words correspond to codes that occurred at least thrice in the example thread. Additional numbered codes occurred infrequently but are included here for comparison with alternative methods of data visualization represented in later figures (1=dependence, 2=requests for personal experiences, 3=offers of relief of blame, 4=vomiting, 5=offers of agreement, 6=offers of advice, 7=nausea, 8=requests for empathy, 9=offers of teaching, 10=requests for agreement, and 11=skipping or forgetting doses).

Although ENA provides a robust framework for modeling dyadic co-occurrences of concepts in Reddit posts, it captures only 1 layer of discourse structure. In this study, ENA was used to preserve sentence-level meaning by identifying which ideas were expressed together at the sentence level. However, ENA edges alone do not distinguish whether these co-occurrences

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reflect thematic overlap or if they also reflect causal attribution. They also do not capture higher-order configurations involving more than 2 concepts. Overall, ENA network edges depict co-occurrences of codes but do not contain any information about the type of relationship between codes, which is necessary for an in-depth analysis of Reddit data.

Figure 2. Weighted epistemic network analysis of social support types and antidepressant side effects. Violet-colored nodes labeled with words correspond to codes which occurred at least three times in the example thread. Darker and thicker lines indicate more frequent co-occurrences whereas lighter and thinner lines indicate fewer co-occurrences. Additional numbered codes infrequently occurred but are included here for comparison with alternative methods of data visualization represented in later figures (1=dependence, 2=requests for personal experiences, 3=offers of relief of blame, 4=vomiting, 5=offers of agreement, 6=offers of advice, 7=nausea, 8=requests for empathy, 9=offers of teaching, 10=requests for agreement, and 11=skipping or forgetting doses).



Complementary Network Representations: Semantic Networks and Hypergraphs

To address the limitations of ENA, we suggest adding two features: (1) the freedom to note types of relationships between nodes (semantic relationships) and (2) the ability to connect more than 2 nodes (hypergraph elements).

For this study, we combined ENA with semantic network analysis and hypergraph modeling to capture different levels of antidepressant use discourse. ENA examined which ideas frequently appeared together within individual posts or sentences. Semantic network analysis identified the types of relationships between these ideas. Hypergraph modeling allowed us to interpret instances in which ≥3 ideas were expressed together in a single statement. There is substantial prior work on semantic networks and conceptual relationships. This work includes ConceptNet, a large semantic network and knowledge base [40], and the Unified Medical Language System semantic network, which identified 54 semantic links as part of a systematic effort to integrate multiple biomedical resources [1]. Previously identified connections include the “is a” relationship, which describes attributes such as types, conceptual containment, and generalization [2]. For instance, dizziness is a side effect of antidepressants. Additional relationships include causal (“produces” and “result of”), temporal (“occurs with” and “prerequisite event of”), spatial (“adjacent to” and “surrounds”), and functional (“prevents” and “motivation of”) links, among many others [41].

Examination of the aggregated semantic structure revealed that withdrawal-related symptoms appeared more frequently with emotional and informational support than did other side effects, suggesting a central role in support-seeking discourse. These observations informed the subsequent addition of hypergraph representations to explore higher-order meanings that were evident in the data but not fully captured by dyadic ENA edges alone.

Further exploration of the data using QNA revealed the need for more expressive representations. For example, although ENA clearly visualized pairwise relationships between codes, it became evident that some meaningful connections involved ≥3 concepts simultaneously. For example, in several threads, withdrawal, dizziness, and empathy were expressed together as part of a single experience. Incorporating hyperedges allowed us to represent these triadic relationships more precisely (Figure 3).

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Similarly, semantic link types (eg, causal vs experiential) added interpretive depth, particularly when distinguishing between personal narratives and support offers.

To exemplify the utility of hyperedges, consider the following statement: "I went cold turkey and had the exact same situation. Vertigo to the point I was unable to leave the house for 3 days." This statement offers empathy for dizziness caused by withdrawal. The connection among the 3 codes (empathy, dizziness, and withdrawal) is conceptually distinct from offering empathy for dizziness alone, as dizziness could be a side effect of antidepressant use, not associated with withdrawal. It is also different from offering empathy for withdrawal generally, as withdrawal often includes additional side effects. Although ENA would represent withdrawal-dizziness, dizziness-empathy, and withdrawal-empathy as 3 independent dyadic relationships, the hyperedge explicitly represents their co-occurrence. This distinction matters analytically because it differentiates empathy for an individual's experience of depression or side effects from antidepressant use in general from empathy specifically tied to antidepressant withdrawal–related experiences.

Additionally, the ENA network contains 3 primary types of relationships: causality, support requests, and support offers. These relationship types and their associated directionality were captured using colored arrows in QNA.

Figure 3. A qualitative network analysis representation of social support types and antidepressant side effects. Each node corresponds to a code. Arrows represent relationships between codes including causality (black), requests for support (blue), and offers of support (green).

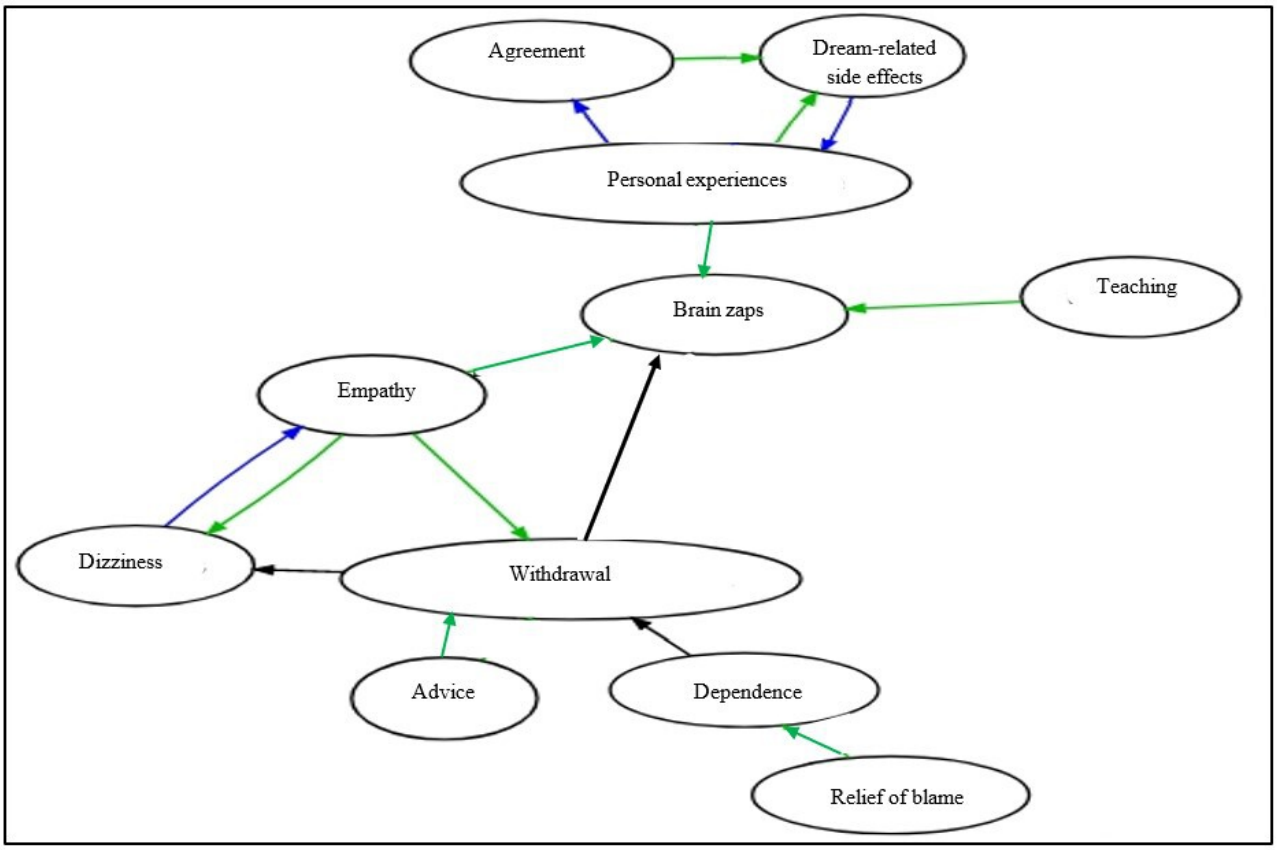
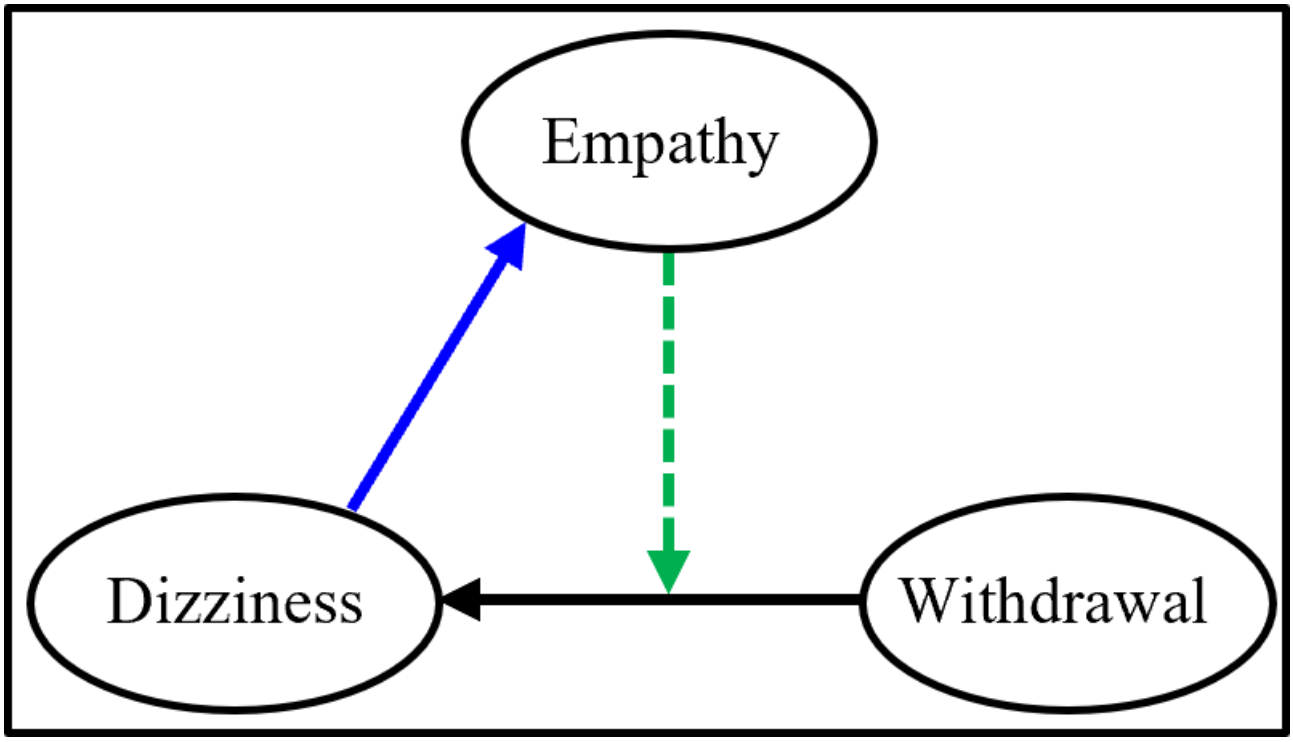


Figure 4 shows a modified QNA representation with a hyperedge connecting 3 codes. In addition to a causal relationship between withdrawal and dizziness (black) and requests for empathy related to dizziness (blue), the example thread included offers of empathy for users who reported dizziness caused by antidepressant withdrawal (green dashed). QNA visualization allowed these patterns to be represented as directed and color-coded edges, clarifying the flow of discourse across codes.

The incorporation of semantic network properties and hyperedges into ENA raises issues related to network construction and interpretation. This study serves as a starting point for a rich discussion on the value of a multimethod approach for enhancing the depth and applicability of network analysis in the examination of social media discourse related to the use of antidepressants, side effects, and withdrawal experiences.

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Figure 4. Modified QNA representation showing a relationship between more than two codes. In addition to a causal relationship between withdrawal and dizziness (black) and requests for empathy related to dizziness (blue), the example thread included offers of empathy for dizziness caused by withdrawal (green dashed).



Discussion

Principal Findings

This pilot study examined how individuals discuss antidepressant side effects and withdrawal experiences on Reddit and how different forms of social support are embedded within these conversations. Using ENA complemented by semantic networks and hypergraph representations in QNA, we found that discussions of withdrawal-related symptoms, particularly dizziness and cognitive effects, frequently co-occurred with emotional and informational support. Posts describing withdrawal experiences tended to co-occur with offers of empathy and shared personal narratives, whereas other side effects were more commonly associated with informational exchanges. These patterns align with prior research showing that mental health discussions on Reddit are characterized by a high level of self-disclosure and active peer-to-peer support exchanges [14], and they extend established observations that online health communities often concentrate support around lived experience narratives and informational guidance [23-25]. The prominence of withdrawal-linked neurologic symptoms in our data is also consistent with clinical and patient-reported literature describing discontinuation effects such as dizziness and "brain zaps" as salient and, for some individuals, persistent [13]. At the same time, our finding that emotional flattening, sleep disruption, and memory or "brain" issues were especially prominent in original posts differs somewhat from that of large-scale social media work emphasizing sexual, weight, sleep, and pain-related side effect domains as major clusters [39]. This divergence may reflect differences in platform context, subreddit norms, sampling strategy (ie, high-engagement threads), and the analytic focus on co-occurrence structures rather than prevalence alone [39].

This study demonstrates the value of using ENA to explore complex discussions of antidepressant use, side effects, and withdrawal on Reddit. By modeling co-occurrences of themes and incorporating the SSBC, we identified meaningful patterns in how individuals seek and offer support around sensitive experiences with antidepressants. Our findings highlight not only the prevalence of commonly reported side effects, such as emotional flattening, dizziness, and sexual dysfunction, but also the layered ways in which these experiences are embedded in peer-to-peer support narratives on social media.

Although ENA proved effective for mapping conceptual relationships, our analysis also revealed its limitations when applied to large-scale, multidimensional social media data. Specifically, ENA's pairwise edge structure can obscure more complex relationships involving multiple interrelated concepts or semantic links. To address this, we introduced the use of hyperedges and semantic networks within QNA to enhance the granularity and interpretive power of the network. Together, these methods offer a more nuanced lens for analyzing online health discourse and pave the way for future research integrating semantic meaning and structural complexity into digital health data analysis. Clinicians may use these findings to better understand patient language around withdrawal and side effects, thereby improving counseling and patient-centered care.

Still, Reddit users discussing antidepressants may not reflect the broader patient population. Useful extensions of this work may include cross-subreddit comparisons, temporal evolution of support patterns, or large-scale automated coding pipelines.

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Conclusions

Study findings can serve as a template for clinicians and digital health researchers seeking information about the types of support patients are already accessing online. Findings also highlight the need to complement, rather than replace, these peer-driven networks. Integrating these insights into clinical practice and digital intervention design may help bridge communication gaps, tailor patient education, and enhance trust by aligning clinical guidance with the real-world experiences expressed in online mental health communities.

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The authors declare that no generative artificial intelligence technologies were used in the conception, analysis, interpretation, writing, or preparation of this manuscript.

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Data Availability

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

Authors' Contributions

EYS and AR contributed to the conceptualization and design of the study, data collection, analysis, and interpretation of the data, and drafting and revising the manuscript. Both authors approved the final version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Computation steps for epistemic network analyses.
[DOCX File, 27 KB - jopm_v18i1e85812_app1.docx]

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Abbreviations

ENA: epistemic network analysis
QNA: qualitative network analysis
ROCK: Reproducible Open Coding Kit
SSBC: Social Support Behavior Code
SSRI: selective serotonin reuptake inhibitor

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Real-Time Cardiac Biofeedback Intervention: Experiences of Patient and Public Involvement in a Randomized Controlled Trial

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Abstract

Background: Patient and public involvement (PPI) is crucial for enhancing research quality and relevance and addressing health inequalities. PPI ensures that studies tackle relevant and meaningful questions, as there is a recognized need by the research community to document and share PPI studies to advance the field and encourage the adoption of such activities.

Objective: The study aimed to provide a detailed report on the PPI activities undertaken to develop and implement a randomized controlled trial of a novel therapeutic tool designed to increase interoception and metacognition (ie, the Interoceptive Insight and Metacognitive Efficacy beliefs [InMe] trial).

Methods: The InMe trial integrated insights from experts by experience, as well as from clinical and academic experts. This collaborative approach resulted in the development of a comprehensive trial across 4 main stages—design, delivery, results interpretation, and future planning.

Results: Here, we highlighted the unique insights and the added value in incorporating PPI activities into our trial development and implementation, while reporting challenges and shortcomings that were identified throughout this process.

Conclusions: PPI activities within the InMe trial led to meaningful changes, while collaborators expressed satisfaction and increased interest in interoception research. Further improvements on how to best support experts by experience when sharing their experiences were also identified.

Trial Registration: ISRCTN Registry ISRCTN16762367; https://www.isrctn.com/ISRCTN16762367

(J Particip Med 2026;18:e84737) doi:10.2196/84737

KEYWORDS

patient and public involvement; PPI; interoception; biofeedback; smartwatch; mental health; eating disorders

Introduction

Patient and Public Involvement

Historically, research has been driven by academics and clinicians with expertise in a given field, with little or no involvement of those with lived, living, or other forms of relevant experience. Lack of involvement of individuals with relevant experience could potentially lead to a "mismatch" between the researcher and patient needs addressed, which has been described as a key contributor to research waste [1,2]. Research waste arises from poor research conduct and ambiguous reporting of research outcomes, which renders research unusable, as direct conclusions cannot be drawn [3]. Patient and public involvement (PPI) offers a potential solution to this problem. By engaging individuals with relevant experience, researchers can identify methodological drawbacks, enhance study design, improve feasibility within public health services, and ensure acceptability of interventions to patients. Additionally, PPI can ameliorate research reporting and dissemination, thereby improving the overall quality and impact of studies [4,5]. Indeed, evidence suggests that PPI initiatives provide unique perspectives, ensuring that research outcomes have meaningful impacts on service users [6-8].

According to the guidelines of the Center for Engagement and Dissemination within the National Institute for Health and Care Research (NIHR; replacing what was previously known as INVOLVE), PPI is commonly defined as research "being carried out with or by members of the public rather than to, about or for them" [9]. Here, "members of the public" refers to patients

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with lived or living experience, but also carers of patients directly impacted by them and health care professionals. Indeed, in the last 2 decades, there has been an increasing interest in the active involvement of patients and members of the public in research, which has become a common requirement and priority for major institutions and funders in the research innovation industry. These institutions range from the UK Medical Research Council [10] to major research charities such as the Wellcome Trust [11]. Moreover, different initiatives such as the UK Standards for Public Involvement and NIHR Center for Engagement and Dissemination have been developed to promote and guide researchers to carry out consistent and standardized PPI collaboration activities, thus allowing research to become more relevant to patients and clinicians within the health care system. Additionally, PPI initiatives have gained prominence across several European countries, with the Netherlands and Scandinavian countries being at the forefront of such developments [12,13]. Other considerations, such as the engagement and involvement of minority and marginalized communities in research, have further enhanced research equality and diversity, rendering research also relevant to underrepresented populations [14,15]. However, challenges have been observed, particularly in how members of the public are recruited and supported throughout the involvement process. These observations call for further research resources and infrastructure changes to maintain a long-term and meaningful collaboration [15].

Accordingly, the present study presents and critically evaluates the PPI activities and collaboration that occurred for the development and completion of the Interoceptive Insight and Metacognitive Efficacy beliefs (InMe) trial. In the following section, a brief summary of the randomized controlled trial's (RCT's) background and design will be provided, before proceeding to the aims and procedures of the PPI and concluding with the coevaluation and discussion of the advantages and disadvantages of this PPI effort.

Intervention Background and Scope

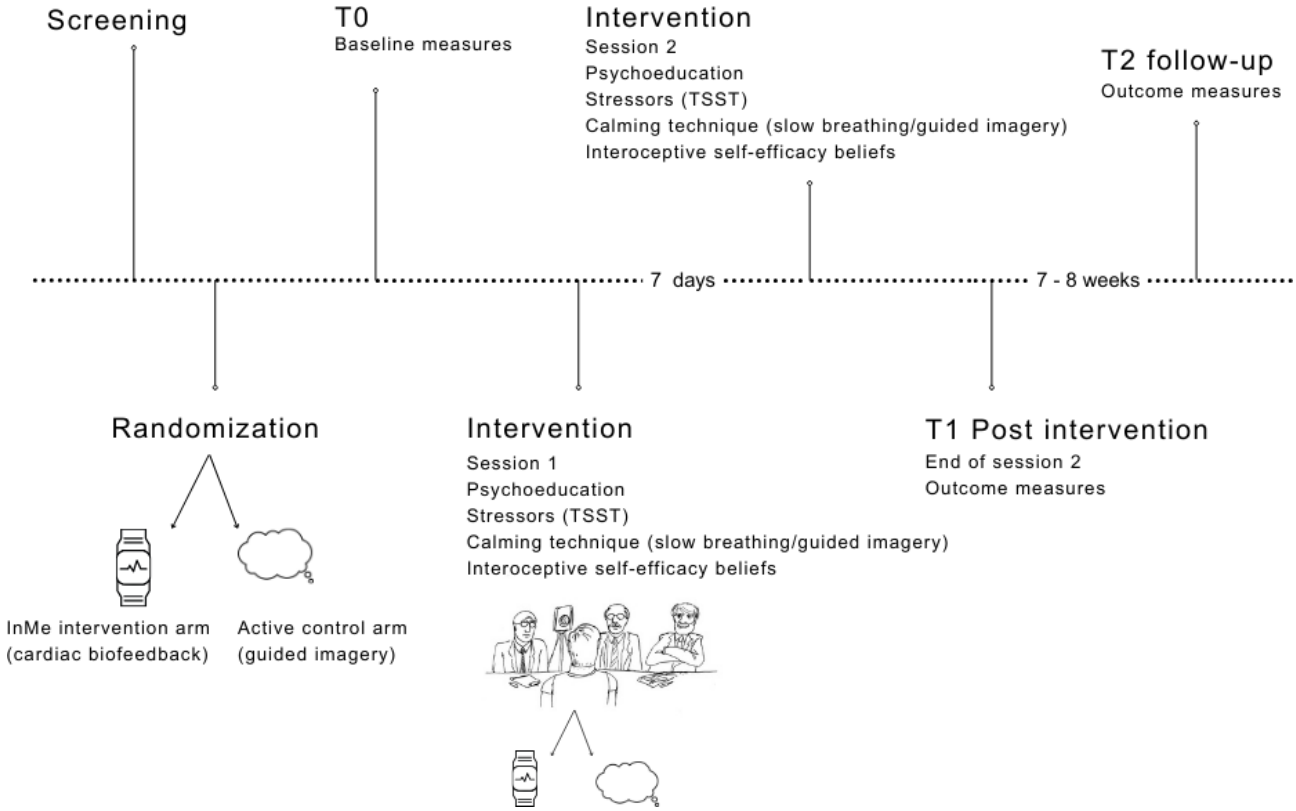
The InMe trial was developed as part of a series of studies, aimed at developing and testing the feasibility and efficacy of a novel, behavioral therapeutic intervention that can enhance interoceptive self-efficacy beliefs, that is, the beliefs of one's ability to regulate their internal body signals (known as interoceptive signals). Interoception is defined as the process of sensing, integrating, and interpreting physiological body signals arising from major visceral systems such as the gastrointestinal, respiratory, and cardiovascular systems [16]. Previous research has shown that dysregulations or disturbances in interoceptive processing are associated with psychopathology, including but not limited to somatic symptom disorders and eating disorders (EDs) [17-20]. Nevertheless, the evidence concerning the efficacy of interoception-based interventions remains inconclusive, indicating a need for further research and specific targeting of both physiological signals themselves and related interoceptive beliefs (for systematic review see [21]). We thus aimed to develop an intervention and first test its feasibility and efficacy in a randomized controlled setting, with a subclinical sample. Here, we report the PPI activities that informed the development of the InMe trial, following its efficacy testing in a subclinical RCT, which is fully reported elsewhere [22].

Overview of Trial Procedures

The subclinical trial aimed to investigate whether the InMe intervention, which incorporated slow breathing, cardiac biofeedback, and interoceptive beliefs training, could significantly enhance interoceptive self-efficacy beliefs under stressful conditions, in comparison to a control intervention. The trial recruited a general population, predominantly university students, with low interoception as measured by the Body Awareness Questionnaire [23]. Participants were randomized into 2 groups: the InMe intervention group or an active control group that used a guided imagery technique. After randomization, participants completed a comprehensive set of baseline questionnaires, designed to measure symptoms including disordered eating, as measured by the Eating Disorder Examination Questionnaire [24], and somatic symptom disorders measured by the Patient Health Questionnaire-15 [25]. As part of the intervention, participants were provided with psychoeducation about heart rate, including how heart rate fluctuates under stress and can be regulated. Following this educational component, participants underwent a stress induction procedure using the standardized Trier Social Stress Test (TSST) [26]. During the TSST, participants were instructed to use either the slow breathing technique (InMe intervention) or the guided imagery technique (active control) to downregulate their stress response and build related self-efficacy beliefs. Seven days after the initial session, participants repeated the intervention and completed postintervention measures. Finally, a follow-up session was conducted 7 - 8 weeks after the intervention to evaluate sustained effects. The detailed InMe trial procedures are shown in Figure 1.

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Figure 1. Interoceptive Insight and Metacognitive Efficacy beliefs trial timeline and procedures. TSST: Trier Social Stress Test.



Aims of the PPI

The aim of this paper was to provide a detailed report on the involvement and contribution of patients and members of the public in the development of the InMe trial. PPI has been a key element in the conception, design, development, and completion of the InMe trial, with the involvement of external collaborators also playing a significant role in the interpretation of trial results and informing future clinical trial planning and practice. Additionally, this paper aims to provide insights regarding challenges that arose during each phase of the research process and offers suggestions on how research teams incorporating PPI might address similar challenges in the future. An overview of the PPI activities and the aims achieved within the framework of this collaboration is presented below (Table 1).

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Table . Detailed list of the PPI[a] aims and time frames within which they should be achieved.

Aims	PPI activities				
	Discussion 1	Email	In person	Discussion 2	Discussion 3
Development of operating procedures	✓				
Outcome measure development	✓				
Sample specific stressor	✓				
Statistical analysis plan development		✓			
Development of participant-facing documents		✓			
Trial advertisement strategy		✓			
Research team training & optimization			✓		
Optimization of intervention procedures			✓	✓	
Consideration of development of patient-specific stressors				✓	
Discussion on treatment differences in EDs[b] and somatic symptom disorders				✓	
Planning for implementation in a clinical setting				✓	
Adherence to intervention					✓
Considerations on breathing exercise and biofeedback					✓
Discussion on use of technology barriers within the NHS[c]					✓
Further consideration on patient-specific trial procedures and stressors					✓

[a]PPI: patient and public involvement.

[b]EDs: eating disorders.

[c]NHS: National Health Service.

Methods

Collaboration Approach

Email invitations were sent to experts by experience (of EDs and/or somatic symptom disorders), health care practitioners, and researchers, to collaborate on the development of the InMe trial. These individuals' contact details were obtained from previous clinical and social media contacts. Meetings took place online due to location and time constraints; collaboration occurred in the form of online group discussions, online focus groups, and email communications, supported by audio recordings and note taking. The InMe trial was funded by a small grant from InMe, United Kingdom. Within this grant, there was no budget available for the reimbursement of PPI activities for contributors. Therefore, participation in all PPI activities was voluntary, with full administrative support provided by the research team. Engagement expectations of PPI contributors regarding their role in helping to develop and co-design trial procedures were discussed and formalized beforehand via email.

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Ethical Considerations

Institutional ethics approval was granted in February 2022 for the InMe trial, including all its feasibility and other participant feedback measures, under the University College London ethical amendment (CEHP/2019/577; Body to Mind Awareness). Guidance from government organizations (eg, UK Health Research Authority) and recent academic, peer-reviewed work [27] suggests that activities such as the present PPI work do not require formal ethical approval from an ethics committee. All participants were informed about the collaboration, their role and involvement, the conditions of anonymity and confidentiality, and agreed to be involved. InMe trial participants received written information about the study's objectives, procedures, and potential risks before providing written informed consent. Those who participated in the RCT were offered a choice of either £37 (US $49.50) or credit points (1 credit point per hour of participation, applicable to University College London psychology students only) as reimbursement upon completing the study.

Collaborators

The lived experience advisory panel members (also referred to as "experts by experience") were selected based on their self-declared experience with somatic symptom disorders or EDs. Specifically, the lived experience advisory panel (n=5) was comprised of members with functional neurological disorder (n=1), eating disorder diagnoses (EDs; n=3), and other diagnoses (n=1). The clinical-academic steering committee members (n=10) included UK Health and Care Professions Council-registered clinical and counseling psychologists (n=3), a consultant neurologist and a senior academic neurological psychotherapist working within the National Health Service (NHS) (n=2), academics conducting research relevant to the trial (n=3), and statisticians advising on trial methodology (n=2).

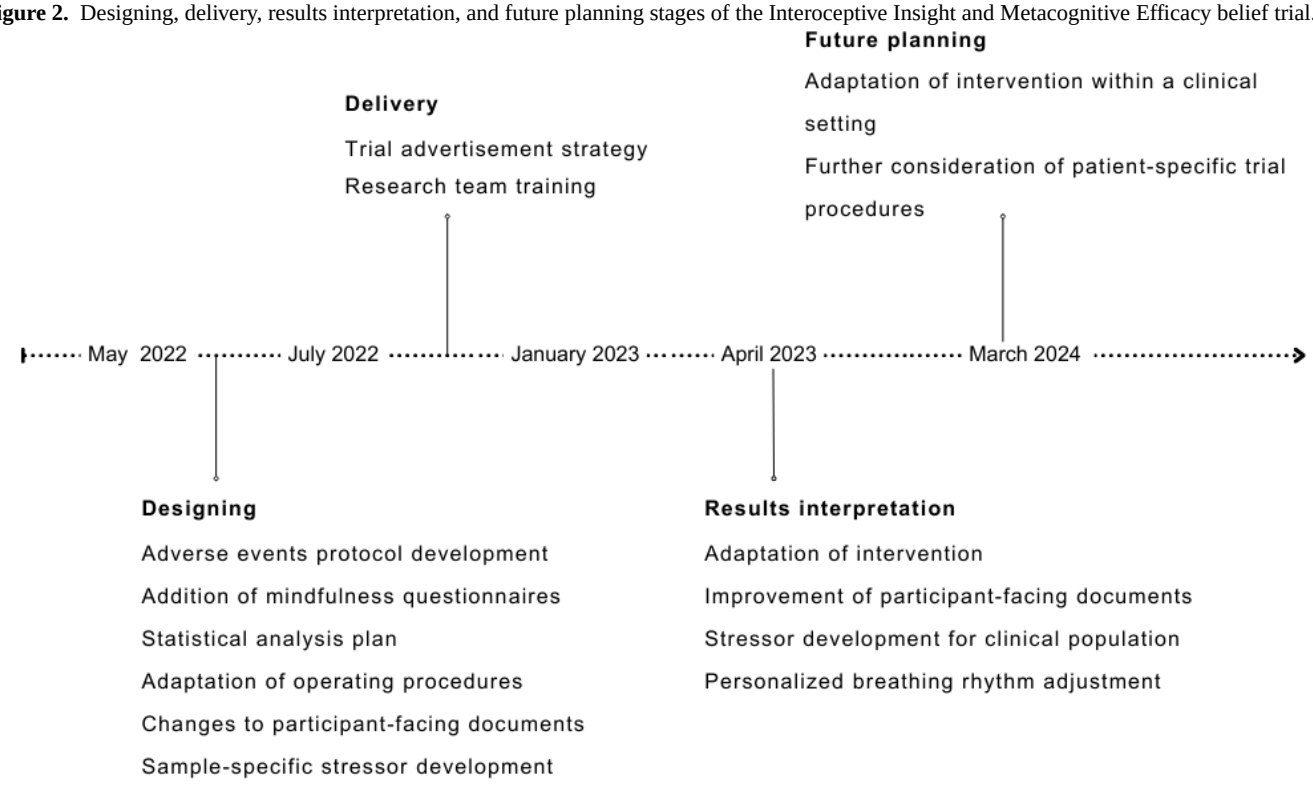
PPI Process

Initial planning of the current RCT procedures was informed by the findings of an audit study conducted by the core research team, which also involved PPI collaborations with clinicians and patients within an ED ward in an NHS facility [28]. In their clinical audit, the authors aimed to understand and evaluate whether cardiac biofeedback practice following stress-inducing ward activities (here, weekly meal-planning) was better than existing, local standards of care for anorexia nervosa in helping individuals downregulate their heart rate and increase their self-efficacy beliefs about such abilities [28]. Based on the knowledge and experience gained during this audit about the potential of using biofeedback and interoceptive self-efficacy belief training to enhance existing standard practice, we aimed to develop and undertake a subclinical study testing the role of the InMe biofeedback intervention in collaboration with experts by experience, as summarized in Figure 2.

Lived experience advisory panel and clinical-academic steering committee collaborators were invited to 3 online group discussions in May 2022, April 2023, and March 2024. During the first discussion, researchers introduced and presented the preliminary suggestions for the trial design, which led to the development of the participant-facing documents. Additionally, the research team conducted a distinct discussion group to facilitate the development of the statistical analysis plan with members of the clinical-academic steering committee. Each online discussion was recorded and transcribed into text, which facilitated the research team in identifying key discussion points and feedback provided by the collaborator groups. Following the discussion, collaborators received a lay summary of the meeting including all key points and how these could be addressed by the research team. Near the completion of the trial, during the second discussion, preliminary data were presented, and collaborators discussed and reflected on the feasibility of the RCT in a broader health care setting. Following data analysis, collaborators were invited to a final discussion, in which the research team presented the main analysis results and additional feasibility findings, along with participants' feedback on the trial procedures.

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Figure 2. Designing, delivery, results interpretation, and future planning stages of the Interoceptive Insight and Metacognitive Efficacy belief trial.



Evaluation and Measurement of PPI Impact

PPI outcomes and impacts were qualitatively explored using an impact log, in which all email communications and online meetings were recorded. The impact log was developed according to the Public Involvement Impact Assessment Framework, which provides guidelines on how researchers can measure the impact of participant involvement [29,30]. The Public Involvement Impact Assessment Framework informed the development of the research log by first considering the study's context and design and then developing a more tailored PPI approach to achieve the desired outcomes and was considered the most appropriate for the aims of the present PPI [31]. Moreover, it highlighted the importance of identifying barriers and facilitators in the process to ensure a successful and productive PPI collaboration. Following 2 online PPI group discussions in April 2023 and March 2024, collaborators completed an anonymized feedback form to identify future challenges and shortcomings not previously recognized or identified by the research team. Participants rated satisfaction on a 10-point Likert scale, with 0 being "not at all satisfied" and 10 being "Extremely satisfied." Additionally, collaborators were asked an open-ended question on their overall experience participating in this trial.

Results

Overview

The research team worked together with the lived experience advisory panel and clinical-academic steering committee members to generate a comprehensive trial protocol and procedures, which are all presented and discussed in four stages below: designing, research delivery, results interpretation, and future planning. All procedures have been reported in accordance with the Guidance for Reporting Involvement of Patients and the Public, Version 2 reporting guidelines for PPI in research [32], the impact of which is summarized in Table 1.

Design

Over 4 months, the research team developed a comprehensive research protocol and standardized operating procedures (SOPs) aligned with the trial's aims. At this stage of the design process, a group discussion meeting was convened to gather clinical expertise from health care professionals and insights from patients on the intervention. During the online discussion held in May 2022, researchers presented the intervention's objectives, trial measurements, and an overview of the procedures. Participants were encouraged to provide feedback during the presentation, followed by an open discussion. This approach was widely regarded by the research team as a key facilitator for fostering dynamic and productive conversations [33]. The discussion was centered on two primary points: (1) individuals' experience with slow breathing as a calming technique and (2) individuals' responses under stressful conditions. A lived experience advisory panel member noted that slow-paced breathing might pose challenges for individuals without prior experience. This feedback led to the development of an adverse event protocol to guide researchers in responding to issues such as difficulty breathing, light-headedness, or panic attacks during the slow breathing exercise or stressors. The development of this protocol underscored the importance of participant safety and demonstrated how input from experts by experience could enhance the trial's value and procedures. Additionally, to better understand variability in breathing practices, the research team incorporated baseline questionnaires to assess participants' previous experience with slow breathing and other mindfulness or breathwork techniques. Following consultation with a

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clinical-academic steering committee member, the TSST, which involves mental arithmetic and free speech in front of experimenters, was modified to better suit a sample of 18- to 30-year-old participants, predominantly university students. The adapted stressor procedures were refined and summarized in a document circulated via email to all attendees, who were invited to provide further comments on the implemented changes.

In May 2022, an in-person meeting was arranged for a clinical-academic steering committee and a lived experience advisory panel member to evaluate and optimize the trial's assessment procedures. This resulted in improvements to the language of the SOP, adjustments to TSST timing, and reorganization of the panel of experimenters. Due to scheduling challenges, the members attended separately. After refining the stressor description and duration, the research team consulted directly with a clinical-academic steering committee member experienced in conducting TSSTs, who validated the changes to the stressor procedures.

Email communications also had a pivotal role during the design stage, facilitating the refinement of participant-facing documents such as consent forms, information sheets, and SOPs for researchers. A collaborator with expertise in research methods and statistics contributed via email to the development of a descriptive statistical analysis plan. Additionally, psychoeducation procedures, where participants were informed about fluctuations in their heart rate and breathing rhythm, were reviewed by a clinical-academic steering committee member. The psychoeducation materials for both the intervention and active control arms were optimized to ensure consistent structure and language, allowing for a direct comparison between groups. Email communication yielded impactful changes, as outlined in Table 2 below.

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Table . Impact log for all patient and public involvement activities within the InMe[a] trial.

Stage and date (MM/YY)	Involvement task	Collaborator	Outcome	Impact
Designing				
05/22	Group discussion	Lived experience advisory panel member	Discussion on slow breathing challenges	Development of a separate adverse event protocol in the occasion of an adverse event, for participant safety
05/22	Group discussion	Clinical-academic steering committee member	Discussion on participant's prior and current experience with mindfulness, yoga, deep breathing, related apps, and self-tracking technologies	Added prior experience questions to baseline battery of questionnaires prior and after intervention
05/22	Group discussion	Clinical-academic steering committee member	Discussion on how stressors can variably affect clinical populations	Development of a separate adverse event protocol to ensure participant safety
05/22	In-person meeting	Clinical-academic steering committee member	Feedback on psychoeducation by English language native speaker	Adjusted SOP[b] text
05/22	In-person meeting	Lived experience advisory panel member	Reviewing TSST[c] components and timing	Adjusted SOP and stressor length
05/22	Email	Clinical-academic steering committee member	Development of statistical analysis plan	Adjustments on design protocol before trial preregistration
06/22	Email	Clinical-academic steering committee member	Discussion on TSST for the intervention	Adapting TSST to fit the purposes of the intervention
07/22	Email	Lived experience advisory panel member	Reviewing consent form and participant information sheet	Clarifying the right of participant withdrawal in consent form and separately added to SOP
07/22	Email	Lived experience advisory panel member	Reviewing consent form and participant information sheet	No adaptation, as lived experience advisory panel considered the documents clear and concise
07/22	Email	Clinical-academic steering committee member	Comparison of control arm guided imagery vs psychoeducation and slow breathing practice texts	Added psychoeducation component to active control arm to allow comparison
Delivery				
07/22	Email	Lived experience advisory panel member	Provided key points to be included in the advertisement	Designing the trial advertisement
07/22	Email	Clinical-academic steering committee member	Discussion on target population to recruit and advertisement adaptation	Produced 2 separate advertisements to be published on different media platforms
07/22	Email	Lived experience advisory panel member	Advertisement dissemination	Redesigning the advertisement, removed barcode and cut down on text
Results interpretation				

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Stage and date (MM/YY)	Involvement task	Collaborator	Outcome	Impact
04/23	Group discussion	Clinical-academic steering committee member	Patients with EDs[d] and somatic symptoms are less likely to be interested in the intervention	Researchers should opt for a graded exposure technique into the trial.
04/23	Group discussion	Lived experience advisory panel member	For patients with somatic symptom disorders, accessibility to research site should be considered.	Information sheet should provide all the information including maps and accessibility, prior to the participant's visit.
04/23	Group discussion	Clinical-academic steering committee member	Generate a diagnosis-specific stressor	Meal planning for EDs and push test for somatic symptom disorders. For both describing their worst day in terms of symptoms
04/23	Group discussion	Clinical-academic steering committee member	Not at all participants reacted the same to slow breathing to reduce stress	Aim to tailor breathing rhythm to each participant
04/23	Group discussion	Lived experience advisory panel member	Engagement of results and praise for future research	Agreement with discussion
Future planning				
03/24	Group discussion	Clinical-academic steering committee member	InMe module could be used as prehabilitation or add-on to standard of care.	Consideration on prehabilitation & standard treatments the module could be paired with
03/24	Group discussion	Lived experience advisory panel member	Prehabilitation could be challenging in EDs	Focusing only on standard of care as participants would lack further support in prehabilitation
03/24	Group discussion	Clinical-academic steering committee member	Discussion on how EDs and somatic symptom disorder populations respond to treatment	Consideration on application of the InMe module in somatic symptom disorders

[a]InMe: Interoceptive Insight and Metacognitive Efficacy belief.

[b]SOP: standardized operating procedures.

[c]TSST: Trier Social Stress Test.

[d]ED: eating disorder.

Research Delivery: Outcomes and Impact

Following the formalization and approval of trial procedures, the research team proceeded to plan the participant recruitment strategy. At this stage, after being provided with guidelines for the advertisement, a lived experience advisory panel member generated the InMe trial poster, targeting individuals aged between 18 - 30 years. Furthermore, with additional feedback from a clinical-academic steering committee advisor and another lived experience advisory panel member, the team improved the poster layout and content, which is visually presented in Figure 3.

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Figure 3. Advertisement before and after consultation with lived experience advisory panel members.



Results Interpretation

Outcomes and Impact

Once the preliminary analysis was conducted, the research team invited the lived experience advisory panel and clinical-academic steering committee collaborators to an online 1.5-hour discussion in April 2023. During this meeting, the efficacy and feasibility outcomes relevant to the stressors and participant acceptability of the procedures were presented. Presentation of the RCT outcomes on efficacy and feasibility goes beyond the scope of this paper and is presented fully elsewhere [22]; however, results will be briefly outlined here to contextualize the relevant PPI activities. The online discussion in April 2023 was centered on the main trial results, their clinical impact, and exploring ways to further optimize the intervention. During the discussion, two points were raised: (1) where the InMe trial intervention could be used and whether it should be used in conjunction with standardized treatments and (2) whether patients with somatic symptom disorders and EDs should be treated similarly or whether clinical differences should be considered.

Trial Outcomes

Results indicated that the InMe intervention was efficacious in improving the primary outcome of the RCT, namely interoceptive awareness, as measured by the Multidimensional Assessment of Interoceptive Awareness [34]. Improvements were noted in both trial arms immediately postintervention, but only participants in the InMe arm—and not those in the active control arm—experienced a maintained improvement at follow-up, which occurred 2 months postintervention. Attendees expressed an interest in the results but highlighted that patients with EDs and somatic symptom disorders might hesitate to participate in an intervention involving stressors. Additionally, considerations regarding accessibility to the study site were discussed by a lived experience advisory panel member, especially in cases of mobility challenges. From experience, experts with somatic symptom disorders emphasized that all information about accessibility to the study site should be provided in the information sheet. Thus, coproduction of participant-facing documents in future trials would be especially beneficial as it would help streamline such challenges. Regarding feasibility outcomes, the trial was deemed feasible and acceptable by participants, as TSST procedures were shown to effectively increase participants' heart rates, and similarly, the slow breathing technique effectively reduced their heart rates.

Intervention and Standardized Treatment

Following the results interpretation, as the InMe intervention was deemed feasible, a clinical-academic steering committee member with clinical experience suggested that going forward, the InMe intervention could be paired with an established standard of practice therapy. The practice of the InMe intervention can be monitored and encouraged differently in each setting. During the discussion, the possibility of digitizing the InMe intervention for home practice was proposed by a researcher. However, it was concluded that participants awaiting treatment might lose motivation to participate in a self-paced intervention. In addition, a lived experience advisory panel member noted that the intervention should not be carried out online, as it might induce anxiety since some individuals with EDs disregard bodily sensations as a coping mechanism [35]. The differing perspectives between researchers and lived experience experts regarding the future use of the trial prompted further constructive dialog within the research team. A clinical-academic steering committee member suggested the intervention be used as prehabilitation to support individuals on long waiting lists for standardized treatment. This proposal was mutually agreed upon, as it would help ensure early patient engagement with the relatively easy-to-use technique, potentially offering a temporary solution to patients on waiting lists before standard treatment becomes available.

Treatment Differences Among EDs and Somatic Symptom Disorders

On the second discussion point, as results indicated that no other symptoms apart from disordered eating symptoms improved following the intervention, a lived experience advisory panel attendee raised a question about whether ED and somatic symptom disorder patients should be treated similarly when planning future research. The InMe intervention showed clear improvements in EDs but not in somatic symptom disorders, signifying further ambiguity in the latter. It was discussed that, in both cases, participants experience bodily uncertainty, and an intervention such as the one presented should be beneficial

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if administered appropriately. However, the mechanisms maintaining symptoms in EDs and somatic symptom disorders may rely on processes beyond those targeted by the presented InMe intervention, and these mechanisms may vary between populations.

Future Planning

Outcomes and Impact

After the completion of the trial, the research team invited members of the clinical-academic steering committee and lived experience advisory panel for an evidence-based discussion on conducting the intervention within a health care setting. The discussion occurred in March 2024 and lasted 2 hours in total. The discussion aimed to understand if the proposed therapeutic biofeedback intervention could be translated into a clinical setting, and how it should be adjusted moving forward. Additionally, during the discussion, attendees were presented with the recruitment and dropout rates to enable further discussion. The three points discussed were the following: (1) Adherence to intervention in EDs and somatic symptom disorder populations, (2) The nature of stressors according to the patient's clinical profile, and (3) Biofeedback, slow breathing, and how this can be used in a clinical setting.

Adherence to Intervention

From recruitment outcomes, a researcher (MT) responsible for participant randomization and stratification observed that participants with disordered eating behaviors and somatic symptoms were more likely to withdraw from the trial, even prior to attending the first session. Overall, higher drop-out rates have been observed in outpatient facilities compared to in-patient, as patients might experience a drop in motivation. Additionally, a barrier identified from the lived experience advisory panel, which can complicate adherence in terms of the intervention (considering that the aim of the intervention was to increase self-efficacy by providing explicit biofeedback), was the fear of patients with EDs attending to their bodies [36]. Expanding on these barriers, a clinical-academic steering committee member with expertise working with ED populations suggested that moving forward, a more graded exposure to the cardiac biofeedback intervention would be appropriate, rather than an intensive 2-session intervention. Such observations are considered useful as they will aid in developing an intervention, which will evoke interest in research participants and result in higher adherence rates, following consideration of the previous suggestions made.

Stressor Future Considerations

Another point on the intervention brought into discussion was the nature of the stressors. The InMe trial stressors were based on the TSST protocol, changing the free speech stressor to a stressor more relevant to a student sample (ie, an interview to join a prestigious university society). However, in the group discussion, clinical-academic steering committee members considered that future studies should develop clinically relevant stressors based on the participant's diagnosis. For instance, in the case of EDs, participants could potentially be asked to plan their meals for the weekly schedule (as in our initial clinical audit [28]), which is stress-inducing but also clinically relevant. Further, in the case of somatic symptom disorders, a clinical-academic steering committee member suggested that participants could be invited to explain their worst day in terms of symptoms, perform the Hoover sign or tremor entrainment test [37], which is also considered stressful and triggering to patients. Both suggestions will be piloted by the research team in future clinical work, investigating if stressor relevance to diagnosis could be effective in evoking a stress response, and thus increasing participants' heart rate.

Biofeedback Future Considerations

As a last discussion point, the research team suggested the possibility of the slow breathing rhythm being adjusted to each participant, rather than all participants following the standardized slow breathing technique [38]. Effectively, adjusting the breathing technique to the individual's breathing rhythm has optimal effects in improving mood and relaxation, while reducing the possibility of adverse events [39]. However, implementing a tailored breathing rhythm raises concerns regarding technical complexity and scalability. Specifically, accurately determining individualized heart rate variability would require multiple assessment sessions [40], potentially increasing trial burden and complexity and leading some clinical experts to advise against its use.

Therefore, the extent to which this can be applied within the NHS setting in a clinical population needs further consideration and should be piloted in future research. Clinicians in attendance suggested that technology used in the NHS should remain simple and inexpensive, to not only facilitate staff in administering the intervention, but to also and importantly support interested patients in implementing this intervention at home or over an extended period of time.

PPI Feedback

Following 2 online PPI group discussions in April 2023 and March 2024, collaborators provided their feedback and evaluated the PPI activities. Participants rated their satisfaction on a 10-point Likert scale, the results of which are presented in Table 3 below. As evident, attendees reported no negative feedback and highlighted improved understanding of concepts like interoception.

Table . Participants' mean satisfaction (0-10 Likert scale) following April 2023 and March 2024 discussions.

Discussion session	Overall satisfaction, mean (SD)
April 2023	8.6 (1.67)
March 2024	9.0 (0.93)

Specifically, in response to the open-ended question, a clinical advisor noted that participating in the trial hugely increased their interest in working with interoceptive difficulties in eating disorders. Additionally, a lived experience advisory panel

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member was very satisfied participating in the trial, noting that it "set a new bar for lived-experience involvement. Researchers have been thoughtful, detail-oriented, and disability-literate. While my own involvement was curtailed at some points by active health problems, I always felt listened to and it was evident that researchers sought to make the process accessible, predictable, and transparent throughout." As in previous PPI efforts, collaborators expressed their interest in the research conducted, gaining knowledge on the topics discussed, while lived-experience members felt empowered [6]. In contrast, other lived experience advisory panel collaborators considered the discussion challenging to follow, saying, "Having little or no academic or clinical experience in this field of study I felt rather ill-equipped to share my lived experience or couch them in the language that academics use." This barrier was also observed by the research team when discussing research findings, as clinical-academic steering committee members contributed more during the discussion. To raise the level of discussion and contribute to efficient collaboration with the possibility of coproduction, training opportunities for both experts by experience and researchers conducting PPI activities should be prioritized in the planning of a research trial [31]. Moreover, researchers should explore opportunities available within the organization supporting their research, which can provide guidance throughout.

Discussion

Key Findings

The group discussions conducted throughout the design, delivery, and after-trial phases highlighted several key findings relevant to the feasibility, safety, and future implementation of the InMe intervention. Feedback regarding participants' prior experience with slow-paced breathing led to the introduction of baseline assessments and the development of an adverse event protocol, ensuring appropriate responses in the instance of light-headedness, panic, or breathing discomfort. Adaptations to the stressor procedures were also informed by collaborator input, emphasizing the importance of tailoring experimental stressors to the characteristics of the university student population. Notably, all changes proposed by lived experience experts were successfully implemented during the trial design phase. It is important to acknowledge, however, that the scope of their input was limited by practical considerations, including study funding and timelines, which may limit the feasibility of some suggestions in other contexts. Collectively, these findings underscored the value of co-design in enhancing participant safety and methodological robustness.

Further discussions focused on the clinical translation and future optimization of the intervention. The differing recommendations from researchers and experts by experience regarding the future implementation of the trial indicate that further discussion and piloting with clinicians is needed to determine the most appropriate mode of delivery. It emerged that the InMe trial should be delivered alongside established standardized treatment approaches with a health care professional, rather than as a standalone or online intervention, due to concerns regarding motivation and anxiety in ED populations. The intervention demonstrated symptom-specific benefits for individuals with EDs but not for somatic symptom disorders, suggesting that different maintaining mechanisms cannot be generalized. Withdrawal rates in individuals with subclinical EDs and somatic symptom disorders highlighted challenges in adherence, reinforcing recommendations for graded exposure to biofeedback and the use of diagnosis-specific stressors in future studies. Finally, while tailoring the breathing rhythm to individual physiology may facilitate stress reduction, concerns regarding technical complexity and scalability suggest that any future clinical application, particularly within health care settings, should prioritize simplicity, affordability, and ease of implementation.

Limitations

After the design phase, recruitment, participant testing, data analysis, and discussion proceeded without the continued involvement of experts by experience, representing a key limitation of the study. Furthermore, collaborators were not included as coauthors on the manuscript, despite growing recognition that coauthorship constitutes good practice within PPI research [41]. The impact log also reflects that clinical-academic steering committee members contributed more than lived experience advisory panel members, which is commonly observed when online meetings and conversation dynamics are not appropriately managed [33]. One way to address this could be by holding online discussion groups or in-person workshops exclusively with lived experience advisory panel members to align the discussion with patients' needs, creating a less intimidating environment, while educating members of the public on the specific research discipline [42]. Alternatively, when resources permit, longer workshops with specific prompts could be used to address power dynamics, and training could be provided to PPI partners. Such training has been shown to be a key driver of efficient collaboration [43]. Additionally, lived experience advisory panel members were outnumbered by clinical-academic steering committee members, primarily due to the lack of financial reimbursement and the reliance on social media and previous contacts for recruitment. One of the main barriers to efficient collaboration is the issue of limited funding for PPI activities, which has been highlighted in previous research as a persistent challenge [44,45] and should be carefully addressed in future research proposals. Many organizations supporting the research trial could also offer access to databases of lived experience experts who have previously partnered in research, such as the recently formed Center for Equality Research in Brain Sciences at University College London. Moreover, due to the lack of involvement of community members in the PPI activities, the panels consisted of more health care professionals with a different primary source of income. Unequal dynamics between health care professionals and experts by experience during PPI activities should be particularly monitored, as it can hinder meaningful change [46,47]. Thus, funding opportunities should consider monetary compensation, which is equivalent to a full-time source of income, for members of the public to be involved in research.

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Future Considerations

Coresearch

Future research should explore opportunities to collaborate with coresearchers in conducting research and disseminating findings, as this enables meaningful involvement and prioritizes patient-identified priorities [48]. This approach aligns with NIHR guidance and supports lived experience advisory panel members in developing a sense of ownership, empowerment, and shared responsibility in decision-making throughout the research process [41].

Funding

Funders of subclinical, feasibility, and pilot studies should consider allocating budgets for PPI activities. Effective PPI is greatly beneficial but requires time and appropriate preparation and funding [49].

Community Representation

Due to the lack of involvement of community members in the PPI activities, panels commonly consist of more health care professionals with a different primary source of income. Unequal dynamics between health care professionals and experts by experience during PPI activities should be particularly monitored, as it can hinder meaningful change [46,47]. Many organizations supporting the research trial could also offer access to databases of lived experience experts who have previously partnered in research, such as the recently formed Center for Equality Research in Brain Sciences in the United Kingdom.

Training and Tools

Further time should be invested in planning the goals and intentions of the aforementioned training activities as part of a general onboarding process for the trial team, as early engagement with collaborators was identified as the main facilitator in refining the research protocol and procedures [50]. Previous reviews on the topic have identified the need for substantial training and time for experts by experience, clinicians, and academics to develop good rapport with each other and efficient communication channels, in order to identify common research priorities [6,33,49,51]. Additionally, initiatives could incorporate training tools that could facilitate and support the experts by experience and members of the public involvement team [52]. For instance, this could include interactive training courses provided by the NIHR [53], along with guidance for researchers conducting PPI activities. This guidance may include the 4Pi framework, developed by the National Involvement Partnership project [54], which outlines principles for good practice, as well as for monitoring and evaluating PPI, developed by experts by experience. Similarly, the UK Standards for Public Involvement, a partnership initiative across the 4 nations since 2016, aims to improve the quality of PPI in research [31].

Conclusion

Overall, the findings from this study highlight the importance of meaningful collaboration with health care professionals and individuals with lived experience across the development of the intervention, trial design, and implementation. PPI contributors informed and collaborated in the design, delivery, future planning, and interpretation of results for the InMe trial, including the development of trial materials, refinement of participant communications, input into the nature of the intervention, contributions to the statistical analysis plan, and support with dissemination of findings. The intervention was deemed most appropriate as an adjunct to standard care, particularly as a prehabilitation tool for individuals on waiting lists. Discussions with PPI contributors on how participants can better engage with slow breathing suggested that future studies may benefit from adjusting breathing rhythms to individual participants to support more efficient downregulation of heart rate following stressor exposure. Another important contribution to future research design was the recommendation to develop a graded therapeutic intervention to ease participants into the process, whereby cardiac biofeedback, interoceptive belief training, and stressor exposure are introduced progressively across multiple sessions. Challenges related to engagement and adherence, particularly among outpatient populations, further reinforce the need for such graded approaches, alongside diagnosis-specific procedures and simple delivery models. PPI members expressed overall satisfaction with the PPI activities and reported increased interest in interoception research. However, the research team acknowledges that there is opportunity for improvement, emphasizing the importance of early planning of PPI activities to enable impactful coproduction with members of the public and experts by experience, which requires appropriate funding. Finally, this study highlights the ongoing underrepresentation of minorities in research, which does not reflect the diversity of the setting in which this work was conducted and should be actively addressed in future studies.

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Data Availability

The datasets generated or analyzed in this study are not publicly available because the recorded patient and public involvement collaboration transcripts are confidential. However, they can be made available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization: MB, AS, PMJ, AF
Data analysis: MB
Data curation: MB, MT, AF
Funding acquisition: CS, AF
Supervision: MT, AF
Writing - original draft: MB
Writing - review and editing: MB, MT, AS, CS, PMJ, AF

Conflicts of Interest

None declared.

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Abbreviations

ED: eating disorder
InMe: Interoceptive Insight and Metacognitive Efficacy beliefs
NHS: National Health Service
NIHR: National Institute for Health and Care Research
PPI: patient and public involvement
RCT: randomized controlled trial
SOP: standardized operating procedure
TSST: Trier Social Stress Test

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Experiences and Challenges of Patients With Chronic Respiratory Disease During a Virtual Research Study: Qualitative Study

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Abstract

Background: Virtual research has emerged as a promising and convenient approach. This study investigates the experiences and challenges faced by patients with chronic respiratory diseases who participated in a virtual research study.

Objective: This study aimed to explore the experiences of adults with chronic respiratory diseases participating in a virtual research study and to identify challenges they encountered to inform future virtual research design and implementation.

Methods: Adults with a diagnosis of asthma or chronic obstructive pulmonary disease taking medications for their condition were recruited from the Greater Vancouver Area. A total of 185 participants completed an asthma-specific or chronic obstructive pulmonary disease–specific health literacy measurement tool through telephone interviews and then completed a postinterview checklist (n=36) or survey (n=149) on their experience with virtual research. To test the health literacy tool's reproducibility, 110 participants were retested and completed the same checklist (n=79) or survey (n=31). Interviews were transcribed and thematic analyses were conducted on interviews, surveys, and checklists.

Results: Six overarching themes were identified: overall experience with virtual research, clarity of instructions, technology, communication, condition and cognition, and logistics. While participants generally reported a positive experience, the study identified significant challenges, including technological barriers, the need for clear and concise instructions, mental fatigue, and communication difficulties.

Conclusions: These findings highlight the importance of providing comprehensive technical support, ensuring clear communication, and addressing ethical considerations in virtual research. This study contributes valuable insights to the growing body of literature on the viability and challenges of virtual research in health care.

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KEYWORDS

virtual research; respiratory diseases; qualitative methods; research challenges; health literacy

Introduction

The COVID-19 pandemic disrupted research and health care delivery, resulting in transitions to virtual platforms [1,2]. Health care professionals increasingly used eHealth tools, defined as the provision of health care services to patients through the use of technology [3]. Additionally, researchers, particularly qualitative researchers, have applied virtual data collection methods such as online surveys and virtual interviewing through video and telephone calls, emails, and SMS text messages [4]. These methods offer the benefits of synchronous or asynchronous communication [5]. The various approaches of

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virtual research have unique advantages and disadvantages for both researchers and participants.

Advantages of virtual research include cost and time efficiency, flexible scheduling, and more representative samples by reducing barriers to travel, enabling geographically dispersed and mobility-friendly participation [6-8]. Additionally, virtual methods often provide a higher degree of perceived and actual anonymity, which may encourage participation from vulnerable groups and facilitate the discussion of sensitive topics [5,6,8,9]. Consequently, studies show that virtual data collection methods can be as effective as traditional in-person approaches [10-17].

However, virtual research presents challenges such as technological barriers, lessened data familiarity, and shortened participant engagement. Researchers have limited control over participants' technological issues such as internet connectivity, device compatibility, and familiarity with technology [4,18]. Additionally, sampling bias may occur, favoring participants with better technological skills [18,19]. Advances in technology have led to the utilization of automatic transcription in videoconferencing software; however, this may lead to researchers becoming less familiar with their data compared with manual transcription [4]. Both participants and researchers may also be susceptible to "Zoom fatigue" or distractions at home, such as interruptions from children and pets, and on-screen notifications leading to reduced engagement [4,20].

Privacy and data integrity concerns represent critical challenges to both the participant and the researcher in virtual research, especially when using international technology platforms. Platforms such as Zoom (Zoom Communications, Inc) and Microsoft Teams (Microsoft Corporation) offer Health Insurance Portability and Accountability Act–compliant versions with encryption, but they are potentially vulnerable to data breaches, cyberattacks, and third-party data-handling practices [21-24]. In Canada, the regulatory landscape governing health data privacy in research is complex, characterized by overlapping federal and provincial privacy laws without harmonized national standards. While not a specific aim of this research paper, it is important to follow Canadian privacy legislation which requires safeguards proportionate to data sensitivity. International data sharing is permitted, but researchers remain accountable for protecting participant privacy which is relevant when using cloud-based platforms hosted outside Canada [25-28]. Researchers should also be aware of the potential of fraudulent participants, who may have ulterior motives for participating in research, and consider incorporating ways to minimize and detect fraudulent participation [29-34].

While several studies discuss potential challenges and offer recommendations for virtual research, these are mostly commentaries focusing on researchers' perspectives [5,35]. The lived experiences and challenges of participants, especially within specific demographic cohorts such as patients with chronic respiratory disease (CRD), are important. To address this gap and identify areas to improve participant experience and study quality, this paper explores the experiences of patient participants with CRD in a virtual research study using qualitative methods. It is part of a larger study validating a health literacy (HL) tool for patients with CRD through virtual or phone interviews [36]. The primary objective of this substudy was to understand the experiences of patients with CRD with virtual research methods participating in the HL measurement tool study.

Methods

Ethical Considerations

The study received approval from The University of British Columbia Office of Behavioral Research Ethics (H15-01954).

Participant Recruitment and Eligibility

Participants were recruited between August 2019 and June 2020. A research recruitment service was used where community patients were reached via random phone callouts in the Greater Vancouver Area. Patients were offered to receive a call back if they were interested in the study and met the eligibility criteria. Eligibility criteria included the following: (1) aged 19 years and older, (2) able to read and communicate in English, (3) physician-diagnosed asthma and/or chronic obstructive pulmonary disease, and (4) current use of a medication for asthma and/or chronic obstructive pulmonary disease.

Survey and Checklist Development

The study involved 2 stages: first, a 6-question open-ended survey (Multimedia Appendix 1) was developed to elicit participants' challenges and experiences in virtual research. The survey focused on communication and technological challenges from the perspectives of the participant and the interviewer and was developed through research team discussions, a thorough literature review, and consultation with observation notes (ONs). During the second stage, participant and interviewer responses to the open-ended survey and interview ONs informed the development of an 18-item checklist (Multimedia Appendix 1). The checklist covered preinterview challenges (eg, recruitment- and communication-related) and interview difficulties (eg, questionnaire-, communication-, and technology-related) for participants and interviewers. Both tools underwent pilot testing among a group of participants and revisions were integrated.

Interview Procedures and Data Collection

Participants provided written informed consent through a digital consent form. They selected an interview date and received a confirmation email with study details and the HL questionnaire. Participants used a computer, tablet, or smartphone to view the questionnaire and provided responses to questions to the research assistant over the phone. Participants with no compatible device received a physical copy of the ethics protocol and questionnaire via courier. Telephone interviews lasted 40 - 80 minutes. All participants were offered a CAD $30 (US $21) honorarium. After completing the questionnaire, participants were given the virtual research survey or checklist, with responses recorded verbatim. The research assistant took observational notes during the interviews for further data contextualization. All observational notes, interview recordings, and transcripts were deidentified and stored using password-protected files on institutional servers.

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Data Analysis

Initially, 3 members of the research team (NT, AM, and YSC) thoroughly reviewed the survey or checklist and corresponding ONs. While doing so, each team member independently created a list of challenges inductively. Meetings were then held to develop a coding guide in which conceptually similar codes were combined, infrequent codes were removed, and definitions were developed.

The coding guide was then piloted with 2 coders (NT and AM), who separately coded a random 15% of the data with equal distribution of survey or checklist and initial or retest interviews. The goal was to achieve 80% interrater agreement during the pilot, a benchmark accepted by many researchers [37]. After the initial trial of coding, the desired agreement level was not reached. The coding framework was subsequently revised by NT and AM by once again removing unnecessary items, clarifying definitions, and combining similar items. The coders then coded a new, random 15% of the data (with equal distribution of survey or checklist and initial or retest interviews) and achieved the desired interrater agreement (≥80%).

Each coder then coded half of the remaining 85% of data. Subsequently, codes were reviewed by YSC, who identified incorrect or missed codes. The team then resolved issues through discussion. Any disagreements between the coder (either NT or AM) and the reviewer (YSC) were resolved by the other coder. Both direct quotes (DQs) and ONs were coded. Following coding, thematic analysis [38] took place. The codes from the framework were discussed and synthesized into larger overarching themes. Constant feedback on the emerging themes was elicited from team members. Themes not explicitly relating to virtual challenges were removed.

Results

Overview

From June to October 2020, participants completed a virtual phone interview where they completed the questionnaire with a research assistant. Some of these were considered initial interviews, where the participant filled out the questionnaire for the first time (n=185) and completed a postinterview checklist (n=36) or survey on virtual research (n=149). To test the HL tool's reproducibility, 110 participants completed another interview, with the postinterview checklist (n=79) or survey (n=31), on their experience with virtual research challenges. Participants primarily identified as female (122/185, 65.95%), were older than 50 years (167/185, 90.27%), had asthma (108/185, 58.38%), and had a disease duration of less than 20 years (110/185, 59.46%). Additional participant characteristics can be found in Table 1.

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Table . Patient characteristics (N=185).

Characteristic	Initial interview (n=185)	Retest interview (n=110)
Form, n (%)		
Checklist	36 (19.46)	149 (80.54)
Survey	79 (71.82)	31 (28.18)
Self-reported sex, n (%)		
Female	122 (65.95)	63 (34.05)
Male	75 68.18)	35 (31.82)
Condition, n (%)		
Asthma	108 (58.38)	77 (41.62)
COPD[a]/ACO[b]	65 (59.09)	45 (40.91)
Age (years), range, n (%)		
<50	18 (9.73)	9 (8.18)
50-70	80 (43.24)	50 (45.45)
>70	87 (47.03)	51 (46.36)
Self-reported ethnicity, n (%)		
White	159 (85.95)	26 (14.05)
Non-White	92 (83.64)	18 (16.36)
Education level, n (%)		
High school diploma or less	55 (29.73)	130 (70.27)
Post high school diploma	29 (26.36)	81 (73.64)
Disease duration (years), n (%)		
<20	110 (59.46)	9 (53.64)
20-40	50 (27.03)	33 (30)
>40	24 (12.97)	17 (15.45)
Unreported	1 (0.54)	1 (0.91)
First language, n (%)		
English	160 (86.49)	25 (13.51)
Non-English	94 (85.45)	16 (14.55)
Received education for condition, n (%)		
No	47 (25.41)	28 (25.45)
Yes	137 (74.05)	81 (73.64)
Unreported	1 (0.54)	1 (0.91)
Primary education source, n (%)		
Family doctor	116 (62.70)	66 (60)
Multiple	8 (4.32)	3 (2.73)
Other	6 (3.24)	3 (2.73)
Pharmacist	3 (1.62)	2 (1.82)
Respiratory educator	5 (2.70)	3 (2.73)
Respirologist	47 (25.41)	33 (30)

[a]COPD: chronic obstructive pulmonary disease.

[b]ACO: asthma-COPD overlap.

The following sections describe the 6 overarching themes and 23 subthemes derived from analysis: theme 1: overall experience with virtual research, theme 2: clarity of instructions, theme 3: technology, theme 4: communication, theme 5: condition and

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cognition, and theme 6: logistics. Participants' direct quotes are indicated by "DQ" and researchers' observation notes with "ON." Identifiers for each participant, denoted by the letters "HL" and followed by a number, are used to anonymously identify which interviews the quotes or notes came from. Textbox 1 contains additional DQs and ONs from the 6 themes.

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Textbox 1. Participants' direct quotes and researchers' observation notes.

Theme 1: overall experience with virtual research

Positive overall telehealth experience

- Overall, he was satisfied with the questionnaire and thought that the questions are well made. "I had a very pleasant experience being interviewed today." [HL01, ON]
- She found the questionnaire interesting, learnt a few things, and [it] enabled her to think about certain things with some of the questions that she normally would not have. [HL68, ON]
- Thought [that the] interview went very well and didn't know what to expect. "I was able to provide information about me and was happy that I was able to participate and enjoyed being a part of the study. The study had a purpose." [HL101, DQ]
- "I think it was very worthwhile accumulating more data...health professionals are learning more and more and they're acquiring and making better results for patients." [HL101, DQ]
- He said that the interview was very helpful as he had never thought [about] where and from whom [to] find the health information. [HL109, ON]
- Participant expressed [a] good experience. She felt her participation made her more aware, to ask more questions about her asthma which is a good thing. [HL123, ON]
- At the end, she said: "I'm glad to participate in the study. It's helpful and I learned a lot." [HL162, ON]

Negative overall telehealth experience

- For the last section of the questionnaire, he refused to answer three questions because he thought they were vague and [weren't] worth answering. [HL21, ON]
- He mentioned that the questionnaire was very elementary and [at a] grade 6 or 7 level and complained that it was not helpful at all. [HL177, ON]

Wants to be updated

- At the end of the interview he stated that he would like to receive the results of this study. [HL24, ON]
- She also mentioned that if in the future we develop a tool with information for people with asthma and how to manage it she would like to receive it. [HL29, ON]
- He was happy about participating and contributing to the study and asked about the next steps. [HL45, ON]
- "I'm just wondering, is it possible to be notified of the study results after everything is complete?" [HL65, DQ]
- After completing the questionnaire, she asked what we will be doing with the data collected and said she would like to receive a copy of our paper after it is published. [HL85, ON]

Theme 2: clarity of instructions

Documents

- Clarity of instructions over the phone and email about the consent form and meeting receipt weren't really clear from the beginning. She mentioned how she was confused about it to me right when we first talked as the consent form that was sent was not interactive. [HL18, ON]
- "There are lots of emails and I'm confused." [HL178, DQ]

Email

- Wasn't obvious that there was an attachment of the questionnaire on the email. [HL47, ON]
- "You should send the emails individually [rather] than grouping them together"—he didn't appreciate the fact that there were three [e-form] emails sent in one setting. [He had to receive 3 [e-form] forms because he didn't sign the meeting receipt from the first interview and had another meeting receipt form and the consent form sent doing the retest interview]. [HL69, ON]

Interview

- She also mentioned that she was not aware that the better way to do the interview was on a computer rather than an iPhone. [HL37, ON]
- He also said he had looked over the questionnaire but didn't realize he needed to have it open in front of him. However, it only took a minute or two for him to find the email and open it. [HL179, ON]

Purpose

- Another comment he mentioned was that the literacy study that we are conducting is tricky because he doesn't know whether our objective of this study [is] to test the individual's capability to follow instructions or whether to test how much they know based [on] their own knowledge. [HL34, ON]
- "In [the] first interview, the purpose of the study was not clear, [and I even] received a call and e-mail from the study, but, I now have better understanding regarding the health literacy after the retest." [HL116, DQ]

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- When we got to the passages, she was wondering what the purpose of the passages were if they didn't apply to her [e.g., she didn't use inhalers]. [HL121, ON]
- "What is the purpose of the study? I don't get if the study is trying to understand how well people can understand material or how accurate the measurement tool is." [HL181, DQ]

Recruitment

- She wasn't sure if she was eligible initially. [HL96, ON]
- Yes, I had to communicate with her over email multiple times because she was unsure of [1] if she was eligible; and [2] when she had to sign the receipt form. [HL96, ON]

Theme 3: technology

Device and internet

- [The] receipt form could not be signed through [her] iPhone as it would not let her complete the signature portion, [so] she had to switch to her iPad to complete it. [HL20, ON]
- His computer didn't start. [HL23, ON]
- [The participant] viewed [the study documents] on [an] iPhone and had different things popping up [e.g., copy/highlight tool]. [HL62, ON]
- "Problems came from my computer. It was just downloading for a long time. Laptops can be slow at times." [HL65, DQ]
- Participant may have an older computer that couldn't open up all the graphics or text. [HL68, ON]
- His laptop has a scrolling issue so that was a bit frustrating for him at times. [HL139, ON]
- She needed to charge her computer in the middle of interview and said: "I got frustrated with my computer." [HL187, ON]
- "Just my issue with my internet." [HL104, DQ]
- "Why isn't it letting me open it?"—[the participant] had trouble opening the questionnaire due to [a] slow internet connection. [HL104, ON]

Knowledge

- He was an older gentleman and needed help using his computer and email to sign the forms and open and view the questionnaire. [HL01, ON]
- She scrolled past questions on the questionnaire occasionally but said that this was because she doesn't handle computers much and not because of the layout of the questionnaire. [HL15, ON]
- He had a woman who I assume was his caretaker to help him with the emails and technology-based aspects of this study, as he wouldn't have been able to work the computer on his own. [HL49, ON]
- She said: I am not a computer person and signing a document on the computer is hard for me. [HL105, ON]
- I prefer a paper in front of me rather than computer and [an] in person interview is more convenient. [HL105, ON]
- "I'm not very computer savvy so when there are many things coming up on my computer it throws me off." [HL157, DQ]
- "I am over seventy years old, this [working online] is foreign to me." [HL157, DQ]

Navigation

- [The participant] had trouble scrolling [and] would skip pages by accident. [HL05, ON]
- "I don't like scrolling through documents over email because I don't have a mouse and it hurts my hand to scroll after a while, so now my hand hurts." [HL12, DQ]
- She had trouble scrolling back and forth when doing the Air Quality passage questions: "I'm losing track because I keep going back and forth." [HL65, ON]
- Would get lost when scrolling back and forth through the Weather and Air Quality section; he would have to ask me to tell him what question he was on. This happened three times during the interview. [HL69, ON]
- The constant scrolling up and down with the passages and answering the questions were somewhat cumbersome since she was doing it on her phone. She lost the page on several occasions. [HL86, ON]
- [The participant] had trouble scrolling and lost her place in the questionnaire many times. [HL128, ON]
- She lost the pages frequently while looking back the passages and said: "I'm scrolling the wrong way." [HL134, ON]
- "Again, the scrolling back and forth was challenging. I lost track of which question I was answering several times having to go back and forth." [HL168, DQ]

Document opening

- The participant struggled quite a bit getting the documents open. [HL43, ON]

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- As the participant mentioned, she had trouble finding the email with the questionnaire attached and opening the attachments. [HL72, ON]
- "Bloody hell. Oh, Christmas tree! I just got rid of it! How did I do that?...What happened is, I touched something and I got rid...my thing went away. I have to open the document again." [HL138, DQ]
- The email logged her out, so she had to re-open the document 3 times during the interview. [HL138, ON]

Document retrieval

- She needed help finding the study email in her inbox and opening the PDF file. [HL16, ON]
- Once he filled out the consent form, he was initially confused about where to find the questionnaire, as he thought that it was also on [the e-consent form website]; however, after clarifying it was in his email he required the document to be resent to him. [HL39, ON]
- The participant lost the initial email from [the principal investigator] at some point, so I had to send her another one with the questionnaire attached. [HL118, ON]
- [The patient did] not initially notice the email containing the link [for] signing the consent form. [The] patient was only looking at the email [that the principal investigator] sent. [HL125, ON]
- She hadn't noticed [that] there was a questionnaire attached to her email. [HL150, ON]
- She asked me to wait until she could find the questionnaire. However, she called me back 24 minutes later. [HL186, ON]

Consent form

- The participant appeared to be slightly confused while carrying out the process of the e-signature; however, he was able to do it after further clarification. [HL01, ON]
- She had trouble signing and submitting the consent and meeting receipt forms because she wasn't familiar with the process. [HL16, ON]
- She could not easily tell if she had successfully completed the [e-signature] forms. [HL20, ON]
- [The patient had] trouble signing the form online using the signing technology, had never done it before. [HL31, ON]
- Struggled with the informed consent form and providing an e-signature as she was using an iPad—however, she was able to figure it out in the end. [HL35, ON]
- She also had difficulty filling out her e-signature on her iPhone and ultimately had to move to computer. [HL37, ON]
- "I had problem signing the form. It wouldn't take my signature, so I had to get my wife to do it for me." [HL62, DQ]
- We had a few technical difficulties with the consent form as it was harder for her to go through it and sign it. We had to go through the steps slowly, and after around 15 minutes, we finally signed both the documents. [HL162, ON]
- "I had problems with the actual signing of the paper. But that was the only technical glitch." [HL170, DQ]

Theme 4: communication

Contact

- Email following up the initial phone. [HL26, ON]
- "[I] sent an email back to [the principal investigator] but I didn't hear back but I did receive a few reminders to complete the [online consent form]." [HL114, DQ]
- "I did leave a message with [the principal investigator] about the witness but I didn't get a response and I figure I would clear it up with [the research assistant] when she called." [HL168, DQ]

Interruption

- "Just going to get the dog out of this room. He is a puppy and likes to come after me and bark"—before the interview began she had to make sure she wouldn't be distracted while doing the interview at home. [HL36, ON]
- He had to leave the interview for a second to talk to his family member. [HL69, ON]
- It was difficult to obtain his responses because there was a lot of static over the phone and we got disconnected a few times due to [the] phone running out of battery. [HL80, ON]
- Throughout the interview, the phone would cut out and I would not be able to hear some of her responses, so I had to repeat and clarify multiple times. [HL100, ON]
- [The participant]had to take a phone call in the middle of the interview. [HL124, ON]
- One of the handsets for the patient's home phone [ran out of power] near the end of the interview, requiring that I call back. [HL125, ON]
- In the middle of [the] interview she said: "I have to take something out of my oven and I'll be right back." [HL132, ON]
- "I only had one problem. It was just the attention stuff going on around me." She was referring to distractions, including her cat. [HL167, ON]

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- She had a phone call in the middle of the interview. [HL169, ON]
- The participant's dog was constantly barking in the background. She later had to leave the interview for about 10 seconds to take care of her dog. [HL170, ON]

Interview

- Could not hear the [participant] clearly during [the] initial call [as she] spoke very quickly. [HL04, ON]
- Her only issues were [the] quality of [the] call [couldn't always understand or hear]. [HL40, ON]
- He went to find his medications to read and he was difficult to hear because he put it on speaker phone and read them from where he was. [HL67, ON]
- When we first started to conduct the interview, the participant mentioned she was not able to hear me that well, so I switched to speaker phone and spoke a bit louder, and that seemed to solve the issue. [HL89, ON]
- She mentioned that there were parts where I've cut out and she couldn't hear me well. I told her to let me know if she's experiencing difficulties in hearing me, and I'll slow down and repeat what I've said. [HL172, ON]

Theme 5: condition and cognition

Anxiety or worries

- [The participant] was worried that he was taking too long to complete questions. [HL, 23, ON]
- She mentioned [that] she felt pressed for time and felt some pressure to read through the passage as quickly as possible. [HL35, ON]
- She did mention that she thought she would have answered better if she had been able to see the questionnaire before the phone interview, as seeing it for the first time while on the phone cause her some anxiety. [HL72, ON]
- She also commented she felt anxious on the mental process of having to read through each passage and having to provide a response. [HL73, ON]
- She mentioned that she felt pressure when having to respond over the phone to the research assistant. I assured her that she did a great job and there are no correct or incorrect answers. [HL110, ON]
- "Because you are inevitably required to read on one page and asked to answer questions on another page, it caused a little bit of mental distress." [HL181, DQ]

Font, format, and eyesight

- "I'm not sure what that number is...it looks like 15? But there is no 15!" [HL02, DQ]
- "Is that E5 I see? I cannot really tell." [HL02, DQ]
- "It was annoying because you guys have various fonts used in the document." [HL12, DQ]
- [Asthma Control Test] section—"Excruciatingly small print!" [HL21, ON]
- When [completing] the Hospital Map section: "[The] numbers are so small, it is almost unreadable!"—he was very dissatisfied with the font size. [HL21, ON]
- "I can't read the damn map!"—he complained about the small font size for the Hospital Map section. [HL47, ON]
- "I wish I could have both the question and the passage in the same page." [HL105, DQ]
- "Yes, it says don't print out the questionnaire which would [have] made it much easier for me if I had it in front of me...instead [of] having to scroll back and forth." [HL106, DQ]
- "I've got a cataract in one eye so it makes it difficult to see the hospital map." [HL111, DQ]
- "It would be better if the participants can see the passages and questions at the same time. People over 70 dealing with eye problems such as [a] cataract [may find it] difficult for them to scroll back and forward." [HL134, DQ]
- "For old people, you should make it big enough so that it could be read." [HL173, DQ]

Condition

- We were able to get through half of the questionnaire before she started to feel ill and we had to reschedule. [HL40, ON]
- The participant said she has a hearing aid which may have led to her not hearing some parts of the questionnaire. [HL98, ON]
- He indicated that he had difficulty [talking] loudly and for a long time. [HL139, ON]
- During the interview he frequently coughed and cleared his throat. [HL109, ON]
- She could not speak very well because of voice hoarseness and had to clear her throat every minute. [HL161, ON]
- She had her wrist broken and it was difficult for her to work on [a] computer with one hand. [HL161, ON]

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- During the interview, I could hear her wheezing sounds over the phone. [HL166, ON]

Theme 6: logistics

Confidentiality

- While filling out the e-signature document she questioned whether the website was secure in terms of getting hacked. [HL12, ON]
- He had some questions at the end about the anonymity of results which I had some trouble answering as I'm not completely knowledgeable of the whole process. However, I referred him to [the principal investigator] for more information. [HL28, ON]
- She also had a question as to whether the phone call was being recorded, but I told her it wasn't and that I was just recording on a computer the answers that she gave me to the questions. This seemed like a concern about privacy but my answer was OK with her. [HL99, ON]

Rescheduling and delays

- During the initial questionnaire interview call on Tuesday, the participant asked for a postponement to a later time in the same day. The second scheduled call was also unfruitful as she was still travelling back home. [HL40, ON]
- We were able to get through half of the questionnaire before she started to feel ill and we had to reschedule. [HL40, ON]
- She was unreachable for the first 17 minutes—she was walking her dog. [The] interview ended up starting 25 minutes late. [HL104, ON]
- Her cell phone was silent so the interview was delayed. [HL130, ON]
- She asked me to wait until she could find the questionnaire. However, she called me back 24 minutes later. [HL186, ON]

Team error

- There was a typo in the participant's email, and she had not received the documents initially so the documents had to be forwarded to her. [HL22, ON]
- She said that with the initial compensation, she did not receive the password, and was not able to access it. [HL22, ON]
- The wrong number was listed in the [study contact list], [so] I had to look for the corresponding number using the call ID system that we created. This led to the interview being conducted 30 minutes late. [HL24, ON]
- Due to my impatience and my computer lagging, I accidentally was sending the participant multiple emails from the e-signature website. [HL148, ON]

Theme 1: Overall Experience With Virtual Research

Participation was generally satisfying and meaningful to participants.

Overall Telehealth Experience

Most participants found their first experience with virtual research positive. They appreciated learning about relevant self-management topics through the questionnaire. This sentiment was captured by one individual who mentioned that it was both "educational and informative" [HL94, DQ].

Negative Overall Telehealth Experience

Few participants expressed dissatisfaction, with the main complaints surrounding the questionnaire, with one participant "[refusing] to answer three questions because he thought they were vague" [HL21, ON].

Wants to Be Updated

Participants took pride in contributing to research that might benefit others with similar health conditions and many expressed interest in learning the study's outcomes. One asked "Is it possible to be notified of the study results after everything is complete?" [HL65, DQ]

Theme 2: Clarity of Instructions

Instructions regarding the study's requirements, delivered via email and phone, were sometimes a source of confusion.

Documents

For some participants, confusion arose from understanding which documents required signatures and the process of phone-based questionnaires. One asked "which [form] should be signed" [HL147, ON]. Additionally, some were unsure whether signed copies they received needed further action.

Email

Some participants struggled to discern the importance of the various emails they received. One participant thought that the content and documentation were excessive but assumed "it's all necessary" [HL156, DQ].

Interview

Participants were occasionally caught off guard by the nature of the interview, especially those unfamiliar with the field of HL. One was confused over the method of data collection: "I thought I could fill out the questionnaire instead of verbally telling you my answers over the phone" [HL185, DQ]. The need for very clear expectations was expressed.

Purpose

Some participants questioned the purpose of the study and the tasks they were asked to perform, discussing the need for clarification and reiteration. One commented: "In [the] first interview, the purpose of the study was not clear" [HL116, DQ].

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Recruitment

Despite eligibility screening during recruitment, some participants still had questions about their eligibility at the interview stage. For one participant, the research assistant noted: "although her doctor diagnosed her with COPD, she doesn't have any symptoms and asked if she is still eligible to be part of this study" [HL175, ON].

Theme 3: Technology

Virtual study conduction necessitated technological engagement, leading to several challenges.

Device and Internet

Participants sometimes grappled with device-related challenges. Issues included tablet or phone incompatibilities with document formats, unexpected system behaviors (eg, start-ups or restarts and low battery), and distractions from app notifications. For instance, one participant's phone screen could not adequately display the full document: "the screen wasn't big enough to have the full [file] format because I was opening the document from my cell phone" [HL62, DQ]. Poor internet signal caused difficulties in accessing documents and signing online forms.

Knowledge

For many, unfamiliarity with technology caused challenges opening documents, adjusting view settings, and signing digital forms. There was a preference among some for in-person interviews or alternatives such as Zoom: "It would have been easier if it was face-to-face or in-person...maybe even by Zoom" [HL157, DQ].

Navigation

Scrolling through the digital questionnaire was troublesome for some. In the digital format, participants often had to scroll to reference material to answer questions, leading to disorientation in the document. One lamented the constant movement or scrolling, feeling like they were going "up and down like a yo-yo" [HL16, ON].

Document Opening

A minority of participants encountered difficulties in opening study documents due to the absence of instructions on how to access PDF or Microsoft Word attachments within emails. For instance, a participant mentioned that they, "had trouble getting the questionnaire to open at first as an attachment to the email" [HL50, ON].

Document Retrieval

Some participants had difficulty retrieving study documents from emails misrouted to the "junk" folder or lost in their inbox. For example, "the emails had initially gone to her junk mail so there was a bit of difficulty on finding the documents" [HL37, ON].

Consent Form

Participants experienced various issues with the online consent form. Some reported that the provided link was nonfunctional: "the link to the consent form...did not work" [HL05, ON]. Mobile and tablet users faced navigation and compatibility issues, and the signature process was cumbersome for many, with one describing it as "doing etch-a-sketch with the mouse" [HL61, ON]. A frequent concern was the lack of submission confirmation, leading participants to often seek verification from the research assistant.

Theme 4: Communication

Communication issues occurred between research staff and participants throughout the research process. These challenges are categorized as challenges with contacting the research team, interruptions during the interview, and other challenges.

Contact

On rare occasions, participants had trouble communicating with the research team postrecruitment and prequestionnaire or interview, which made scheduling difficult. One reported that they "didn't know how to get a hold of [the research team] after [the] initial call" [HL26, ON].

Interruption

Telephone interviews, conducted at a location of participants' convenience, led to interruptions from external sources, such as pets, family members, other calls, and phone connection issues. A notable instance was when a participant asked the researcher to hold the call for 6 minutes while answering another [HL08, ON].

Interview

Phone interviews sometimes had communication hitches from poor call quality, background disturbances, or participants' swift responses. One research assistant reported: "[the] participant was reading out answers very quickly, I had to slow [them] down to keep up" [HL103, ON].

Theme 5: Condition and Cognition

Some participants had health and/or cognitive conditions that caused difficulties during the research study.

Anxiety or Worries

Despite no set time limit, some participants indicated that they felt pressure to answer swiftly, as evidenced by one individual who felt the strain of "analyzing the passage while on the spot" [HL110, ON]. Another cause of stress for participants was feeling as though they were being assessed.

Font and Formatting (Eyesight)

Several participants found the font size in the questionnaire too small and often attributed this to their poor eyesight, as one mentioned: "numbers are too small" [HL16, ON].

Condition (Noneyesight)

Some participants had hearing difficulties which complicated the phone interview, while others had breathing issues due to their respiratory conditions. In the case of one participant, "[they] coughed a lot and asked for [a] 10-minute break in the middle of the interview and took [their] inhaler" [HL 154, ON].

Theme 6: Logistics

There were also logistical and planning challenges that arose throughout the study.

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Confidentiality

A few participants raised concerns about confidentiality, particularly regarding their initial contact (random callouts) and potential data sharing with third parties. Some individuals were also initially concerned with how their personal information might be used and how or where their information would be stored. One participant thought that "some of these studies share info with insurance and pharmaceutical companies [as] every year his list of allowed or covered medications [had] gone down" [HL138, ON].

Rescheduling and Delays

Interviews often faced rescheduling due to participants being unprepared, forgetful, falling ill, or having other commitments.

Team Error

Errors from the research team, although infrequent, did arise. Examples include incorrect email entries and honorarium transfer discrepancies, which were promptly addressed.

Discussion

Principal Findings

Our findings illustrate the experiences and challenges faced by participants in a virtual research study validating an online HL tool. Six themes emerged, showing that participants generally reported a positive experience but faced challenges with technology, mental fatigue, and data confidentiality concerns. Communication issues, such as distractions and unclear instructions, were also noted.

The virtual nature of this study allowed participants to engage at a convenient time and location, eliminating travel-related time and cost burdens. Individuals whose health limited their ability to attend in-person sessions were also able to participate, enhancing the diversity of the sample. These 2 advantages align with literature supporting virtual research as more cost-effective and time-efficient, allowing for broader geographical reach and greater sample diversity [4-6,8]. However, later we discuss how factors such as participant response times may not always make virtual research more time- and cost-effective than in-person research.

A common concern with virtual methods is the exclusion of individuals with lower technological skill, particularly older adults [39,40]. In this study, most participants were aged 50 years or older, with 43% (80/185) being aged 50 - 70 years and 47% (87/185) being older than 70 years. Additionally, internet use among older adults in British Columbia is high, with 88% of adults aged 45-64 years and 56% of adults aged 65 years and older using the internet [41]. Despite high rates of internet use, the digital divide persists among older adults, particularly those with lower socioeconomic status, limited education, and rural residences [42-44]. Even for older adults with internet access, disparities exist in the breadth and depth of digital engagement, with many lacking the skills to perform health-related tasks such as accessing patient portals, booking appointments, or participating in telehealth [43-45]. Barriers extend beyond access to include physical and cognitive impairments, privacy concerns, lack of social support, and preference for face-to-face interactions [46-49]. Without interventions such as digital literacy training or infrastructure improvements, virtual methods can risk exacerbating health disparities by excluding older adults with the greatest health needs and fewest resources [44,50,51].

Challenges arose with communication about study expectations. Despite regular contact through email and phone, participants occasionally felt unclear about the study's objectives, the data collection process, and documents requiring their signature before receiving further clarification. This highlights the need for clear, concise instructions and avoidance of overburdening participants, while also ensuring opportunities to ask questions. Research teams should create detailed and user-friendly instructional materials and provide multiple avenues for participants to seek clarification. These recommendations also apply to in-person research, where recruitment and interview coordination often also occur online [4].

Participation in virtual studies requires technology and internet access. In this study, participants used various devices including laptops, tablets, and smartphones. While this allowed a wide range of individuals to participate, technological skills varied, leading to challenges such as difficulty opening attachments, navigating documents, and phone users struggling to display documents in full. The research assistants supported these participants by asking them to explain the issue they were experiencing in their own words and then providing tangible steps at their technology literacy level. This contributed to varied amounts of time spent with each participant. Thus, virtual research may not always be more cost-effective or time-efficient than in-person research and depends on the individual participant [52]. Some virtual studies have reported additional time spent supporting participants with technology and higher participant cancellation and no-show rates [53]. This was also observed in our study as participants sometimes had to reschedule interviews due to being unprepared, forgetting, falling sick, or having multiple commitments at the same time. While rescheduling may happen more often in virtual studies, it can be seen as an advantage as the virtual environment allows for more flexible rescheduling instead of participant dropouts [4,7].

Throughout the study, communication issues were encountered. Since virtual studies can be conducted from any location, there were interruptions from external sources such as family members, pets, other calls, and connection issues. These interruptions can be detrimental to the quality of data collected, as distractions can lead to less contextually rich information provided, and poor call quality can result in missing information. Additionally, some participants also experienced mental fatigue and difficulty focusing, further contributing to decreased data quality [20]. These challenges are common in virtual research [5,18,52,54]. To avoid this, researchers can proactively ask participants to prepare a quiet environment to minimize distractions, ensure that questionnaires and interviews are not too lengthy, take breaks when necessary, and offer adequate incentives to maintain participant engagement.

This study generated several practical lessons for future virtual research design. In summary, participants benefited from simplified and consolidated communication. Sending fewer emails with clearly labeled attachments and step-by-step

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instructions can help reduce confusion. Electronic consent procedures should also be optimized for mobile devices and include confirmation messages indicating successful submission. Document design should minimize scrolling demands and allow participants to view passages and questions simultaneously where possible, particularly for older adults or those with visual impairments. Researchers should anticipate varying levels of digital literacy and allocate sufficient time for individualized technical support. Finally, participants should be encouraged to prepare a quiet environment and be informed in advance about interview expectations, duration, and required materials to minimize interruptions and anxiety during participation.

Documenting patient experiences in virtual research is fundamental to participatory medicine and patient-centered research. Participatory medicine is guided by the phrase "nothing about me without me" and incorporates patient perspectives at every step of the research process, from question selection and study design through data collection, analysis, and dissemination [55-58]. Participants in this study emphasized the importance of clear communication, opportunities for clarification, technical support, and understanding the purpose of research. Many participants also expressed a desire to receive study findings and remain informed about how their contributions would be used. These observations reinforce the principle that participants should be treated as active partners in research. By capturing the lived experiences of patients with CRD with virtual research methods, this study contributes practical insights for designing patient-centered research.

Strengths and Limitations

This study has several strengths. The virtual nature allowed for broader participation, likely leading to a more representative sample. Furthermore, the data analysis used investigator triangulation to maintain consistency between coders. However, limitations were identified, including potential sampling bias by excluding participants without access to reliable technology. To mitigate this, we mailed surveys to a couple of participants who requested it. Furthermore, inconsistent time was spent with each participant due to the varied technological skill level. However, this variety meant that perspectives were being collected from a diverse set of participants and did not favor participants with better technological skill. Future research should focus on comparing synchronous and asynchronous methods and explore participant engagement strategies. Additionally, addressing ethical considerations will help optimize the effectiveness of virtual research.

In conclusion, this study identified the experiences and challenges of patients with CRD with virtual research. Participants generally reported a positive experience and expressed satisfaction to participate in research that may benefit individuals with similar medical conditions. Challenges mainly encompassed technological barriers, the need for clear and concise instructions, mental fatigue, and concerns about data confidentiality. These findings emphasize the importance of providing comprehensive technical support, clear and concise instructions, and assurance of secure data storage methods to ensure effective, ethical, and inclusive virtual research. With these considerations, virtual research can remain a viable and valuable method, even among older adults. Future research should focus on enhancing participant engagement and improving digital technology accessibility post COVID-19 pandemic.

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Data Availability

The datasets generated or analyzed during this study are not publicly available in accordance with our institution's ethics policy. To maintain participant confidentiality, we cannot publicly share transcripts as there is a risk of identification. Data are available from the corresponding author on reasonable request.

Authors' Contributions

NT, AM, and YSC participated in writing – original draft. AD, BP, MM, JB, and IP participated in writing – review & editing.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Sample survey and checklist.
[DOCX File, 26 KB - jopm_v18i1e80216_app1.docx]

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Abbreviations:

CRD: chronic respiratory disease
DQ: direct quote
HL: health literacy
ON: observer note

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Understanding Recovery Colleges Through Partaker Narratives: Qualitative Diary-Interview Study

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Abstract

Background: Recovery colleges (RCs) facilitate peer-supported learning communities where people experiencing mental disruption work on recovery. How recovery processes unfold, especially within RCs, remains insufficiently understood.

Objective: Using a narrative approach, this study scrutinized how recovery processes unfold for RC partakers within RCs and in their everyday lives, and what RC attendance means in those processes.

Methods: This study's design, recruitment, data collection, analysis, and manuscript drafting were co-created with experiential researchers (ie, RC partakers). Following an interview study (N=26), a diary-interview study was conducted (N=5) between November 2022 and January 2023. RC partakers completed qualitative diaries for 1 or 2 months, every other day, and reflected on this diary period in an evaluative interview (conducted by an academic and an experiential researcher). Recovery narratives of 3 diary participants (Emma, Robin, and Norah) are presented.

Results: For Emma, peer-to-peer contact within the RC helps rebuild a supportive social network and stimulates her to face her anxieties. Robin described how RC attendance offers new perspectives, invites her to trust her own judgments, and reconsider possibilities such as paid employment. Norah's narrative illustrates how RC partaking in various capacities supported a shift in her identity from feeling like a failure to seeing herself as a valuable contributor. Considering all narratives, a cross-case analysis foregrounded the value of experiential knowledge in the recovery processes of the RC partakers. Two mutually reinforcing learning processes were identified: learning by exchanging and learning by doing. It also became clear that the RC explicitly facilitated contexts in which these processes can unfold, as partakers experienced recognition, inspiration, hope, perspective, supportive structures, and social safety. Experiences stemmed from learning processes and acted as catalysts for further learning. Importantly, these processes were not linear: partakers also experienced challenges in their everyday lives and within the RC.

Conclusions: Our findings underscore the value of RCs in landscapes of mental care and support as they explicitly facilitate space for exchanging experiences among peers and experimenting with new behaviors. We illustrate the importance of investigating supportive processes and contexts to understand how recovery unfolds. We also present practical implications for RC offerings and participatory health initiatives more broadly.

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KEYWORDS

peer support; mental health challenges; experiential knowledge; mental health recovery; recovery education; recovery narratives

Introduction

Background

Recovery colleges (RCs) facilitate peer-supported learning communities where people experiencing mental vulnerabilities or disruption (ie, peers) engage in their recovery process [1,2]. Recovery processes are considered "black boxes" [3], and how they unfold remains insufficiently understood. Based on a narrative approach, this study scrutinized how recovery processes of RC partakers unfold, with a specific focus on the meaning of RC attendance within their everyday lives.

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Defining Recovery as Situated, Relational Learning Processes

Defining recovery requires considering what it means to experience mental disruption (irrespective of formal diagnoses). This does not only involve intrinsic distress or "symptoms" but also stigmatizing and marginalizing interactions with individuals, organizations, communities, and systems [4,5]. Within such complex experiences, people often encounter feelings of powerlessness, hopelessness, and loss of identity and self-confidence. As Wilma Boevink described [6]:

> *During my psychiatric career I got reduced to different diagnoses and became detached from my original experiences. My symptoms and the context in which they developed lost their meaningful connection. [...]. I had experiences I did not understand, which made me feel powerless.*

First-person accounts as such fueled a redefinition of recovery [7,8], moving beyond a focus on symptom reduction [9,10]. As such, recovery is defined as the personal learning processes of (re)developing identity, agency, and meaning in life [11,12]. Over the years, academics attempted to conceptualize recovery in frameworks, paradigms, and models [13-16]. Among them is the CHIME (connectedness, hope, identity, meaningfulness, and empowerment) framework [14], describing 5 recovery processes (ie, connectedness, hope, identity, meaningfulness, and empowerment).

Many conceptualizations of recovery have an intrapsychic focus, suggesting that recovery as a transformational process takes place within the individual, as a transformation of "the self." Though, several scholars have made philosophically and empirically grounded propositions that such transformation is not merely personal or individual, but relational [17-20], as individuals are not "in relationships" but "relational beings" [21]. In terms of recovery, experiences of empowerment, hope, and identity largely exist by virtue of interactions between individuals and their relations and situated (social) contexts [22,23].

RCs as Recovery-Supportive Learning Contexts

RCs aspire to facilitate contexts that support recovery by approaching it from an educational rather than a clinical perspective [2,24]. In that line, learning theories offer a useful lens to understand how RC contexts can facilitate a space for recovery processes to unfold [25]. Across diverse learning traditions, 3 recurring principles are particularly relevant. Learning is proposed to be (1) inherently situated and relational, (2) a transformative process through experience, and (3) driven by learners' agency, through which learners shape their own learning trajectories (eg, [26-28]). Considering this, principles of learning and the characterization of recovery processes seem to overlap, which RCs explicitly bring into practice.

First, RCs facilitate peer-supported learning communities, foregrounding the relational and situated nature of recovery. Knowledge hierarchies and epistemic inequalities are actively dismantled [29], and instead an "ethic of dialogue" prevails [25]. Within RCs, collaborative learning takes place through the exchange of experiences among peers, where all input is equally valued. In peer interactions, individuals can learn from role models (in which they recognize themselves) enacting hopeful, inspiring behaviors [30] and give meaning to their experiences through comparison with others [31]. Like that, peers can be "authors of alternative identities," countering self-stigmatization and increasing confidence in positive change [32].

Second, RCs support transformative learning processes. Within RCs, there are opportunities to reflect on lived experiences, explore alternative narratives, and experiment with new roles and behaviors [33]. This especially foregrounds in how RCs (and their offerings) are organized. Namely, RC practices are collaboratively shaped by all partakers [2,34] and can therefore be considered communities of practice [26]: peer communities where everyone contributes through their personal experiences.

Third, RCs emphasize the empowerment and agency of partakers, inviting them to acknowledge their expertise in their own recovery process. The diversity of RC activities and roles, combined with the absence of predefined pathways, enables partakers to acquire knowledge and skills that they personally value. Namely, partakers can shape their involvement in ways that are meaningful to them [33]. By allowing partakers to actively determine how they engage, RCs seek to redefine power dynamics, transforming peers from "passive patients" to "active co-creators" in their recovery [35,36].

Understanding "How"

Literature suggests that RCs can successfully foster recovery, with positive effects reported for, for example, experienced empowerment, social support, and societal participation [37,38]. Scholars have also identified mechanisms of change or action that can explain these outcomes. Proposed mechanisms of change within RCs are facilitating empowering and judgment-free environments, fostering supportive relationships, promoting personal growth through collaborative learning, and redistributing power through reciprocity, co-creation, and role modeling [1,25,39-41].

While existing work provides important insights into "why" RCs can foster recovery, they offer more limited understanding of "how" such processes unfold in practice, across contexts, and over time. Especially the interplay between RC experiences and broader everyday contexts remains underexplored. Addressing this gap requires a process-oriented approach that attends to partakers' experiences within the RC in relation to their everyday lives, including their social networks, living conditions, use of care and support services, and engagement in meaningful activities. Therefore, using a narrative approach, this study explores recovery processes of RC partakers within and beyond the RC and the role of RC attendance in how these processes unfold.

Methods

Design

This diary-interview study was part of a large mixed-methods, co-created investigation of the meaning and effectiveness of RCs [42]. The study was carried out by collaborative teams of academic and experiential researchers (ie, RC partakers), who

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were substantially involved across all stages of the research process, including study design, data collection, analysis, and dissemination of results [43,44]. Centralizing co-creation and experiential knowledge in our research aligned with RCs' philosophy and contributed to improved research quality [45-47]. While similar approaches have been described in the literature as co-production (eg, [43]), our approach is best characterized as participatory research [44], given the challenges of realizing full shared decision-making and ownership within the context of an academic dissertation.

An analysis of participatory observations, internal documents, and interviews has been reported elsewhere [33]. This diary-interview study was a follow-up to the "initial interviews." It combines synthesized, dialogical reflections from interviews with diary entries written in close temporal proximity to actual events. In this way, we captured both interpretations constructed in co-creation (between researcher and participant, in the interviews) and individually (by the participant, in their diary [48-50]).

Recruitment and Participants

Interviewees from the initial interviews [33] were invited to participate in the follow-up diary-interview study during debriefing. They received a flyer with more information about the study's goals and procedures and took time to consider their willingness to participate. Five participants were enrolled (mean age 49, SD 9.5 years, all identified as women), of whom 3 narratives are presented (Emma, Robin, and Norah).

Setting

The study was conducted at Enik Recovery College (ie, Enik RC or Enik in short), a Dutch RC in the region of Utrecht, hosting 7 locations. Enik RC was established in 2015 and is nationally recognized as a leading example. A 100% peer-run philosophy is central: Enik RC is co-created by and for peers. Enik RC offers an elaborate self-help recovery curriculum, including established courses such as the Wellness Recovery Action Planning (WRAP [51]) and Honest, Open, Proud (HOP [52]), and co-created activities and workgroups. There are also social meeting points for peer-to-peer contact and volunteering opportunities. In light of these RC offerings, we use "RC partaker" as an overall term to indicate individuals active at the RC (in any capacity) with further specifications as RC students (attendants of workshops or activities), visitors (of the social meeting point), volunteers, and peer workers (RC employees). RC attendance is free of charge, and there are no diagnostic criteria or formal referrals. In 2024, Enik RC offered 700 curricular activities and welcomed 1300 unique students, 50 employees, and 200 volunteers [53].

Materials

Diary themes were established in co-creation with experiential researchers. Initially, academic researchers envisioned an experience sampling method study, so in a co-design session, validated questionnaires such as the Netherlands Empowerment List [54], Mental Health Inventory-5 [55], and the Maastricht Quality of Life Scale [56] were consulted as inspiration. However, discussions within the experiential research team revealed that a qualitative, less frequent diary approach would better capture context-dependent meaning of recovery-related events and align more closely with participants' needs. One experiential researcher, for example, shared how being asked 5 times per day, "How do you feel now?" would be very stressful, and another experiential researcher shared how they were overwhelmed by questionnaires in health care already.

Inspired by questionnaire items (eg, "I am not afraid to rely on myself" and "I do the things that I think are important" from the Netherlands Empowerment List) and personal experiences of experiential researchers, five diary themes were defined: (1) meaning and fulfillment, (2) social support, (3) recognition and acknowledgment, (4) self-image and confidence, and (5) empowerment. For each diary theme, participants answered a dichotomous question (eg, "Were you able to do things you found important during the past 24 h?" for meaning and fulfillment, with answer options "predominantly yes" vs "predominantly no"). Then they provided qualitative reflections on the theme and on whether (not) attending the RC impacted their entries.

While the diary-interview study was the dominant data source, the initial interviews of Emma, Robin, and Norah were also reanalyzed as they provided more context for their recovery stories. These interviews were semistructured and focused on first encounters with the RC, experienced RC dynamics, and experienced impacts on recovery [33].

Procedure

The diary interview study was conducted from November 2022 to January 2023, including a start-up session, the diary period, and an evaluative interview. All start-up sessions (not analyzed) took place at the RC and served as design sessions during which participants selected predefined themes to be included in their diaries. All participants decided to include all themes.

The diary period lasted 1 month, with an option to extend it by another month (which Emma and Norah did). Diaries were distributed every other day via Qualtrics (compliance rates: Emma=48%, 15/31; Robin=81%, 13/16; and Norah=68%, 21/31). During the diary period, participants could log into a personalized RShiny dashboard displaying the number of diaries received (top left, green) and completed (top right, orange), graphs per diary theme (displaying frequency of "predominantly yes"; orange bar=days of RC attendance and green bar=days of nonattendance), and explanatory text balloons (Figure 1).

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Figure 1. Example of a personalized Shiny dashboard.



Aligned with the initial interviews, the evaluative interviews were conducted by an academic and an experiential researcher, at the RC or the participant's home. Both interviewers had a shared and equivalent role in asking questions. While one interviewer typically opened the conversation, follow-up questions emerged naturally through the dialogue. During the evaluative interviews, participants logged into their dashboard and gave meaning to the graphs, discussing important events during the diary period. Interviewers systematically invited participants to relate salient patterns in the graphs to their lived experiences, for instance, by asking about typical days associated with higher or lower scores or how participants understood observed differences between RC and non-RC days. Qualitative diary entries were analyzed afterward and were not accessed prior to or during this evaluative interview.

Data Analysis

Data analysis was collaborative and co-created. To integrate the diverse perspectives, knowledge, and competencies of the research team [45,57], the analysis was open and flexible [33]. Theoretically, elements of narrative approaches and reflexive thematic analysis informed our analysis strategy. Narrative approaches explore the intertwinement of processes and their situated meaning in everyday life [58], considering not only content but also narrative form [59]. Furthermore, the diversity of perspectives and knowledge within the research group is acknowledged as a valuable source in interpretative and reflexive analysis [60,61]. Our collaborative analysis was iterative and combined deductive and inductive analytic strategies. The analytic team (4 experiential researchers and the first author) met in 6 co-analysis sessions.

In the first session, we sharpened our research question, developed an analytic plan, and divided the transcripts to familiarize ourselves with the data (the first author read all transcripts). We began with the evaluative interview data, expecting these to highlight the most prominent events and plot twists from the diary period. In the second session, we explored the evaluative interviews deductively using the predefined diary themes. For each theme, we explored temporal development, influencing factors (general and RC-specific), and their meaning within recovery processes. These factors were identified inductively and organized with colored sticky notes to establish a thematic framework. We then noted recurring and unique patterns across participants' accounts. In session 3, we attempted to compile composite narratives (inspired by Willis [62]) using the diaries, synthesizing themes and summarizing profiles across participants. Soon, we realized that such an approach risked oversimplifying and decontextualizing complex, unique recovery narratives [59].

To preserve the richness and situated meaning of participants' experiences, we therefore selected Emma, Robin, and Norah for in-depth analysis, focusing on how meaning unfolded within their lived contexts [58]. These cases were selected based on data richness and the diversity of their recovery processes and RC involvement (including the duration and nature of attendance). A shared narrative structure was developed to explore participants' recovery journeys, including contextual backgrounds, personal meanings of recovery, and experiences during the diary period, with particular attention to RC-specific processes unfolding. In preparation for sessions 4 and 5, we reread all data from the 3 selected participants with this structure in mind. The interviews provided overarching reflections, while the diaries offered more detailed insights into temporal development and concrete, everyday examples of recovery-related experiences. We also checked for discrepancies between diary entries and retrospective reflections, which did

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not occur. Sessions 4 and 5 served to inductively code important themes per participant. Based on this, the first author wrote concept narratives (including reflections) in Dutch and fine-tuned them within the research team and in correspondence with the participants. In a sixth session, we explored cross-case patterns across the 3 narratives and identified overarching processes that captured how interaction within Enik RC contributed to recovery. To achieve this, we examined how cross-case patterns related and interacted and explored whether patterns could be meaningfully organized using frameworks such as self-determination theory and CHIME. Through iterative comparison and reclustering, we ultimately identified 2 overarching processes that best captured the observed dynamics. This analysis was fine-tuned in collaboration during paper drafting and revision. Coauthors (academic and experiential researchers) provided feedback on paper drafts, which the first author incorporated.

Consensus within the co-analysis team was reached through iterative dialogues. The first author facilitated the process by guiding discussions, summarizing interpretations, and drafting analytical texts between sessions. To support a diversity of perspectives during co-analysis, we intentionally had an experiential researcher take notes on the flip-over during our sessions, and we routinely brought preliminary interpretations back to the group for critical reflection and refinement. While consensus was typically achieved in these dialogues, final responsibility for analytic decisions formally rested with the first author.

Ethical Considerations

Experiential researchers emphasized ownership of data collection and analysis by (1) inviting participants to partly shape their diaries, (2) scheduling evaluative interviews to jointly interpret diary scores, and (3) developing a personalized dashboard that participants could bring to these interviews as input.

All participants provided written informed consent. For member checks, Emma, Robin, and Norah were contacted via email. They were invited to read a first concept of their narratives and provided additional comments. Names and contextual details (eg, family relations) have been altered in collaboration with the participants to achieve the desired level of anonymity [63,64]. Participants indicated to what extent they wanted to disguise their identity and which details they considered identifiable. Requested revisions were made by the first author based on participants' input and subsequently returned for confirmation prior to publication. Ethical approval was granted by the Ethical Review Board of Tilburg University (TSB_RP390).

Reflexivity

The work was part of the first author's PhD dissertation, who also had lived experience with recovery. Furthermore, academic researchers with scientific knowledge of recovery and mental health, and experiential researchers, who were RC partakers, collaborated (see a study by van Wezel et al [33] for details on their backgrounds). Within the analysis, several layers were intertwined: (1) participants' analytical reflections on their diary period from the evaluative interviews, (2) researchers' analytical reflections (shaped by their own experiences), and (3) theoretical frameworks and predefined themes. Throughout the analysis, we critically reflected on where insights stemmed from.

We also reflected on how varying degrees of contextual access shaped the analysis. Some analysts only had access to written transcripts, while others had conducted interviews, and in Emma's case, even visited her home. This provided additional insights into narrative form and context that might be unavailable in written text. To address this, interviewers shared their observations about tone and setting, ensuring that such contextual nuances informed the interpretation [59].

Moreover, the co-research team stemming from the same community as the research participants prompted critical reflections regarding internal confidentiality [64]. While names were omitted from the data, original contextual details were retained during analysis. Experiential researchers sometimes believed they identified participants, potentially introducing assumptions based on prior knowledge. In reflexive dialogues, we discussed whether our interpretations were grounded in the data or influenced by personal assumptions. We also considered how speculating about participants' identities—often an attempt to enrich our understanding—carried analytic risks, as it may lead to unfounded conclusions.

Results

Overview

This section first provides the narratives of 3 RC partakers: Emma, Robin, and Norah (descriptives in Table 1). The narratives provide insights into what recovery means to them and how their recovery processes unfold within everyday life and the RC. Notably, all narratives stem from participants with sustained engagement in the RC, and they predominantly emphasize experiences of growth. As an analytic structure, each narrative concludes with a short reflection, highlighting which processes are most prominent and how the RC plays a role in them. Finally, a cross-case analysis is presented, synthesizing insights from the narratives and identifying common threads.

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Table . Descriptive information of Emma, Robin, and Norah.

Pseudonym	Age category (years)	Gender	RC[a] partaker roles	Duration of RC involvement (prestudy; years)
Emma	50 - 59	Female	RC student, visitor, volunteer	3 - 4
Robin	40 - 49	Female	RC student, visitor	1 - 2
Norah	50 - 59	Female	RC peer worker (former volunteer, student, visitor)	≥4

[a]RC: recovery college.

Emma: Redefining Social Contact

Emma first contacted us by email, responding to the recruitment for our survey study. Her email was critical. She warned of selection bias, reaching only those who benefit from the RC, as those who do not tend to drop out. We invited her to discuss this further and pointed at the interviews. She wanted to participate. We met Emma for the first time at her apartment, just outside Utrecht. Due to physical impairments she experienced at that time, she was unable to travel to the RC. After this initial interview, Emma decided to participate in the diary-interview study. We concluded the 2-month diary period with a second interview at her home. Recalling the diary period, Emma remarked that she often forgot to complete diaries when she felt unwell:

> *Then I'm really stuck in my head and stressed out, or anxious. I don't really have room for anything else anymore. I get so caught up in my thoughts and I don't even think about it [completing the diary, red.].*

We decided to keep this in mind when analyzing her dashboard.

In our initial interview, Emma shared that social contact induces a lot of tension. In the past, she had been bullied, and she had experienced an unsafe childhood. Paralyzing anxiety and depressive feelings regularly took hold of her, and her self-confidence was low. Besides, she did not have a supportive social network for quite some time:

> *I moved here a few years ago and I had nothing. And it was really difficult to meet people, also because I am not easily comfortable, especially in the past. [...] I always feel like an odd one out and that I have to prove myself more. That I can't truly be myself. And that they disapprove that I have welfare benefits and do not work.*

She wanted to make a difference for others and had tried volunteering at several places, but "that just didn't work." For Emma, mentalization-based treatment therapy was the start of a learning process to reevaluate social contact:

> *That is where the roots are. You learn that people think of you differently from what you think. Because honestly, I felt utterly rejected by everyone, and I started checking that. Often, it simply turned out to be incorrect.*

She became active at the RC as a hostess, which helped her to overcome years of loneliness and build a supportive social network:

> *For a long time I just sat at home, hidden from everything and everyone. [...] I met my best friends there [at the RC, red.].*

Contrary to her earlier beliefs, Emma now finds that social contact, if with the right people, brings her energy and happiness. As she wrote in her diary:

> *I told my partner: I feel happy. I have a home, two bunnies, a partner, three friends, and Enik !! Because of Enik I more and more experience that I like to be surrounded by people. Something that I didn't have before. Then, I was really lonely.*

In her expanding social network, she finds support, both emotionally and practically. For example, when she experienced internet problems, which she found stressful, she wrote in her diary:

> *All kinds of calamities come to mind. I can't defend myself against them. Terrifying.*

She talks about it with her friends, her support worker, and therapist, and 1 day later, she writes:

> *I need assurance, putting things into perspective, and practical advice. And I receive that. So happy with my circle!!! [...] My anxieties about everything that could go wrong took hold of me. But I reached out about it to my environment. It is scary. But there is support.*

Besides volunteering at the social meeting point, Emma takes part in courses and activities at the RC. Soon she developed ideas for new activities, which she put into practice and facilitated. She also facilitated other existing courses. She considers the RC as a safe haven she can always return to, to practice what she learns in therapy and services for mental health support.

All in all, Emma feels she has grown in showing her true self. She shared in our initial interview:

> *I have become much more visible [...]. When I enter, I am here. I am not a grey little mouse that sneaks in and says nothing. In the past, I did not have a conversation [...]. Now, I say a lot.*

During the diary period, Emma practiced further with self-expression. She wrote:

> *I went to Enik and attended a workgroup. I felt very bad about myself there, because I talked myself down and felt that I couldn't make anything of it. At the end I said I didn't like it at all for that reason. And then*

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> *I received some nice reactions from those who facilitated it. I felt sad, but that was OK. After that, I talked to the JijenIk'er [hostess, red.] in the social meeting point. It was very nice to find so much recognition with each other. I left with a smile on my face. That was seen by [peer worker] who said something about it, and I liked that a lot, that I was seen.*

A week later she wrote:

> *I went to the workgroup at Enik. I was really dreading it because I was so severely critical of my own writing. But it was very good that I went because the theme was "being allowed to make mistakes". And I also just discussed that with [mental healthcare provider] that morning. Because I expressed my uncertainties last time, a connection and safety for me emerged in the group, and because of that, others expressed uncertainties too. So it was very nice to practice in a safe environment. [...] And I dared to read my writing aloud after all. [...] The more I open up, the more I receive in the form of feeling seen, that I am taken into account, that people appreciate me... That is a really nice feeling, and it makes me more proactive.*

However, when Emma experienced stress due to her internet problems, she experienced crossing her boundaries when sharing something in the workgroup. While she was happy she self-expressed a few weeks before, she now wrote:

> *Despite that I wanted to leave, I stayed. [...] Read my pieces where I made myself far too vulnerable in front of a group where I did not feel safe.*

Emma not only practices within the RC but also in other contexts. She shared in the evaluative interview how she used to experience complicated interactions with a street vendor:

> *There is always a street vendor, and he always looked at me very angry, and did not say anything when I greeted him. Every time I felt so miserable about that. While it is someone I don't know at all, [...] but the theme of "rejection" surfaced. And then I discussed this in the workgroup and the conclusion was: "Go there and ask him: Are you angry with me?" [...] Eventually, I went to the man, and I asked whether we could have a chat. And then we cleared the air, and now we greet each other friendly. So, I would have never done that without the workgroup!*

In this situation, Emma faced her social anxiety and experienced success in that. Emma explained how the workgroup's facilitator played a crucial role in this and concluded how he served as an inspirational example:

> *If my partner had said, "Go and have a chat with that vendor", I am not sure whether I'd have done it. [...] If he [the facilitator] says something, I take that very seriously. [...] I find him a very socially intelligent man. He also says we are very similar in the things we struggle with. But he is more advanced in it.*

Due to her autism diagnosis she received a few years ago, and the support that came with it, Emma continues to learn what she needs:

> *Through the discovery of that autism, I suddenly realized, "I have to take good care of myself. How do I do that?"*

Conversations with her psychologist are helpful, as she wrote in her diary:

> *Because there I can have good, supportive, insightful conversations !!*

From this connection with herself and insights into what she needs, Emma increasingly practices setting boundaries. She experiences the RC as a place that stimulates this. Once, she walked away from a conversation in the social meeting point because someone was very hyperactive, and she wanted to avoid becoming overstimulated:

> ***Interviewer:*** *How was that for you, to take that step and stand behind the bar?*
>
> ***Emma:*** *It felt really good. At Enik, you learn much more to stand up for yourself anyway, to say it when you don't like something, and that is, in fact, rewarded. [...] I've really learned a lot.*

Though, setting boundaries is not always successful. During the diary period, Emma was assigned a new support worker at her own request. While she was happy with this decision, it also meant a period of uncertainty, getting acquainted and attuned. Setting boundaries in this was more challenging. She wrote in her diary:

> *I did not set my boundary with my support worker. The conversation took too long. I was exhausted.*

Reflection on Emma's Narrative

Volunteering at the RC marks a key turning point for Emma. It ends years of loneliness and allows her to build a supportive social network, practice social skills, and apply what she learned (and continues to learn) in therapy and support. For Emma, the RC is a space for practice and for contact with peers. Support services offer practical support, and therapy is for acquiring insights.

Emma's motivation to learn and develop herself is put into action when she experiences social safety. At the RC, recognition and supportive interactions when she shares vulnerabilities stimulate others to do the same, which increases safety and encourages more openness. This transition from concealment to being seen and heard, and ultimately revealing and expressing herself, increases her self-confidence.

Recognition Emma experiences within the RC also motivates her to face fears beyond its walls, further boosting self-confidence. These self-reinforcing processes are apparent throughout Emma's narrative and fueled by experiencing new things. Despite this, Emma's narrative also reveals that recovery is erratic, with good and more challenging days. This makes clear that the self-reinforcing cycle also works the other way around. External stressors (eg, internet problems) can disrupt

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her sense of safety, increasing anxiety and self-doubt: even within the RC setting.

Robin: New Perspectives

Robin applied for the interview study after encountering the recruitment poster at the RC and requested the questions in advance so she could reflect on them. We spoke with her twice at the RC, and she completed the diary for a month. In the evaluative interview, Robin shared how journaling gave her a better overview:

> *I have very little overview. And by filling out the diaries, you acquire that. You realize that it [attending the RC, red.] offers you more than you thought. I appreciated that a lot.*

Journaling also led her to redefine what she considers meaningful activities, such as cleaning the house and cooking dinner for her family.

She recounted how she came into contact with the RC by coincidence, during her role as a moderator of peer support groups for an association that rents RC course rooms for its meetings. During that time, she felt hopeless and discouraged. For years, she had experienced depression, anxiety, and chronic fatigue:

> *I was very angry that I did not have that much energy and could not enjoy things anymore. [...] I received regular care, but then not again for years. At that time, I did nothing, merely survived. [...] When I first attended [the RC, red.] I had no more hope. I remember that one of the support pillars of the WRAP was hope, and that I wanted to throw something across the room. That I thought, "Get lost with your hope, what hope?". Then you go through all those stupid clichés. The light at the end of the tunnel. I thought, "I don't have light at the end of the tunnel for ten years, I move on because I have to".*

Her partner stimulated her to move from fighting it to acceptance.

> *It helped that my partner said many times, "You spend energy you don't have on something you can't change. Just look at what is possible."*

She was also stimulated by the RC's offerings presented on the flyers that she distributed at the peer support meetings she moderated. As a result, she started attending RC activities: the HOP, the WRAP, and various recovery workgroups.

Besides her partner, Robin has a few good friends with whom she regularly calls or meets up. She has no lack of social contact but still experiences loneliness in how she feels. This loneliness particularly surfaces when she experiences no or little recognition from others. On such a day, she answered the "recognition" diary question as follows:

> *Only my partner, because he is tired too. The rest of the world just keeps going, so it seems. It makes you feel lonely.*

Robin finds recognition with "people for whom life also did not unfold as expected or aspired," such as peers she encounters in group therapy. She wrote in her diary:

> *Someone recognized being so tired [...] that you can't get anything done. She was very happy with that, too, that recognition, it creates a bond. [...] Contact with peers makes the difference. I feel heard and seen. And really understood, because they know what it feels like to feel this way.*

Exchanging experiences with peers occurs in various ways in Robin's life: in group therapy, at association meetings, and in RC workgroups. Whereas group therapy and the association meetings are mostly about recognizing similar challenges (eg, fatigue or depression), peer contact within the RC is more diverse. Exchanging with peers who have lived experience with mental disruption in the broader sense helps Robin to put things into perspective. She described a moment in an RC workgroup (both during the initial and the evaluative interviews):

> *I was in the workgroup, and then there was someone who heard voices all day. You saw how he was suffering: it was so sad. *Becomes emotional* [...] Because sometimes I find myself very pathetic, because my friends are employed [...] and go on fun holidays. And then I saw him and thought, "Robin, stop whining, look at him. He also persists". I find that so inspiring. You see people who suffer much more than you do. [...] It opens the possibility of seeing: What do I have? I have a home, a relationship, a child.*

Robin discussed this moment with her psychologist:

> *And I remember my psychologist saying, "You shouldn't go there, this is too heavy for you." Then I think, "Hey, listen to me, this is actually really helpful."*

When she explained this to her psychologist, they kept insisting:

> *They did not listen because they think they know what's good for me. [...] "This is too heavy for you, but you don't see it." [...] And then I'm giving up, and think "Never mind."*

Instead of listening to her psychologist, Robin keeps attending the RC. She feels that this is good for her, and this only became clearer when she completed her diaries:

> *I knew it mattered, but I did not know it mattered so much for me sometimes [...] I realize that I am doing things that are good for myself, [...] that really help me move forward.*

For Robin, it confirmed that she was able to make good decisions, which increased her self-confidence. This feeling continued after she visited the RC, as she explained:

> *Then I feel more powerful. On Wednesdays, I am babysitting and [...] I noticed that decisions I made, [...] all is more clear. [...] That you feel good about yourself. More confident. Usually I find myself endlessly ruminating, "Is this a good plan, or would*

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> *something different be better?". And now you think, "This is a good idea, let's go."*

But Robin often struggled to trust her choices. Her physical and mental complaints then seemed to take over control. On such a day, she wrote in her diary:

> *I barely succeeded in doing things I find important because I was too tired and disorganized. [...] On days like that, I feel like I have too much on my plate and I don't know anything and can't handle anything. It is an unpleasant feeling, like life is not safe, and it happens to you and takes you by surprise. It is heavy and sad. It discourages me.*

In general, she found the question "Are you in charge of your own life?" very confronting and unpleasant to answer, as she explained in the evaluative interview:

> *You can't do anything with that. It is really in your face, you are responsible for everything yourself. [...] While at the same time you feel, "I just have to do deal with all the limitations I have."*

For Robin, the RC is a place where she finds tools to maintain control over her life, as far as that is possible. After a day of feeling overwhelmed, she reflected in her diary on the fact that she had not attended the RC and how this could have impacted her day:

> *At Enik I would have experienced more recognition. And reminders, such as: pay attention to your boundaries, what is good self-care, mind your WRAP.*

Preferably, she would attend the RC every day, but that is not possible due to her limited energy levels. Anyway, it is a place where she wants to develop further.

Besides feeling hopeless, Robin also experienced hope again. Before, she saw limited future perspectives:

> *When you are depressed you think, [...] we all die someday and whatever.*

Now, she feels differently:

> *Something is happening, and that is more than what has happened in the past ten years.*

She is considering paid employment again:

> *In the past, when someone asked me, "Can you ever work again?," I always said, "Yes," but I thought "No." Because I thought, "I say that, because I want that, but I don't believe in it anymore." And after a year and a half of Enik, I think, "Yes, it could be possible." [...] Because at Enik, you see the living proof that other people who also experience(d) disruption lead a group, work there. [...] Imagine being able to work for four mornings per week; that would be fantastic. [...] You can also start with three times one hour. I think you see more possibilities here.*

She would like to work at the RC as a (voluntary) facilitator. However, she encounters obstacles in that:

> *I would love to be co-facilitator, but it is unclear how this is arranged. I asked someday, but one said, "You should have your own subject and submit that" [...] but I found that very scary. [...] And I said, "Are there no groups where you can join?" But this one person said "No." [...] And the other said, "Maybe". And yet another person said, "There is the training 'Learning to facilitate'." But that seems to be some kind of secret group that is hard to join. [...] And they facilitate that three days in a row, that doesn't work. [...] I'm already wiped out by day two.*

This touches old pain related to feeling excluded and also fosters self-doubt:

> *I start making assumptions about everything. [...] Most of all I would like to know, is there anyone who has decided, "This Robin is not suitable"?*

She wants to work as an RC facilitator to make a difference for others. This is also possible as student, but as said, Robin also experiences a strong (rediscovered) desire to work. She shared:

> *Imagine that Enik would cease to exist tomorrow, which I would find a real shame, but still, I would take that with me. I thought I could not be switched back "on" by anything, but I can.*

Robin was not working as a facilitator yet. In the initial interview, she said she gave up on this:

> *It is sad, but it is such a pattern. There are many things that I wanted that don't work out.*

During the diary period, becoming a facilitator no longer seemed to be a topic.

During a member check (December 2025, 2 years later), Robin requested an update to her narrative. Eventually, she became a voluntary facilitator within the RC, after a peer worker invited her to do so. This brought her a lot. At this moment, she was doing so well that she was employed for a few hours per week elsewhere. She felt "endlessly grateful" for the life she lives, which seemed impossible 5 years ago. She stated that this was achieved partly due to the RC.

Reflection on Robin's Narrative

Robin already found support and recognition with peers in group therapy and association meetings. However, becoming acquainted with the RC opened a new pathway in her recovery process and allowed her to move forward. At the RC, Robin hears diverse experiences that offer her new perspectives. Noticing others' struggles makes her more aware of what she cherishes in life. She learns to trust her own choices and keeps attending the RC, despite her psychologist's advice, because she finds it helpful and experiences change that she had not experienced for a long time. Besides hopelessness, hope appears, motivating her to learn, develop, and consider paid employment again: something she once thought impossible.

Nevertheless, Robin's recovery process is not a linear, upward process. She often feels out of control and dominated by her complaints. The struggle of becoming an RC facilitator also evokes pain and self-doubt. Though, when we inquire about the impact of these struggles, Robin emphasizes that these do not temper her enthusiasm for the RC. There, she found a

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self-chosen place where she experiences that her recovery is not "finished" yet, but advancing.

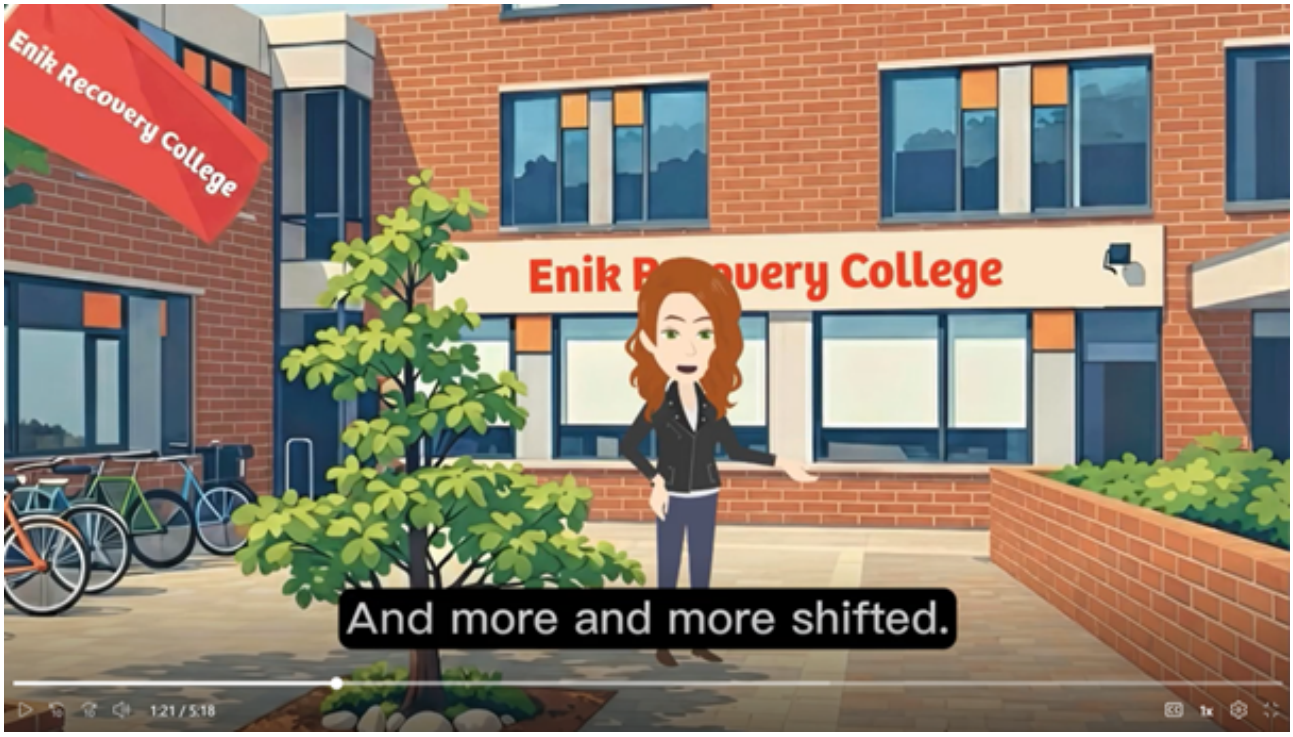
Norah: Role Development

For us researchers, Norah is a familiar face within the RC. We frequently encounter her in the social meeting point or as a facilitator. She is enthusiastic about our research and supports us, for example, when recruiting participants, and also values participating herself. We interviewed her twice at different RC locations, and she completed a diary for 2 months. At first, she enjoyed completing the diaries, but over time, she became less elaborate, partly due to being tired after long working days:

> *On the days I don't work, I literally and figuratively have more space for it [completing the diaries, red.].*

To disseminate our findings, Norah accepted the invitation to translate her narrative into an animation (Multimedia Appendix 1; Figure 2).

Figure 2. Still from Norah's animated narrative.



For a long time, Norah's life revolved around health care. She explained:

> *It felt like I had missed the boat when it came to finishing education, having a relationship, kids. Those things just didn't seem possible for me. [...] I just envisioned myself as a complete failure with no hope.*

The mental health care organization where she was "in treatment" offered a VERS (Vaardigheden emotieregulatiestoornissen; [Skills for Emotion Regulation Disorders]) training, which was the first thing she had completed in years:

> *That was really good for my self-confidence.*

Around that time, she also attended the WRAP, facilitated by the organization from which she received mental health support. There, the aspiration to study or seek employment surfaced again:

> *Because before I did that, I pictured myself spending the rest of my life just sitting at home, doing nothing. [...] That had to do with my self-image, not my talents, but I experienced that differently at that time.*

When she attended a lecture by an expert-by-experience about the ideology of RCs, she felt inspired:

> *That was the first time I thought, "Perhaps there is still something more in store for me."*

She started attending the RC, and she narrated about those early days:

> *I found it very inspiring to meet all kinds of people who had also been through a lot of "shit," but still found their place in life. So that gave me hope. In the sense that, I could possibly do that too. And then I just literally got back to work there. Partly through those trainings, but also through volunteering, I really noticed that I actually have quite a lot to offer. So, in a year and a half, I've gone from thinking, "I'll be lucky if I can volunteer somewhere," to thinking, "They'll be very lucky to have me as a volunteer." Of course, that is already a major thing. And then, slowly, the hope emerged: maybe I can get a job here.*

After a journey of trial and error as a student and volunteer, that is what happened. After years, she was hired as a peer worker at the RC.

The RC played a significant role in Norah's life, as seen in her diaries. In the evaluative interview, she shared:

> *For me, it reflects how important my work is for me. But also, being at Enik.*

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She recounted a period where she stopped attending the RC and then became active again:

> *I noticed how beneficial it was for me when I started reintegrating at Enik, just to be there again. And that it really was my place. And that I had really missed it.*

On days she was not at the RC, she was less active and had little social contact:

> *Outside Enik, I simply encounter way fewer people, and spend much more time alone.*

At those moments, she felt less well, as she wrote on such a day:

> *Struggling to take good care of myself in the sense of healthy food and that makes me feel sad and kind of powerless and feeling like a failure. [...] I just can't manage to turn things around.*

Norah emphasized that social contact was very important to her. She found this at her RC job, but she was also expanding her social network elsewhere, to her own surprise:

> *I'm starting to get girlfriends. I've never had that before. [...] The last few months, I met some nice people at Enik and at my volunteering job [not at the RC, red.], and something is starting... [...] but girlfriends, in plural. It's really special.*

Still, the RC seemed the most significant base site in her everyday life. This became clear when there were insecurities at work during the diary period, causing a lot of stress. Norah did not complete diaries for a week, and then she wrote:

> *Too sad because of the events at work last week to really achieve anything. [...] Once again, I feel very much like a failure and falling short when it comes to dealing with misunderstandings and disappointments in a mature way, and I have little confidence that I will ever really be able to do so. [...] Then thoughts that I'd be better off not being here quickly resurface.*

After this week, the insecurities proved to be less pronounced than anticipated. Norah felt supported by colleagues, friends, and family, and things were said that made her feel seen and acknowledged. She felt better again:

> *I feel more powerful and I'm starting to believe in myself again. [...] The fact that I feel reconnected to my colleagues, that I enjoy my work so much, and that I've met new people, are important reasons for that.*

Norah explained how her job benefited her by providing weekly structure that supported good self-care. Her clear role at the RC offered safety to practice things she found scary, such as working in groups. Financially, the job allowed her to earn her own money and become less dependent on the *Uitvoeringsinstituut werknemersverzekeringen* (UWV [Dutch Employee Insurance Agency]; ie, responsible for implementing unemployment benefits). Norah remarked that these could be benefits of any employment, provided the workplace offers a supportive environment where expectations are clear and she feels connected to colleagues.

Nevertheless, the RC also offered a specific supportive context, in which she could work on her learning goals. One important learning goal for Norah was asking for support. She struggled with this, but she felt the need for it:

> *I very much tend to do everything myself, and I've fallen flat on my face a few times because of that.*

It was an important theme in sessions with her coach, and she increasingly practiced it. This was easier when she experienced supportive social contact. For example, she more easily asked for support if others had spontaneously offered support to her before. This occurred at the RC, according to Norah, following from conscious attention and sensitivity:

> *At Enik, there are a lot of very kind people, often also very sensitive people attentive to these things.*

She characterized her new friends in the same way. She also shared that asking for support at the RC was facilitated because the RC was based on shared responsibility:

> *The other day, I had overloaded myself with tasks that I took over. And then [colleague] said: "Then we have to go back to the drawing board. [...] Than we have to find something for..." – That feels very much united.*

She also emphasized the impact of shared experiences with struggle, which are a given within the RC:

> *Of course, here at Enik, you discuss what you struggle with a lot. [...] Any way, the safety of not having to talk about your problems, but still knowing that everyone understands some of it, or at least doesn't disapprove it, that offers so much air and relaxation to just be who you are.*

Norah's peer worker role helps her rebuild a positive self-image and confidence. It allows her to reciprocate experiences she had as a student and volunteer. For example, it meant a lot to her that others saw her potential:

> *When I just started volunteering here, how proud I was, how I felt seen and valued, when I was asked to do a chore or brainstorm about something together. [...] Like, "People see something in me, after all". And at that moment, I saw little to nothing in myself. [...] That I received that from others was something for my personal development... [...] I felt like, "I am up for paid employment". That took three years, but eventually, I succeeded. And that is what I wish for others, too. To regain that self-worth and respect, and feel seen.*

She shared how her work offered her joy and meaning as she could connect people. She addressed their talents and skills and involved them in projects. As an illustration, she described a large project that she co-created with the community, and what this meant for her:

> *Then I really feel empowered, thinking, "I initiated this and eventually, it works out." It becomes what I*

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> *envisioned. And people are as excited about it as I hoped. Because, of course, that is what it's all about in the end. It's not about me wanting this project so much, it's about those people going home, feeling inspired.*

Reflection on Norah's Narrative

Norah describes her development across various roles within the RC. Even as a peer worker, her personal growth continues. She still struggles with low self-image and wants to learn to ask for support when needed. Beyond support from a coach, the RC is important: paid employment offers structure, social contact, and financial independence, while the RC facilitates a context she finds recovery supportive. She highlights the special bond among RC partakers based on shared experiences with mental vulnerability and unconditional support. As a peer worker, she learns to reciprocate what she once experienced: being seen, valued, and encouraged. She learns how she is of value to others, growing her self-confidence.

It becomes evident that the RC encompasses a significant part of her everyday life, and outside it, loneliness often prevails. She struggles with self-motivation and self-worth. While Norah experiences great value in her RC involvement, its central role can also introduce vulnerability: when the RC is both workplace and support system, work-related stressors can threaten her sense of a "safe haven." However, during the diary period, Norah also builds a supportive network outside the RC.

Cross-Case Analysis

Overview

Within the RC, Emma, Robin, and Norah experienced recognition, inspiration, hope, supportive structures, and social safety. These were not discrete outcomes, but ongoing, intertwined, and situated processes. Peer interactions especially surfaced as meaningful contexts for these experiences. Similar experiences sometimes arose in partakers' everyday lives, for example, when experiencing support and safety in relationships with significant others or care and support providers. Nonetheless, the RC deliberately facilitated space for the exchange and development of experiential knowledge, which could foster recovery processes to unfold.

Learning by Exchanging and Learning by Doing

Across cases, we identified 2 unfolding processes: learning by exchanging and learning by doing. While analytically distinct, these were intertwined and mutually reinforcing. Learning by exchange was primarily a process of knowledge expansion, involving interpersonal and relational sense-making through (non)verbal input, such as insights, role modeling, or supportive behaviors. Emma, Robin, and Norah all noted peers in whom they recognized aspects of themselves, motivating identity reconstruction and new behaviors. For example, Emma's exchange with a peer facilitator stimulated her to overcome her social anxiety, Robin reconnected with her ambition to work, and Norah, experiencing collegial support, became more aware of seeking help.

Learning by doing transformed abstract knowledge that was previously detached from the self into lived experiential knowledge through practice. Emma not only "knew" social interactions are not as daunting as she used to believe, Robin not only "knew" that she can make good decisions for herself, and Norah not only "knew" that she has things to offer: after "doing," they "experienced" it too.

Challenges

The narratives also revealed experienced challenges. Recovery was nonlinear and erratic, with partakers facing negative self-cognitions and emotions. In addition, navigating the RC could be challenging, for example, when implicit power relations and role tensions foregrounded. Norah's narrative illustrated the fragility of an RC functioning both as a workplace and a safe haven, given its central role in her everyday life. Robin encountered unclear pathways to becoming a facilitator: a role that only became accessible upon invitation. These examples highlight how implicit power dynamics within RC context could shape and challenge attendance.

Discussion

Principal Findings

Through detailed, narrative accounts of 3 RC partakers, we have acquired more insights into how their recovery processes unfolded within the RC and their everyday lives. Our findings showed that recovery of the selected RC partakers encompassed processes of learning by exchanging and learning by doing. The RC context was explicitly designed for these processes to evolve, as the peer-supported learning community facilitated space for exchanging experiences among peers and for practicing and experimenting with new behaviors. As such, the RC could be understood as a "community of practice" [26].

The narratives especially foregrounded how the RC partakers valued lived experiences and experiential knowledge as sources to learn from. As Moran et al [65] described:

> *The use of one's lived experience as a source of knowledge transforms that which is most stigmatized into an asset.*

Our findings help to understand the potential value of experiential knowledge in recovery processes [66,67] and align with lived experience accounts articulating experiential knowledge, education, peer support, and personal agency as vital aspects of navigating recovery journeys [12,23].

Existing literature has elaborated on RC experiences and perceived impacts, making clear what RCs potentially have to offer [38,39,68]. RCs are proposed as empowering contexts that redistribute power and foster supportive relationships and personal growth [1,25,39-41]. Our previous work described how RC partakers experienced the RC as spaces for learning, social contact, and low-threshold, co-created organizational forms, inviting to experiment with new roles and skills [33]. Through a narrative approach, this study has acquired more enriched insights into how these spaces can be meaningful contexts for recovery processes to unfold.

Nonetheless, the narratives also illustrated the ongoing and erratic nature of recovery, as RC partakers encountered (mental health) challenges alongside trajectories of growth. Importantly,

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some challenges specifically emerged within the RC context: Emma suddenly feeling unsafe in the workgroup, Robin feeling rejected in her ambitions to become a facilitator, and Norah experiencing work-related, disruptive tensions. These accounts corroborate previous studies reporting that RC attendance is not necessarily easy or straightforward and may evoke tensions or negative experiences too [33,69,70]. These included, for example, challenging power dynamics (eg, in the context of decision-making) and role tensions, which have also been described in contexts of peer-led mental health care [71] and participatory research [72].

Altogether, our findings suggest that RCs should not be understood as "causing" recovery, but as facilitating conditions under which recovery may become possible at certain moments. This resonates with the concept of "generative causation" as described in realist evaluation literature [73,74]. As such, recovery unfolded over time through interwoven, personal, relational, and situated processes, echoing broader understandings of recovery as nonlinear, contextually embedded, and unique [17,23,75].

Theoretical Implications

Unraveling how recovery can be fostered often involves a search for mechanisms of action or change, and scholars have identified such mechanisms in peer-supported and recovery educational contexts [1,32,40,41,65]. At the same time, conceptual ambiguity remains regarding what constitutes a mechanism [73,74]. By taking processes as its primary analytic focus, our narrative analysis offered complementary insights into how recovery unfolds in practice. These insights are less visible in mechanism-based descriptions. Theoretically, this suggests that, while mechanism-based explanations are helpful in articulating "why" interventions may facilitate conditions for change, these remain at a level of abstraction that obscures how recovery actually takes shape. Attempts to understand recovery may therefore also benefit from approaches that attend to "how" generative processes become meaningful, interact, and vary across persons and situations over time.

Practical Implications

The 3 presented narratives offered situated insights into the value of experts-by-experiences' (or peers', more generally) unique "position to know" [76,77] through their bodily and emotional involvement in recovery processes [78-80]. This aligns with broader developments in mental health care and research, where experiential knowledge is increasingly recognized as an epistemically legitimate source alongside scientific and professional knowledge (eg, in discussions on epistemic justice [43]). This development is reflected in the growing professionalization of expertise-by-experience [81,82] and in care providers increasingly disclosing about personal lived experiences in their profession (eg, as "wounded healers" [66,83]). At the same time, the institutional embedding of expertise-by-experience is not without concerns, including risks of abstraction, cooptation, and assimilation within health care frameworks [76,82,84,85].

Within this context, the presented narratives illustrated how an RC (or other participatory health initiative) can explicitly facilitate space where experiential knowledge can be shared, explored, and developed. This dedicated space is characterized by organizational and relational conditions under which recovery could unfold (such as experiences of recognition, safety, and personalized opportunities to partake). Importantly, literature emphasizes that such "free space" does not emerge automatically and requires ongoing collective effort and explicit safeguarding within the community [33]. Also, our findings suggest that recovery as a learning process is not limited to cognitive or verbal exchange but also unfolds as an embodied process of doing [27,28]. This highlights the value of diverse participatory opportunities, including creative, embodied, and action-oriented practices, to support recovery as a practice-based learning process.

Strengths and Limitations

The qualitative diary-interview design enabled situated insights into recovery processes. Incorporated in a large, mixed-methods research project, the study provides qualitative enrichment of quantitative RC evaluations [86,87] and a more elaborate, experiential description of the meaning of RC spaces [33] for recovery. A key strength lies in the study's participatory and co-created design, which centered the research entirely on participants' lived experiences. This approach particularly attended to power dynamics and meaningful participation for research participants, promoting ownership and agency [45,46]. Collaborative data collection and analysis contributed to ongoing reflexive dialogues, acquiring insights beyond pre-existent personal and/or academic beliefs [45].

The study also has limitations. Most importantly, the study is prone to selection bias in 2 ways. First, because diary studies demand considerable effort, participation is likely limited to RC partakers who have the capacity, resources, and motivation to sustain RC engagement and have a strong motivation to contribute to its evaluation. Second, participants indicated that they less frequently completed diaries on bad days. These forms of selection bias have also been cautioned against in literature [48,88]. Together, these dynamics may have contributed to the empirical material foregrounding experiences of growth while periods of stagnation or withdrawal are likely underrepresented. In addition, while the narratives captured diverse RC attendance in terms of duration and roles, the demographic diversity of the sample was limited. Furthermore, diary entries were guided by predefined themes, which may have limited the breadth of the narratives. Finally, participants could access the dashboard during the diary period, which might have stimulated additional in-between reflections and adjustments. However, dashboard usage was rare (limited to a single, curiosity-driven visit at the start), so its impact is likely negligible.

Future Directions

We propose 2 directions for future research. First, RCs in the Netherlands centralize experiential knowledge and bottom-up co-creation by and for peers [34], while there are also RCs, for example, in the United Kingdom, that equally value and connect sources of professional, experiential, and scientific knowledge [24]. Building on our findings on the meaning of experiential knowledge in a context where it is the dominant source, future research could examine whether learning processes in contexts

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that combine multiple knowledge sources are comparable or distinct.

Second, research could further develop diary-based methods as participatory approaches by examining both the design of such methods and their potential effects on recovery processes. Regarding design, future studies could employ even more participatory designs by giving participants full agency in shaping the study (eg, in defining personal diary questions and collaborating during the entire analysis). Such approaches may better accommodate the uniqueness of recovery, advance ethical principles of ownership, and improve compliance, particularly during difficult periods. Additionally, complementing diaries with more immersive, context-sensitive methods (eg, home-based interviews or ethnographic methods) could help to situate diary entries within participants' everyday contexts and support interpretation of what is recorded.

In terms of effects, literature suggests that journaling can deepen self-knowledge, increase awareness of patterns, and foster higher-order thinking, reflection, and meaning making [89]. In our study, such processes were most prominent in Robin's narrative. While diary methods have been proposed as therapeutic tools with both positive and negative effects—predominantly evaluated in terms of symptom reduction (eg, [90,91])—their potential role in supporting personal recovery processes has received comparatively less attention. Future research could therefore examine how diary-based practices, particularly when designed in more participatory ways, influence the unfolding of recovery processes beyond clinical outcomes.

Conclusions

Three narratives of RC partakers showed how their recovery unfolded as 2 learning processes: learning by exchanging and learning by doing. The RC facilitated space for both: reflecting upon experiences in exchange with peers, and experiencing, practicing, and doing new things. RC context was associated with supportive experiences of recognition, hope, and inspiration, reinforcing recovery processes to unfold. Partakers as such (re)built their self-confidence, empowerment, and a positive identity. Importantly, these processes did not progress in a linear fashion but were erratic: partakers also experienced challenges in their everyday lives and within the RC specifically. The narratives illustrated how RCs can be valuable assets in landscapes of mental care and support. Likewise, experiential knowledge was identified as a valuable knowledge source to learn from in recovery.

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Data Availability

The qualitative data underlying this study are not publicly available and cannot be shared upon request due to privacy and confidentiality considerations.

Authors' Contributions

MMCvW contributed to the conceptualization, methodology, data collection, data analysis, writing of the original draft, writing of the review and editing, and project administration. CM contributed to the funding acquisition, conceptualization, methodology, data analysis, supervision, writing of the review and editing, and project administration. JB contributed to the methodology, data analysis, and writing of the review and editing. FJAS, DvdS, and KL contributed to the methodology, data collection, data analysis, and writing of the review and editing. JL contributed to the data analysis and writing of the review and editing. DM contributed to the funding acquisition, conceptualization, methodology, supervision, and writing of the review and editing. HK contributed to the funding acquisition, conceptualization, methodology, data analysis, supervision, and writing of the review and editing.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Norah's animated narrative.
[MP4 File, 119643 KB - jopm_v18i1e89886_app1.mp4]

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Abbreviations

CHIME: connectedness, hope, identity, meaningfulness, and empowerment
HOP: Honest, Open, Proud
RC: recovery college
UWV: Uitvoeringsinstituut werknemersverzekeringen (Dutch Employee Insurance Agency)
VERS: Vaardigheden emotieregulatiestoornissen (skills emotion regulation disorders)
WRAP: Wellness Recovery Action Planning

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Original Paper

Vietnamese University Students' Perceptions and Attitudes Toward Participation in Clinical Research: Mixed Methods Study

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Abstract

Background: Recruiting and retaining adequate numbers of eligible participants remain the key challenges in clinical research. Understanding the factors associated with participants' motivations is essential to support recruitment efforts, reduce early withdrawals, and consolidate commitment. The Oxford University Clinical Research Unit conducted a longitudinal study, named the SEED project, with a cohort of first- and third-year students at the University of Medicine and Pharmacy at Ho Chi Minh City, Vietnam.

Objective: This paper describes the findings of the SEED project related to students' understanding of clinical research and characterizes factors influencing their motivation to participate.

Methods: We used a mixed methods approach, incorporating surveys, in-depth interviews, and focus group discussions to collect insights from students on ethical and practical aspects of clinical research participation.

Results: A total of 437 students were enrolled, with the majority coming from the general medicine faculty. Of these participants, 74 students contributed to qualitative data. Over 95% of the students agreed that clinical research could make an important contribution to science (430/435, 99%) and the health of society by increasing disease awareness (422/436, 97%) and potential access to more effective treatments (415/435, 95%). Few students (81/435, 19%) expressed concerns about the negative impacts of clinical research on the environment. In terms of risk, most students emphasized unpredictable or serious side effects (226/434, 52%) or inconveniences (257/435, 59%) as major concerns, whereas small proportions worried about the risk of disclosure of personal information (94/436, 22%) or the risk of being treated like an "experimental subject, not human being" (33/434, 8%). In in-depth interviews and focus group discussions, health-related benefits, opportunities for intellectual growth, time requirements, and altruistic attitudes built on the perceived social value of clinical research were highlighted as key factors influencing students' participation.

Conclusions: Students in this study expressed favorable attitudes toward clinical research. By highlighting altruistic motivations built on the perceived social value of clinical research and personal motivations based on perceived health-related benefits for participants, this study provides insights to inform recruitment efforts for clinical studies involving student participants or other young, healthy individuals.

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KEYWORDS

medical students; healthy volunteers; research ethics; clinical research; perception; attitude; motivation; recruitment efforts; young generations; Vietnam; mixed methods study

Introduction

Multiple factors contribute to the success of clinical research, but the ability to recruit and retain adequate numbers of eligible participants is a crucial element and, for many investigators, the most challenging aspect of conducting research [1]. In the context of clinical trials, inadequate enrollment may result in early study terminations or the need for expensive financial and/or time extensions [2]. Similarly, in observational studies, a low participation rate may create nonresponse biases and reduce statistical power, posing a threat to the validity and generalizability of the study findings [3,4]. Understanding the factors associated with participation in clinical research has increasingly been recognized as an essential step to support recruitment efforts, reduce early withdrawals, and consolidate participant commitment [1,5,6].

The existing literature has highlighted a range of determinants that may impact willingness to participate in clinical research, including concerns about potential risks and side effects, limited understanding of the research information presented, mistrust of the research team, time, and location impediments, as well as language, literacy, and other sociocultural factors [5-8]. With respect to study design, high-risk and interventional studies (eg, clinical trials) are associated with higher rates of consent withdrawal and dropout rates, compared to observational studies [9].

Several reports have described participants identified as more likely to be willing to contribute to clinical research as being male [10,11], having the illness under study, or having sick relatives [8,12-14], being middle aged or older people [13,15], having previous experience of participation in clinical research [12,14], or having a generally positive attitude toward participation in clinical research [12,13]. However, other researchers did not identify a significant association between age and willingness to participate in clinical research [11,16,17].

A positive association between having a biomedicine-related degree and willingness to participate in clinical research has been described [10,11,15]. However, despite a desire to contribute to the development of medical science and education [18,19], medical students are sometimes hesitant to participate in clinical research due to time commitment constraints [19]. In addition, concerns about possible coercion by academic tutors involved in the research have been voiced [20,21].

In 2018, we initiated a research project at the Oxford University Clinical Research Unit in Ho Chi Minh City, aiming to engage with a wide range of stakeholders to explore their perceptions and views on clinical research in Vietnam. Involving stakeholders, including funders, policymakers, health practitioners, researchers, and communities, increases legitimacy, credibility, acceptability, and practices aligning with ethical principles in biomedicine research [22]. The first report of our interactions involving senior, national, and international stakeholders was published in 2019 [23]. However, the remit of our project also extended to exploring opinions among younger generations of Vietnamese society, especially students of the health professions, who might conceivably be involved in research in the future, potentially as clinicians, scientists, data collectors, or even as research participants. We conducted a longitudinal study (named the SEED project) involving a cohort of students attending the University of Medicine and Pharmacy (UMP) at Ho Chi Minh City from July 2020 to December 2024. This paper describes the initial findings of the SEED project related to the students' general perceptions of clinical research and their motivations to participate in such research, aiming to specifically characterize the students' understanding of the benefits, risks, and burdens of clinical research.

Methods

The development and overall structure of the SEED cohort have been reported in detail elsewhere [24], but a relevant summary is provided in the Participant Recruitment and Study Procedures section.

Ethical Considerations

The SEED study was approved by the Oxford Tropical Research Ethics Committee (approval: 540-20—dated July 2020) and the ethical committee of the UMP at Ho Chi Minh City (approval: 351/HDDD-DHYD—dated May 26, 2020). Study staff discussed the study program with potential participants and provided them with a written information sheet, describing the purpose of the study, the procedures, possible risks, benefits, and the rights and responsibilities of participants. Written informed consent was obtained from all students before any study procedures were implemented. Students were compensated for time spent and travel, where applicable. All participants provided written consent for publication of deidentified data. Study staff ensured that all information generated in the SEED study remained confidentially and securely stored. Students' privacy was protected by deidentifying personal information and replacing their names with confidential participant numbers.

Participant Recruitment and Study Procedures

Potential participants included first and third-year students attending the faculties of medicine and public health at UMP. Eligible students, who were aged at least 18 years and who expressed willingness to participate in project activities for the next 3 years while studying at UMP, were invited to join the cohort after signing a consent form.

Upon enrollment, students were asked to complete a demographic questionnaire and a comprehensive survey (CS) that included questions about their perceptions and attitudes toward clinical research in general, as well as their thoughts about specific types of research. Subsequently, a variety of topics relating to clinical research in human participants were addressed with students by combining in-depth qualitative methods with synergistic engagement activities. A new topic

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was introduced every 2-3 months in a sequential manner. We organized a series of engagement activities (such as science cafes, science debates, and role play events) as interactive platforms for the cohort participants to learn basic information about each particular topic. Those events also helped us explore the thoughts and opinions related to the often-complex concepts encountered. Later, among those who had attended a related engagement activity, we purposively selected participants for in-depth interviews (IDIs) and focus group discussions (FGDs), ensuring diverse representation of cohort members based on predefined characteristics, including sex, socioeconomic background, faculty, and academic year of study. In this way, we hoped to ensure that the students attending the FGDs and IDIs were aware of general background information about research and well prepared to discuss the relevant issues surrounding each topic in more depth. The selected students received an invitation via email and were free to choose whether to participate in the IDIs or FGDs.

Here, we report our findings related to the main topics addressed with the cohort participants, focusing on students' thoughts around the ethics of clinical research generally and also specifically exploring their thoughts on motivations to participate in research. The four main topics relevant to this report were (1) clinical research and how it is relevant in Vietnam, (2) vaccines and vaccine trials, (3) vulnerability, and (4) reimbursement and compensation.

Data Collection and Analysis

The study used a mixed methods approach using quantitative methods (questionnaires and surveys), which were completed by all SEED cohort participants, together with qualitative data from IDIs and FGDs, which were attended by smaller groups of purposefully selected students.

Comprehensive Survey

The self-administered CS (Multimedia Appendix 1) was designed to collect data on students' attitudes toward benefits, risks, burdens, and motivations regarding clinical research involving human participants. The survey was structured into 4 sections, with the first section focused on exploring their perceptions of clinical research in general, and the subsequent sections specifically exploring their views on observational research, clinical trials, and human challenge studies. For this paper, we report data primarily from the first section. In this section, students rated their level of agreement on a Likert Scale, with several statements on the benefits and risks of clinical research, both for individual study participants and at a community level. In addition, the students were asked to respond to a series of questions about what might influence their own personal decision-making if approached to participate in a clinical research study.

FGDs and IDIs

Questionnaire and interview guides were developed based on the published literature, together with feedback on issues raised by students attending the engagement events. The initial structured questions were designed to encourage students to share their personal narratives and thoughts, later supplemented by more probing questions to allow a deeper exploration of their views.

Data Analysis

All quantitative analyses were performed using R software (R Foundation for Statistical Computing). Descriptive statistics were used to summarize students' demographic information and perception outcomes: frequency and percentages for categorical variables, mean and range for continuous variables. A 5-level Likert scale (strongly disagree, disagree, neutral, agree, and strongly agree) was used to explore students' agreement with factors influencing their decision to participate in clinical research. However, several categories in the original 5-level Likert scale contained very small frequencies for multiple items, particularly at the extreme response levels. To avoid sparse-data bias and ensure stable model estimation, we collapsed the categories of responses from 5 to 3 levels (disagree, neutral, and agree) to ensure that the cell sizes were large enough to perform robust analyses [25]. We used chi-square tests to examine differences in responses between year groups and between medicine and public health students and adjusted for multiple testing using the Benjamin and Hochberg correction method. Results were considered statistically significant at a P value <.05.

All qualitative data were audio-recorded, transcribed verbatim, and then uploaded into NVivo (version 12; Lumivero) software for management and analysis. Although the data from the FGDs and IDIs were transcribed and analyzed in Vietnamese, we used English codes to ensure accessibility for the full research team. We translated the quotes presented in this paper into English after the analysis was completed. A grounded theory coding approach [26] was used to generate the central ideas for data interpretation and to construct a framework to describe the students' perceptions, attitudes, and willingness toward clinical research. Two independent Vietnamese researchers (CHL and VP-T) used open-coding techniques (line-by-line coding) to code a subset of FGDs and IDIs, then compared their analytical approaches and discussed overarching categories with English-speaking team members until they reached consensus on initial codes. Following these discussions, the refined codebook was applied to the full dataset, with ongoing disagreements resolved through consensus meetings during the analysis process. We then conducted 4 additional IDIs to confirm the initial findings. Subsequently, the study team reviewed all the transcripts and codes and refined and linked categories and subcategories into themes. Within the scope of this paper, we report the themes describing the students' perception of clinical research's benefits, risks, and burdens and other factors influencing their motivations to participate.

Results

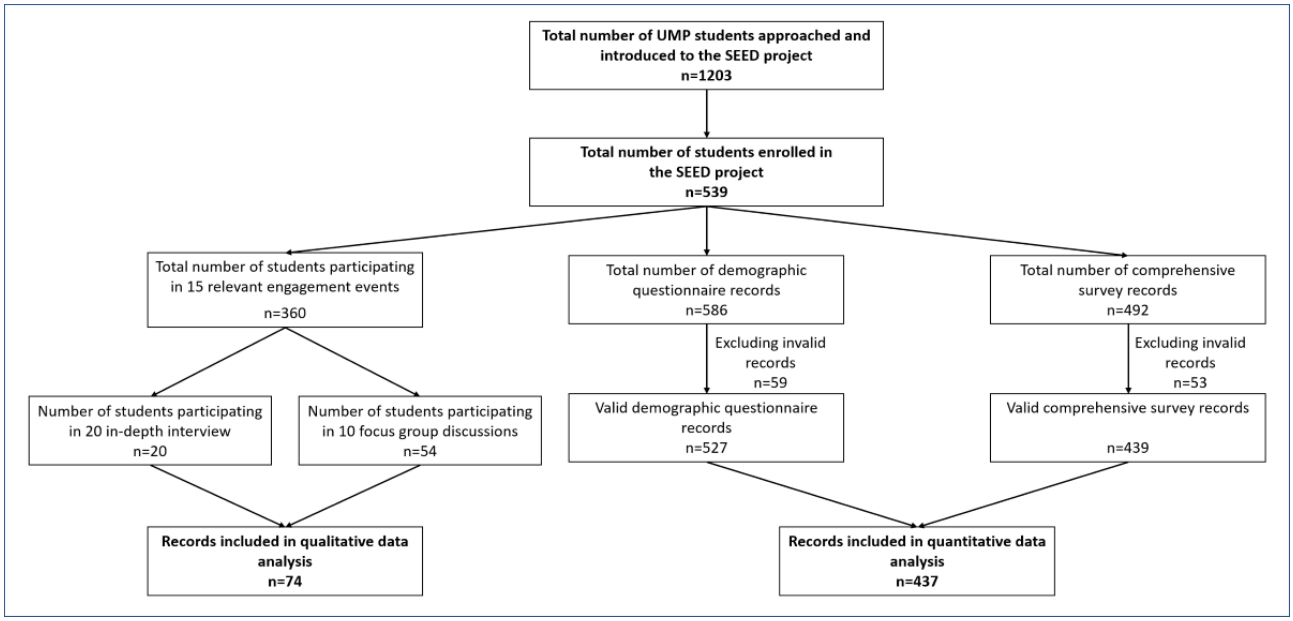
Overview

A total of 1203 UMP students attended one of our introductory events and completed introductory forms between July 2020 and December 2021, during which they were invited to participate in the SEED project (Figure 1). Among this group, 539 students enrolled in the study and were eligible to contribute to the various activities until March 2023; individual students

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attended variable numbers of events ranging from 0 to 6, depending on the timing of their recruitment to the cohort. After removing duplicate or invalid records (due to lack of study code or no consent documented), the final study population for this analysis comprised 437 of 539 students with demographic data available, who had completed the initial CS. Among these individuals, 336 of 437 (77%) students attended at least 1 relevant engagement activity related to the 4 topics of interest. A total of 10 FGDs and 20 IDIs were conducted in parallel with these activities, with 74 students participating in either an IDI (n=20) or an FGD (n=54), thereby providing qualitative as well as quantitative data on the study topics (Figure 1).

Figure 1. Flowchart of participant activities and data collection. UMP: University of Medicine and Pharmacy. The number in each box represents the count of students or records at each stage.



Demographic Characteristics of the Analysis Population

Demographic characteristics of the 437 participants included in this analysis are presented in Table 1. The majority were students of medicine (302/437, 69%), with lower representation from the preventive medicine (63/437, 14%) and public health (45/437, 10%) departments, and only a few students (27/437, 6%) participating from the nutrition department. A little over half the students (254/437, 58%) were enrolled in their first year. Although male and female participants were equally represented in the cohort overall, breakdown by faculty indicated that 64% (192/302) of medical students were male, while 79% (106/135) of public health students were female. Almost all students were ethnic Kinh (392/437, 90%), in line with the expected proportion across the Vietnamese population [27].

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Table 1. Demographic characteristics of SEED cohort students included in this analysis.

	Faculty of General Medicine	Faculty of Public Health[a]			Total (N=437)
	General medicine (n=302, 69%)	Preventive medicine (n=63, 14%)	Public health (n=45, 10%)	Nutrition (n=27, 6%)	
Age (years)					
Mean (SD)	19 (1)	20 (2)	20 (1)	19 (1)	19 (1)
Range	18-23	18-25	19-22	19-21	18-25
Sex, n (%)					
Male	192 (64)	12 (19)	15 (33)	2 (7)	221 (51)
Female	110 (36)	51 (81)	30 (67)	25 (94)	216 (49)
Academic year at enrollment, n (%)					
First year	169 (56)	34 (54)	29 (64)	22 (81)	254 (58)
Third year	133 (44)	29 (46)	16 (36)	5 (19)	183 (42)
Ethnicity[b], n (%)					
Kinh	269 (90)	59 (94)	40 (89)	24 (89)	392 (90)
Hoa	17 (5)	1 (1)	2 (4)	2 (7)	22 (5)
Others	14 (5)	3 (5)	3 (7)	1 (4)	21 (5)
Family monthly income[b,c], n (%)					
Less than 3 million VND	4 (1)	3 (4)	1 (2)	0 (0)	8 (2)
3-10 million VND	62 (22)	17 (27)	14 (34)	7 (27)	100 (24)
10-60 million VND	118 (40)	18 (29)	13 (32)	6 (23)	155 (37)
Over 60 million VND	6 (2)	1 (2)	1 (2)	1 (3)	9 (2)
Do not know	64 (22)	12 (19)	7 (16)	9 (35)	92 (22)
Prefer not to answer	39 (13)	12 (19)	5 (12)	3 (12)	59 (13)
Socioeconomic status[b,d], n (%)					
Poor	18 (6)	5 (8)	2 (5)	2 (7)	27 (6)
Average	244 (83)	49 (79)	33 (77)	20 (74)	346 (82)
Wealthy	0 (0)	1 (2)	1 (2)	0 (0)	2 (0)
Prefer not to answer	33 (11)	7 (11)	7 (16)	5 (19)	52 (12)

[a]Public health faculty includes the departments of preventive medicine, public health, and nutrition.

[b]Missing data: for ethnicity=2; for family monthly income=14; and for socioeconomic status=10.

[c]VND refers to Vietnamese Dong. 1 VND=US $0.00004328 (average VND to US dollar exchange rate in December 2020). For the family income bands, we applied the Vietnamese government's poverty threshold for 2016-2020 [28], and the 21-time disparity in income between the poorest and richest populations identified by Oxfam in their 2017 survey [29].

[d]Socioeconomic status refers to the students' personal assessment of their family's overall socioeconomic status within the Vietnamese context.

Most students (255/423, 61%) reported that their family's monthly income fell within the range of 3 to 60 million VND (approximately equivalent to US $121-$2432 per month, generally considered as "average"). Only a few students (17/423, 4%) stated that their families earned more or less than this range, and 36% (151/423) of the students responded "do not know" or "prefer not to answer" to the income questions. When asked to subjectively characterize their personal circumstances in the Vietnamese context, 346 of 437 (81%) students categorized their families' overall socioeconomic status as average, while a small proportion of students (27/427, 6%) stated their family as poor, the rest preferred not to respond.

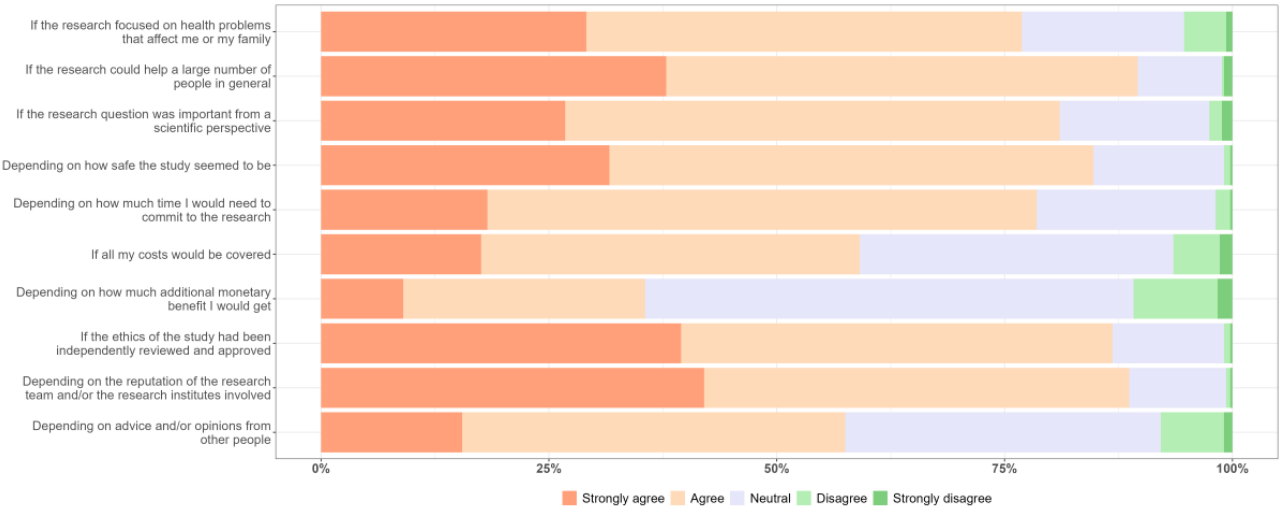
The 437 SEED cohort participants included in this analysis were reasonably representative of the eligible student population, although with a significantly greater proportion of public health students involved (Table S1 in Multimedia Appendix 2). A total of 74 students with diverse demographic characteristics were purposively selected to participate in the FGDs or IDIs (Table S2 in Multimedia Appendix 2).

Overall, students' decision-making about whether to participate in clinical research was often shaped by their perception of benefits, risks, and burdens associated with the studies, highlighting students' recognition of impacts on general society and individual participants. Most students agreed that the factors

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mentioned in Figure 2 might influence their own decision to participate in a clinical research study, except for the promise of additional monetary benefits. When asked to identify the most important factors influencing their decision-making to participate in clinical research, they primarily selected the relevance of research objectives to their own health or their family members' health, the potential for the study to benefit a large number of people, and to what extent the study appeared safe, followed by considerations relating to ethics approvals and the reputation of the institutions involved (Figure S1 in Multimedia Appendix 2). This section presents the quantitative and qualitative data analysis of students' perceptions on benefits, risks, and burdens of clinical research and how these perceptions influence their decision-making to participate (Figure 3).

Figure 2. Factors influencing students' motivation to participate in clinical research.



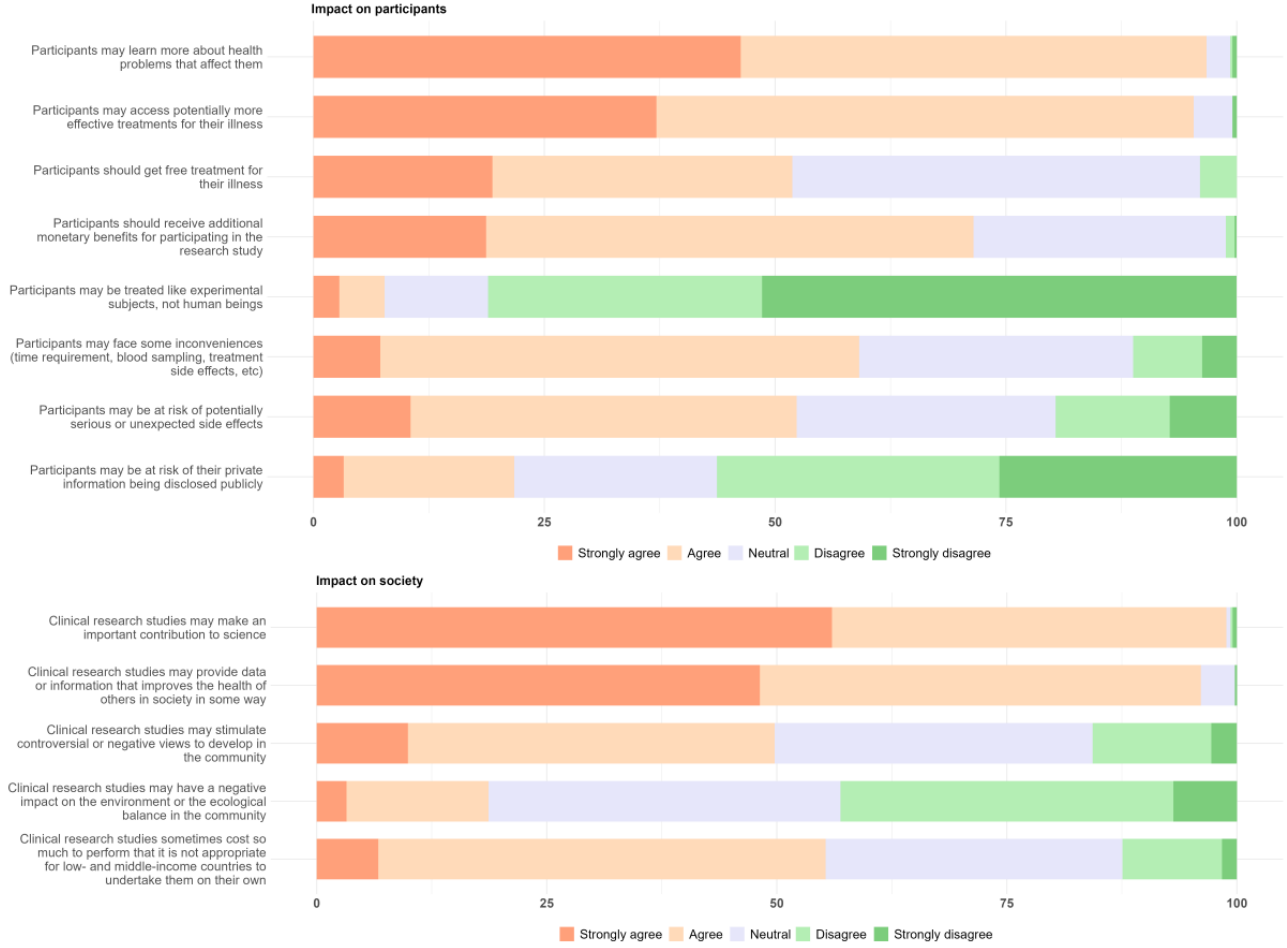
Motivation Driven by Perceived Social Value of Clinical Research

Clinical Research for Health Care Advancements

The data from the CS showed that almost all students (430/435, 99%) agreed that clinical research could make an important contribution to science and that data or information from research could help improve health in society (418/435, 96%; Figure 4). The perception that clinical research could benefit a large number of people was also identified as one of the most important factors influencing students' motivation to participate in clinical research (Figure S1 in Multimedia Appendix 2). In the IDIs and FGDs, students also emphasized how contributing to scientific development was one of the most important outcomes of clinical studies. A crucial principle of research, in their opinion, should be knowledge generation, leading to improvements in medical care or the development of novel public health interventions. Such advances were likely, in turn, to increase public trust in health systems. Students also noted that research conducted in high-prevalence settings could provide a better scientific foundation to explore disease causation and develop treatment strategies appropriate to the local epidemiological characteristics and context. These types of foundations would be directly beneficial to the people who carry the burden of such diseases. Improvements in disease control were another valuable outcome or impact of clinical research mentioned by the students. For instance, local vaccine-related clinical research efforts might result in reduced dependence on external vaccine supplies and greater autonomy in domestic vaccine development and manufacture, which could lead to broader vaccine access for the population, as well as contribute to greater public awareness of the benefits of vaccination. The students also noted that clinical research efforts could impact national solidarity by promoting altruistic values and encouraging community support.

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Figure 4. Students' perceptions of the potential impact of clinical research on society and participants.



> *I think the government provides partial funds for vaccine research. But in addition to government funding resources, there is great support from big corporations or celebrities [public figures in the countries] aiming to buy vaccines or develop domestic vaccines. This creates positive effects [in society] and at the same time enhances national unity, helping us to actively control the disease situation.* [FGD4 on vaccines and vaccine trials]

Conversely, alongside the mission of knowledge advancements, more than half the students (240/435, 55%) had concerns about the need for substantial investment in clinical research, such that it may be inappropriate for low- and middle-income countries to undertake such studies on their own. In the FGDs and IDIs, they explained that government resources should be preferentially allocated to address major public health issues (eg, lack of clean water, air pollution, or hygiene and sanitation) or to enhance health infrastructure and facilities, rather than investing in clinical research, which might be perceived as time-consuming with uncertain benefits.

Research Capacity-Building

Some students expressed the view that the success of specific research would depend on its overall social value for the community, whereas "research failure" would be determined not only by the occurrence of adverse effects on the health of study participants but also by other factors such as not following credible research procedures and lack of adherence to ethical principles. In the case of "unsuccessful research," which the students described as when research findings differ from the investigators' initial hypothesis, they believed that the research could still be valuable, for example, by improving research capacity during the establishment of a clinical study.

> *In my opinion, I think research only fails when it is done by using the wrong process. Even if the results are not as expected, the research still gives you lessons; it teaches you research methods. As for the results, I think that no matter what the result is, it is still a success, to a greater or lesser extent.* [FGD2 on clinical research and how it is relevant in Vietnam]

Local Relevance and Personal Motivation

Regarding the perceived social value of clinical research, a high percentage of students emphasized that they would consider participating if the research could help a large number of people (392/347, 90%) or because of the scientific importance of the research questions (352/435, 80%; Figure 2). In the IDIs and FGDs, they emphasized that they would consider the epidemiology of the disease before making the decision to participate. For instance, they would consider participating in a vaccine trial if the incidence rate of the disease being studied was high in their region and if it was challenging to access vaccines (eg, at the beginning of the COVID-19 pandemic).

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Otherwise, they would not participate in a vaccine trial if the disease was not prevalent in Vietnam.

> *When I participate [in a vaccine trial], I want to gain some benefit for myself. It could be to create an immune response against the disease. But if the disease is not urgent enough to worry me, I will not join.* [FGD5 about vaccine and vaccine trials]

Survey data showed that 77% (336/437) of students indicated that they would participate in clinical research that addresses health problems affecting themselves or their families (Figure 2). Although in the unadjusted analysis, slightly more students enrolled in the medicine than the public health faculty indicated that they would participate if the research focused on health problems relevant to them or their families (P=.04, chi-square test); no significant differences were apparent between the faculties after adjustment for multiple testing (Table S3 in Multimedia Appendix 2). This reflected the students' instrumental motivation, as they believed that their participation could benefit their family members' health by contributing to the ongoing development of relevant investigational products as potential therapeutics, which in turn would benefit society.

> *That is the community-driven mindset of each person, [desire] to contribute something to the community. Then it also a contribution to myself.* [FGD2 on clinical research and how it is relevant in Vietnam]

Interestingly, students were personally motivated to participate in clinical research by intellectual advantages, including the potential to gain new knowledge and experiences that could be valuable for their future careers, especially in the field of biomedical research.

Health-Related Considerations

Physical Health Benefits for Participants

Most students agreed that participants in clinical research could learn more about their disease (422/436, 97%) or access potentially more effective treatments for their illness (415/435, 95%; Figure 4). Additionally, several health-related advantages of clinical research in terms of participants' physical and mental health were mentioned by students in the FGDs and IDIs. First, the students highlighted the possibility of disease remission or cure through access to new drugs or new treatment strategies being applied in a research context, especially if they were experiencing serious illnesses without alternative treatments (eg, cancer).

> *Cancer patients, for example, if they are in the final stage [of the disease] and there is a study about something like a treatment measure that can improve their cancer condition, they might think, "oh I will die anyway, so I could try it."* [IDI10, nutrition, third year, female student]

Students also commented on the potential value of clinical research for vulnerable populations (eg, children, pregnant women, and older people) by providing them with access, under carefully supervised, controlled conditions, to new health care products, treatments, and services that are not typically recommended for them or in tailoring these products specifically for their needs.

> *I think vulnerable groups should be involved in [clinical research]. They should be allowed to participate equally in research compared to other people. Currently, only a limited number of research studies involve vulnerable groups such as children or pregnant women, yet these groups need more attention and care than others.* [IDI10, nutrition, third year, female student]

Personally, the students highlighted that their health conditions could be improved through access to free health check-ups before, during, and after the clinical research process. Further, they thought that they might develop immunity to the disease being studied through participation in vaccine trials, as one student mentioned:

> *If it [the trial vaccine] works, I will be among the first ones having immunity against that virus, won't I? I mean, I will be the one to get protection first.* [IDI4, medicine faculty, first year, female student]

Mental Health Support

A second dimension of health-related benefits for study participants mentioned by the students was mental health support. They included the possibility of developing supportive networks among participants during the clinical research process, encouraging informational and emotional sharing opportunities, as well as providing specific mental health counseling services (eg, stress relief) by the investigators.

> *I think it's possible to create a network with study participants. We have connections and bond them together. Even though the research is over, they [study participants] can still be in contact and help each other ... Some people join the study because they want to express and share their feelings [with other patients] or find solutions for their problems.* [IDI3, medicine faculty, third-year, male student]

Perceived Safety and Risks of Participation in Clinical Research

As shown in Figure 4, half of the students believed that participants in clinical research might be at risk of unpredictable or serious side effects (226/434, 52%), whereas few students worried about the risk of being treated like experimental subjects (33/434, 8%). In the FGDs and IDIs, students also elaborated on potential risks for participants' physical and mental health. For example, anaphylactic reactions, death, and disability were serious physical health consequences noted by the students; some students emphasized that they would refuse to participate in a clinical study if any of these significant health issues were listed in the informed consent, regardless of the likelihood of such events occurring. Others, however, considered the potential value to the community and weighed the severity of the disease (based on incidence and mortality rates) against the risk of participation.

> *If people [investigators] explain that a study, for example, its risks [for participants] could be fatal, or*

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> *could result in disability or paralysis, I feel it's dangerous. I will worry. So, I will not participate. On the other hand, [if the study has] some mild complications, or the incidence rate of severe complication is very low, and its [the study] benefits are great, I will participate.* [IDI3, medicine faculty, third-year, male student]

In terms of side effects, students indicated that they would accept research with temporary or mild side effects, such as fever, pain, or swelling at injection sites.

> *I think the side effects are acceptable if, at a minimum, they won't affect my daily life activities later on. These effects might last a few hours or a few days, but in the future, they might not have much impact. It's okay. These side effects are acceptable.* [FGD3 on vaccines and vaccine trials]

Other concerns revealed by the students in the IDIs and FGDs focused on the investigational products (eg, drugs or vaccine candidates or other interventions) and the study methodologies used in clinical research. The students indicated that they might have a limited understanding of the origin of investigational products and how the research methods were to be applied to estimate and control the interactions of these products with their intended biological targets. This, in turn, could contribute to students' concerns that the investigators might not be able to fully anticipate potential adverse effects on participants' health, leading to reservations about safety or unexpected health issues arising, not only during a study but also in the poststudy period or after completion of the designated follow-up visits. Notably, some students said that they would prefer to participate in studies using investigational products manufactured in high-income countries rather than those developed domestically because of a presumed higher level of manufacturing quality. Additionally, they indicated concerns about access to study-related health benefits, particularly access to the intervention being evaluated, among participants allocated to the control group in placebo-controlled studies. Regarding methodology, the students believed that, although findings from previous studies could provide a useful foundation for ongoing research efforts, using a design previously conducted in a study population with different genetic and epidemiological characteristics could lead to unexpected health consequences. Thus, assessing a vaccine previously tested elsewhere, in a new population, might result in unforeseen adverse effects—for instance, through interactions with other vaccines already deployed in the new setting or due to major differences in preexisting immunological profiles in the new study participants compared to the original group.

> *For example, talking about a trial conducted in America. These people, their physical health, their awareness of health, and the health system are different [to the Vietnamese context]. Their bodies are not exposed to as many infectious diseases as ours [Vietnamese people]. And their body sizes are also larger, and they might have better immunity. If we do the same trial here, the results may be different.* [FGD3 on vaccines and vaccine trials]

Participation Decision Fostered by Trust in Research Leaderships

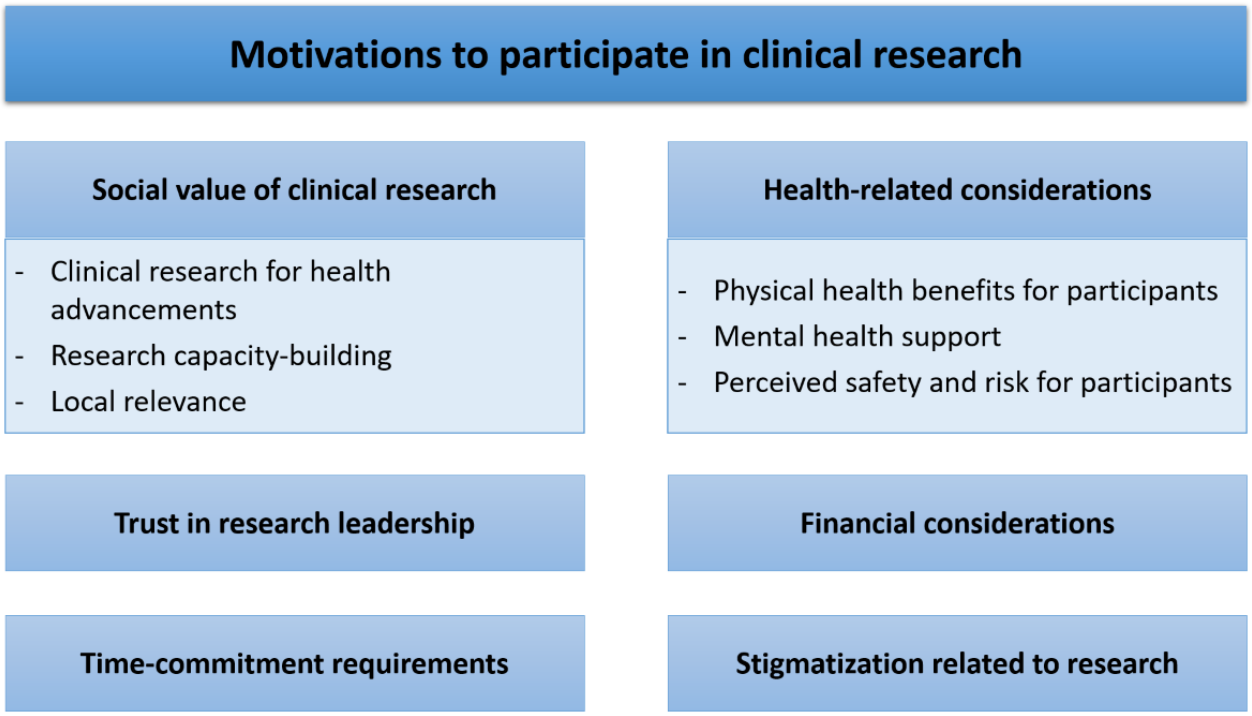
Data from CS showed that approximately 90% (388/437) of students linked their decision to participate in clinical research to the capacity of the research institutions involved (Figure 2). In the IDIs and FGDs, the students preferred studies conducted by institutions with "good reputations," which they assessed based on the number of studies conducted previously, the degree qualifications of the research staff, and collaboration with government agencies such as public hospitals, universities, or the Ministry of Health. Through such partnerships with government agencies, the students believed that the studies were approved ethically and legally, the participants' rights were secure, and compensation was available for any study-related harm. However, some students were still worried about rigorous adherence to safety principles during the research process and about the capacity of the research team and hospital facilities to respond effectively to study-related adverse events. In addition, trust in institutions might be built based on whether the study provided benefits to participants.

> *If research provides remuneration, I feel like that research group is more professional because it has a part to return to the participants what the participants lost. The group carefully calculates the portion that the participant loses, so it will reimburse the exact portion that the participant has lost. And if it's not all about money, but medical support for participants, that's also a form of compensation.*
>
> *... For research that has much impact on human health, by so if ensuring people's safety is given more priority, the research group will be [considered] more professional. As for research on the use of drugs, it has little impact on human safety [e.g., lab-based studies], [providing] more money [to participants] is ... I think it's more professional.* [IDI16, public health faculty, female, third-year student]

In addition, relatively few students (81/435, 19%) worried about potential negative impacts of clinical research on the environment or the ecological balance in the community, although 38% (166/435) of students gave a neutral response (Figure 3). Regarding these attitudes, students explained in the FGDs and IDIs that they believed that the investigators, under the supervision of ethics committees and other government agencies, were obliged to set up procedures to manage research waste and prevent pathogen transmission to the community prior to and throughout the research process.

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Figure 3. A framework for motivation factors of clinical research participation.



Financial Considerations

Monetary factors were discussed, but their impacts on the students' willingness to participate in clinical research were minor. Data from CS showed that over half of the students (260/437, 59%) reported that they would participate in clinical research if all their costs were covered, with a higher preference among first-year students than third-year students (P=.03; Table S3 in Multimedia Appendix 2). A minority of them (156/437, 36%) considered the additional monetary benefits they would get (Figure 2). In the IDIs and FGDs, students elaborated on the impacts of financial considerations on their willingness to participate in clinical research, in terms of reimbursement, compensation, and incentives.

Students pointed out that out-of-pocket expenses associated with participating in a research study (eg, transportation or accommodation expenses) might be a financial barrier for some people, especially those with low incomes. Reimbursement, considered in this study context as money given to the participant to refund their expenses, could encourage people to participate in clinical research. However, the students also conveyed that reimbursements would not be a major influence on their own decision to participate, especially if the study offered health-related benefits. For instance, study-related health benefits such as free access to new vaccines or treatments could motivate them to overcome any inconveniences, even if their expenses were not covered. Incentives, defined here as gifts (ie, money or material items) used to encourage people to participate and commit to research, could be another financial motive. However, students also noted that such incentives would likely have little impact on their own decisions on whether to participate in a study. They might be attracted by incentives, but only for low-risk studies (eg, observational studies) or studies with no health-related benefits. Compensation, the final dimension of remuneration that students discussed in the IDIs and FGDs, was defined as money or items given to participants to acknowledge time spent, data and specimen contributions, or other practical efforts they provided to support the clinical research.

> *When people participate in a study, they must put in some kind of effort. So ... generally, we [the study team] should give people something in return, so that they feel what they put in is worth [their time].* [FGD10 about reimbursement and compensation]

Further, students emphasized the importance of having a mechanism to compensate for unanticipated losses and harms related to the study. This might take the form of health insurance or financial restitution for future consequences of clinical research, such as physical and mental health impairment or disclosure of personal information. They perceived insurance as a right to which all participants should be entitled and as an essential component that should be compulsorily implemented in every study protocol. The provision of a financial support structure was vital to their decision-making to participate in clinical research because it would demonstrate the research team's commitment to addressing the future risks and preventing participants from encountering significant or even catastrophic out-of-pocket health expenditures after completion of the study.

> *Economic burden ... Supposing that I am the breadwinner of the family, and I have a health problem [as a result of the study], then I will become a burden to my family ... Most studies, from what I read, do not show their commitment to support the [participants'] family if something wrong happens, therefore, I think the family will be the first to suffer. And it also causes anxiety for society and for people*

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around me. [IDI4, medicine faculty, first-year, female student]

Perceived Burden and Inconveniences of Clinical Research

Stigmatizations Related to Clinical Research

As shown in Figure 4, half of the students believed that participants in clinical research might be at risk of inconveniences (257/435, 59%), whereas a few students worried about the risk of public disclosure of personal information (94/436, 22%). In the FGDs and IDIs, the students explained that they would not worry about confidentiality because they trusted the ethics committees to supervise data security and ensure that the study team rigorously followed data protection regulations. However, some students commented that participation in certain types of research could make them become a source of onward transmission to third parties (eg, family members or community contacts), and that, in turn, this could result in them experiencing social stigmatization. Furthermore, negative consequences on their physical health, especially severe adverse events, could lead to emotional and financial distress for study participants and their families.

Time-Commitment Requirements

Over 70% (334/437) of students agreed that estimations of time demands were essential for their considerations of participating in clinical research (Figure 2). The required time had more impact on third-year students than first-year students, as shown in both unadjusted (P=.001) and adjusted analyses (P=.01, chi-square test; Table S3 in Multimedia Appendix 2). During the IDIs and FDGs, the students noted that the main burdens making them hesitant to participate in clinical research could be the amount of time they would be required to commit to the study and its potential impact on their academic studies. As health care students often had hectic schedules, they found it difficult to commit to a study requiring a great deal of time. Thus, they worried that participation in clinical research might disrupt their academic studies as well as their daily lives, especially a research project requiring them to be absent from college.

I think that if I participate in research, I must invest a lot of time in it. But as a student, I feel that I do not have enough time to participate in such studies. [IDI1, medicine faculty, first-year, male student]

Discussion

Principal Findings

Clinical research was held in high esteem by students, who expressed positive views of a broad range of societal and personal benefits. The main value of clinical research highlighted by the students was scientific advancement leading to enhanced community health and active disease control. This perceived worth increased their altruistic motivation to participate in clinical research significantly. Personal benefits, such as access to free health care services and opportunities for advanced medical education, were linked to the students' health-related and intellectual motivations.

Although monetary considerations were discussed throughout the FGDs and IDIs, students might not view them as the primary reason supporting their decision to participate in clinical research. This result is comparable to a study conducted by Soule et al [30] examining participants' motivation to enroll in nontreatment-based research studies, in which they found that altruism had a more significant impact on participants' motivation for study involvement than health care or financial benefits. Additionally, given that the majority of students in the cohort considered themselves young and healthy people, their motivations to participate in clinical research using invasive procedures or investigational products are similar to those found in empirical studies on healthy volunteers in clinical research [31,32]. Manton et al [31] found that the prospect of self-development in health science, comprising the gains of valuable learning, life experiences, and opportunities to increase social interactions, could significantly promote healthy people to participate in clinical research. This idea was also brought up when we inquired from the students about their intellectual motivation to participate in our cohort study. The students' intellectual motivation also included curiosity about the scientific rationale behind clinical research, reinforcing their desire to contribute to research to advance future health care options. Therefore, it would be worthwhile to investigate the possibility of a connection between intellectual and altruistic motivations in the future.

The second noteworthy factor motivating students to participate in clinical research, according to our study, is their own self-interest in the positive effects clinical research could have on the community and their own health. This finding is consistent with a variety of literature reporting healthy participants' motivations for clinical trials including altruism, receiving free examinations, access to new advanced preventive treatments, or obtaining money [31-35]. Further, in previous research investigating 4 different forms of contingent relationships between participants' self-interest and altruism, Olsen et al [36] found a large group of people whose participation decision was motivated by altruism but also prioritized avoiding harm. Similarly, in our study, students reported that they would be willing to participate in clinical research for the sake of others but had safety limits to their altruism [36]. Thus, investigators should be aware of the complexity of the motivations during informed consent sessions, clarifying unreasonable expectations of therapeutic benefits, and encouraging altruistic motives involving the desire to help others without expecting personal gains, especially when recruiting healthy volunteers.

The study findings show that approval of ethics committees and the reputation of research institutions, which were also important to students' consideration to participate in clinical research, could be interpreted as a form of trust. In this study, only a few students expressed concerns that participants in clinical research might be at risk of being treated as "experimental subjects, not human beings"—that is, that their personal autonomy, rights, and dignity might be compromised during their participation in clinical research. This perspective indicated their acknowledgment of the ethics committees' roles in scrutinizing clinical research and protecting participants' rights. It has been

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documented in previous research that trust contributes significantly to willingness to participate in clinical research [33,37]. Further, participants' trust in institutions is closely linked to the institutions' research ethics mechanisms and reputation for integrity [37]. Thus, in order to build participants' trust, researchers and institutions should develop and maintain their ethics governance systems to acknowledge and transparently follow ethical guidelines and regulations aligned with the local and international principles [37]. Besides the impacts of institutions on participants' trust, the interpersonal trust between researchers and participants is crucial [11,33,38]. Researchers should consider reframing the participant information sheets and informed consent forms as "trust contracts" that explicitly address what researchers and institutions promise participants to do and not do, in addition to providing crucial research information (eg, research benefits, risks, and requirements). This form of consent could help to foster trust between participants and research teams and enhance motivation to participate in research [37,38].

Contrary to our expectations, we did not find any significant association between the students' characteristics (except academic year) and their attitudes toward various factors affecting their motivation to participate in clinical research. This finding does not support previous research, in which personal factors such as sex, age, health status, and prior clinical research experience were primary factors influencing decision-making regarding clinical research participation [11,17,39]. A possible explanation could be the differences in study population between our cohort—students from UMP at Ho Chi Minh City, who were generally considered themselves young and healthy, and the other study populations that included members of the general public across various age ranges.

Our study findings indicate that a crucial consideration contributing to decision-making around participation in clinical research was whether the research topics might be relevant to the respondents' own health issues or those of their family members. This finding seems to be consistent with previous studies showing that health issues of participants or their family members had major impacts on decisions to participate in clinical research [13,39].

Limitations

This study has some limitations. First, in the SEED project, we initially approached 1203 students registered at the faculties of medicine and public health at UMP to present a brief general study introduction, later providing more detailed information to students who expressed interest, and eventually recruiting a subgroup of 539 students to join the cohort (Figure 1). Despite the similarity in terms of sex balance and academic year distribution, a small difference was apparent in faculty distribution between students in our cohort and those we approached in the original series of introductory talks (Table S1 in Multimedia Appendix 2). This difference suggested that students from the medicine and public health faculties might have varying levels of self-efficacy to manage the demand of cohort activities. Additionally, since we only approached medicine and public health students to introduce the project, the cohort did not include representation from other disciplines such as nursing, medical technology, pharmacy, or traditional medicine. Thus, it is possible that data may not reflect the majority of students from other faculties in UMP. Second, during the ethics review process, the UMP ethics committee was concerned that students might feel coerced to participate in the cohort activities if it could influence their year-end average scores. To mitigate this risk, we clearly assured students in both verbal and written forms that their participation was entirely voluntary and that UMP staff had neither access to the participant list nor involvement in organizing any of the activities. A separate publication is in preparation, describing the students' experience of participating in the SEED project, but informal feedback indicates that coercion was not an issue for them. Third, although a broad overview of clinical research concepts was given to the students, we did not provide them a detailed protocol of a study, including specifics surrounding diseases, study design and methodology, investigational products, levels of invasiveness, and safety controls. Lack of access to detailed study information could lead to discrepancies between our findings and the actual enrollment in clinical research, especially in clinical trials [40,41]. Future studies should examine the specific circumstances under which behavioral intentions could predict actual enrollment and those in which participation intentions do translate into actions. Finally, we did not explore the impact of COVID-19 on the students' views about willingness to participate in clinical research. The data collection for this study started in mid-2020 when the COVID-19 pandemic was effectively controlled in Vietnam, with no community outbreaks but only occasional travel related to infections and vaccines not yet available. At that time, it was decided to not include any COVID-19–related questions. In retrospect, this would have been valuable data to collect, but at the time, we could not predict the magnitude or impact of this pandemic. Thus, to preserve the uniformity of the dataset, data on the impact of the COVID-19 pandemic on students' perception and attitude toward clinical research were not collected, even after COVID-19 became widespread and the Vietnamese government strongly encouraged people with medical backgrounds to volunteer for disease control activities [42]. Many students in our cohort responded to these governmental calls and took part in COVID-19 frontline prevention activities, such as performing diagnostic tests, helping medical professionals treat patients with COVID-19 at hospitals or health centers, or providing information about COVID-19 via free hotlines. Recent studies emphasized the impacts of the COVID-19 pandemic on clinical research recruitment and retention due to heightened anxieties toward clinical research participation, assess barriers, and safety concerns [43,44]. Therefore, we acknowledged that the students' perceived risk of COVID-19 and their experiences during the COVID-19 pandemic could have impacted their attitudes toward clinical research. These findings underscore the need for further studies to explore the students' motivation to participate in clinical research within the pandemic context.

Conclusions

This study found that the majority of students expressed favorable attitudes toward participation in clinical research. Their decision-making was significantly influenced by

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health-related benefits to themselves or family members, the possibility of intellectual growth, and the time commitment required by the study. The altruistic attitudes rooted in their perceived social value of clinical research also partly encouraged their participation in clinical research. These findings might be helpful for clinical researchers' understanding when developing outreach recruitment strategies for clinical studies involving student-participants or other young and healthy participants.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization: BW (lead), EK and JIVN (equal), HHTP, CLP, VP-T, DTHT, NMN, T Dinh The, HVB, TNTV, DDV, and TD Tran (supporting)
Data curation: CLP (lead), HHTP and VP-T (equal), HNTT and TNTV (supporting)
Formal analysis: CLP (lead), VP-T (equal), EK, JIVN, and HHTP (supporting)
Funding acquisition: BW (lead), EK (equal)
Investigation: HHTP (lead), CLP and VP-T (equal), DTHT, NMN, T Dinh The, HVB, KVD, TNTV, and HNTT (supporting)
Methodology: EK (lead), JIVN (equal), CLP, VP-T, and HHTP (supporting)
Project administration: TNTV (lead), HVB and KVD (supporting)
Resources: BW (lead), EW and JIVN (equal), DTHT, NMN, HHTP, and TNTV (supporting)
Software: HVB (lead), VP-T (supporting)
Supervision: BW (lead), EK, JIVN, DDV, and TD Tran (equal), TNTV (supporting)
Validation: BW (lead), EK and JIVN (equal), NMN (supporting)
Visualization: CLP (lead), VP-T (supporting)
Writing—original draft: CLP (lead), VP-T (equal), BW, EK, and JIVN (supporting)
Writing—review and editing: CLP (lead), BW, EK, JIVN, and VP-T (equal), HHTP, DTHT, T Dinh The, NMN, TNTV, HVB, KVD, HNTT, DDV, and TD Tran (supporting)

Conflicts of Interest

None declared.

Multimedia Appendix 1
Comprehensive survey.
[DOCX File , 63 KB - jopm_v18i1e86269_app1.docx]

Multimedia Appendix 2
Additional tables and figures. Table S1: Demographic characteristics of SEED cohort participants included in this analysis compared to those of students initially invited to join the cohort. Table S2: Characteristics of students participating in IDIs and FGDs. Table S3: Factors influencing students' decision to participate in clinical research by faculty and academic year at enrolment (n=437) Figure S1: The most important factors influencing students' motivation/willingness to participate in clinical research.
[DOCX File , 213 KB - jopm_v18i1e86269_app2.docx]

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Abbreviations

CS: comprehensive survey
FGD: focus group discussion
IDI: in-depth interview
UMP: University of Medicine and Pharmacy

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Cocreation of Digital Outcome Measures for Dravet Syndrome: Multistage Co-Design Feasibility Study

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Abstract

Background: Dravet syndrome is a complex developmental and epileptic encephalopathy characterized by treatment-resistant seizures and multiple comorbidities that significantly affect quality of life. Traditional clinic-based assessments often fail to capture real-world functional abilities and behavioral changes.

Objective: This study aimed to (1) identify caregiver-prioritized meaningful aspects of health, (2) co-design digital assessment modalities for home use, and (3) generate preliminary usability and implementation insights to inform future clinical research.

Methods: A multistage patient and public involvement activity was conducted between November 2023 and October 2025 in Spain, in collaboration with a patient advocacy organization and a digital health company. Participants were recruited through the Fundación Síndrome de Dravet using a convenience opt-in sampling approach. The process included a caregiver survey to identify meaningful aspects of health, a design workshop to refine priorities and technology preferences, and a 2-week usability testing of a prototype app, followed by a feedback workshop. Data were analyzed descriptively to inform iterative cocreation; no hypothesis testing was performed.

Results: Fifty caregivers completed the survey. Neuropsychiatric symptoms (17/48, 35%), independence (16/48, 33%), and social or leisure activities (15/48, 31%) were the most commonly reported affected domains. Eight caregivers participated in the design workshop, emphasizing flexibility, age-appropriate tasks, and reduced reporting burden. Usability testing was conducted with 5 caregivers over 2 weeks, with 4 of 5 caregivers providing feedback. Participants reported a generally positive reception of the digital tools, particularly customizable task selection and open-text fields, while identifying challenges related to video-recording logistics and questionnaire repetition. Feedback underscored the need for simplified workflows and individualized approaches to maintain engagement.

Conclusions: Cocreation with caregivers is feasible and appears essential for developing meaningful digital outcome measures for Dravet syndrome. Video-based tasks and remote reporting tools show promise for capturing motor, cognitive, and behavioral domains beyond seizure frequency. Future work should focus on iterative refinement and formal validation of these measures as end points in clinical trials, ensuring that they reflect outcomes that matter most to patients and families.

(J Particip Med 2026;18:e92512) doi:10.2196/92512

KEYWORDS

Dravet syndrome; clinical outcome assessment; cocreation; public and patient involvement; encephalopathy; participatory research; caregivers

Introduction

Dravet syndrome (DS) is a complex developmental and epileptic encephalopathy characterized not only by treatment-resistant seizures but also by pervasive neurodevelopmental, motor, and behavioral comorbidities that drive the day-to-day burden for families [1-6]. Clinic-based assessments, typically episodic and symptom-siloed, often fail to capture meaningful changes in cognition, behavior, autonomy, and participation in real-world contexts. As a result, outcomes that matter most to families, such as independence, communication, and emotional well-being, remain undermeasured and underrepresented in decision-making [7-12]. Despite growing interest in digital health technologies to capture performance in naturalistic settings, there remains a paucity of patient-relevant, DS-specific outcomes that are (1) feasible at home, (2) sensitive to change beyond seizures, and (3) acceptable to caregivers across ages and abilities [13-15].

Digital outcome measures have already been used to evaluate motor function outside a clinical setting [13-16], have been

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proved to be feasible, and are used across a broad range of diseases, including in some clinical trials [17,18]. However, few outcome measures have been robustly validated and formally qualified as primary or secondary end points in clinical trials [17].

This paper reports a multistage patient and public involvement (PPI) cocreation activity designed to inform the early development and future validation of digital outcome measures rather than to test predefined hypotheses. Food and Drug Administration and European Medicines Agency guidance [19,20] on the use of digital health technologies [21] in clinical investigations informed key design decisions, including the prioritization of patient-relevant outcomes, the use of home-based assessment modalities, and attention to participant burden. Patient-focused development frameworks supported the iterative refinement of digital features to align with caregiver priorities and early considerations of future validation and trial readiness.

The determination of what to measure and how to measure it must begin with patients and caregivers so that concepts of interest (COI), modalities, and usage burden align with real-world needs. A PPI approach is, therefore, essential to co-define meaningful aspects of health (MAH) and co-design usable tools that families are willing to adopt [22-24]. In this study, we present a PPI activity involving collaboration between Fundación Síndrome de Dravet (FSD) in Spain and Aparito Ltd (UK). The aim of this PPI activity was to collaboratively cocreate digital outcome measures for DS with caregivers while generating early insights into feasibility, acceptability, and practical implementation. Specifically, we sought to (1) identify caregiver-prioritized MAH, (2) co-design digital assessment modalities suitable for home use, and (3) generate early usability and implementation insights to inform future clinical research and end point development.

Methods

Study Design

We conducted a multistage PPI activity in collaboration with a patient advocacy organization (FSD, Spain) and a digital health company (Aparito Ltd, UK). The activity was carried out remotely using online surveys, virtual workshops, and home-based usability testing of a prototype app.

Design and Framework

The study was guided by Aparito Ltd's Patient Group Accelerator Program framework, which was developed to address unmet needs in rare disease patient groups. The framework incorporates principles of patient engagement, in addition to regulatory guidance proposed by the Food and Drug Administration and the European Medicines Agency, as well as recommendations from the Clinical Trials Transformation Initiative (CTTI) and the Digital Medicine Society on the development of patient-centric digital measures. The cocreation process followed a multistage approach, including a survey, a design workshop, usability testing, and a feedback workshop. A conceptual framework for quality of life (QoL) in DS was subsequently developed as a synthesis of findings from the literature review, survey, and design workshop, capturing key domains prioritized by caregivers and informing the interpretation of the results.

Using surveys and workshops with patient group representatives and caregivers, we aimed to ascertain the MAH, COI, and subsequent outcomes to be measured in a multistage cocreation approach.

Participant numbers at each stage were determined pragmatically, reflecting the exploratory PPI nature of the activity and the sequential, opt-in recruitment across stages. All survey respondents were invited to participate in subsequent stages, with participation declining at each step based on availability, interest, and scheduling constraints rather than predefined quotas.

Each phase of the activity was designed to build sequentially on the outputs of the previous one. Survey findings were summarized and presented to workshop participants at the start of the design workshop, providing a quantitative basis for discussion. Caregivers were asked to reflect on whether the survey results resonated with their own experience, to add nuance to or challenge the priorities identified, and to discuss technology preferences and measurement modalities in greater depth. The workshop thus served to qualitatively validate and refine the survey findings rather than replicate them.

The outputs of the design workshop, including agreed-upon priority domains, preferred activities of daily living (ADL) tasks, and caregiver input on app features such as the seizure diary structure, task flexibility, and questionnaire format, were translated directly into the configuration of the Atom5 prototype app used in usability testing. Specifically, the task list presented to usability testing participants reflected the ADL tasks discussed and endorsed during the workshop, the seizure diary form incorporated the fields and free-text options requested by workshop attendees, and the QoL questionnaire's frequency and format were adjusted in line with caregiver feedback on reporting burden. Usability testing then provided a first empirical test of whether these co-designed features were feasible and acceptable in a real home-use context over 2 weeks.

All the components were not administered as research outcome measures, and their outputs were not subjected to quantitative analysis. Rather, they served as experiential probes to generate caregiver feedback on the feasibility, usability, and acceptability of each feature in a real home-use context. Findings are therefore reported qualitatively as caregiver perceptions of each component rather than as performance or adherence metrics.

Study Timeline

The activity was conducted between November 2023 and April 2025. An initial agreement between Aparito Ltd and FSD was established in November 2023 to initiate the cocreation process. The caregiver survey was launched in January 2024 and remained open for 2 weeks (until January 31, 2024). A design workshop was conducted in May 2024 to refine priorities and explore technology preferences.

Between September 2024 and December 2024, a prototype app was developed, including the configuration of questionnaires,

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seizure diary features, and video-based tasks informed by the earlier phases. Usability testing was conducted between January 2025 and March 2025, with a 2-week testing period for each participant. A final feedback workshop was held in April 2025, after which the project was closed. The sequence and timing of the study activities are illustrated in Figure S1 of Multimedia Appendix 1.

Survey

A caregiver survey was developed to explore MAH, COI, and technology acceptance [25]. Items were adapted from the CTTI Question Bank for Identifying Meaningful Outcome Measures to ensure relevance to DS and feasibility for remote completion [26]. Questions were adapted for language simplification, removal of clinically interpretive items, and the addition of DS-specific examples. Final item selection was agreed upon jointly by patient representatives from FSD and researchers at Aparito Ltd.

Inclusion criteria for the study were (1) being of legal age (≥18 y), (2) residing in Spain, and (3) being a caregiver of a patient with a clinical diagnosis of DS. Informed consent was obtained from all participants. Potential participants were identified and contacted through the established caregiver network of FSD, including its mailing list, online support groups, and social media channels. No purposive or stratified sampling was applied; the survey was distributed broadly to all caregivers registered with or known to FSD. No minimum number of responses was predefined. Eligibility was based on self-identification as a caregiver of an individual with DS and on recruitment through FSD. The majority of participants were already engaged with FSD through support programs, newsletters, or prior interactions, which provides a high level of confidence in caregiver status within the context of service development and cocreation activities. Survey items were not mandatory to reduce respondent burden and allow caregivers to skip questions they considered not applicable. The survey is provided in Multimedia Appendix 1. It consisted of 23 open-ended and structured items organized into 5 domains: MAH, COI, outcomes to be measured, demonstration of therapeutic benefit, and technology acceptance. The survey was administered online through a secure web-based platform and distributed by FSD via its communication channels (eg, newsletters and direct outreach). Responses were collected anonymously, and participants could skip questions to minimize burden.

Design Workshop

A design workshop was conducted to gather qualitative insights and validate survey findings regarding technology modalities. Participants for the design workshop were recruited from among the survey respondents who had expressed willingness to participate in further activities. FSD staff contacted eligible individuals directly via email. Selection was guided by the age of the patient cared for and the area of residence to ensure a balanced distribution across age ranges and geographic locations. Eight caregivers participated. The discussion was facilitated by members of the research team with experience in patient engagement. The session was conducted using semistructured, open-ended prompts to elicit caregiver perspectives on priorities, usability, and technology preferences and lasted for 1.5 hours. The meeting was recorded and automatically transcribed using the built-in transcription feature of Microsoft Teams. Transcripts were subsequently reviewed and manually corrected by a member of the research team to ensure accuracy prior to thematic synthesis. Responses were synthesized thematically through iterative team discussion involving all members of the research team present at the session. Following transcription, each team member independently identified recurring concepts from the transcript before a joint discussion was held to compare observations, resolve discrepancies, and reach consensus on the final themes. Reflexivity was considered informally throughout the process, with team members acknowledging their dual roles as both researchers and members of the patient advocacy organization and actively discussing how this positionality might influence theme identification. Themes were required to reflect concepts raised by multiple participants independently rather than isolated comments to minimize the risk of researcher-driven interpretation. No formal qualitative coding software was used, consistent with the exploratory and hypothesis-generating nature of this PPI activity. Following the design workshop, the codeveloped inputs were translated into a prototype app configured within the Atom5 platform (Aparito Ltd). At the end of the 2-week period, participants provided feedback through a structured user experience survey administered within the app.

Conceptual Framework

The development of the framework was led by members of the research team at Aparito Ltd, including researchers with experience in patient engagement and digital health. Survey results were reviewed descriptively to identify caregiver-prioritized domains, while qualitative insights from the design workshop were examined to capture recurring themes related to daily functioning and QoL. These inputs were iteratively discussed within the study team to group related concepts into broader domains and structure the relationships between them. The resulting framework reflects a pragmatic synthesis of quantitative and qualitative findings, rather than a formal qualitative analysis, and was used to support the interpretation of the cocreation outputs.

Usability Testing

The purpose of the usability testing was to assess the feasibility, acceptability, and perceived usability of the co-designed prototype app in a real home-use context and to identify practical barriers and facilitators to engagement with each app component prior to any future formal validation study. A structured 2-week usability testing period was conducted to explore practical feasibility, caregiver experience, and usability of the codeveloped prototype app (Atom5). Five caregivers identified by FSD participated. Upon providing informed consent, participants received a QR code to download the app and were guided through onboarding via an in-app information module. Daily push notifications were sent to prompt the completion of tasks and questionnaires.

Caregivers were asked to complete 3 predefined components during the testing period: (1) a daily seizure diary, structured as a stepwise form with a yes or no question on seizure

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occurrence and optional fields for seizure type, duration, mood, location, triggers, event description, and postevent status; (2) up to 3 video-based ADL tasks selected by each caregiver from a codeveloped list (Table S1 in Multimedia Appendix 1) according to the patient's abilities and preferences, with standardized filming instructions provided in Spanish; and (3) bespoke QoL questionnaires for patients and caregivers, developed by drawing on validated instruments, including the EQ-5D-5L (EuroQol 5-dimension 5-level) and the DANCE (Dravet Syndrome-Associated Neuropsychiatric Comorbidities Evaluation; Checklist 1) checklist [27]. Questionnaire items were not directly adapted from these instruments but were newly developed by the research team, drawing on the conceptual domains identified in both the literature review and the caregiver survey. The established instruments served as a reference framework to ensure content validity and alignment with previously validated constructs rather than as a source of verbatim or modified items. Video recordings could be captured directly within the app or recorded externally and uploaded to the platform. All videos were stored only for the duration of the testing period on a secure, encrypted platform, with access restricted to a single designated researcher. These instruments were developed specifically for this activity and were not formally pretested or psychometrically validated prior to use, which is consistent with the exploratory PPI nature of the activity.

At the end of the 2-week period, participants completed a structured user experience survey administered through the app that assessed ease of onboarding, app usability, clarity of instructions, comfort with video recording, and perceived usefulness of features such as voice activation and push notifications.

Given the exploratory and hypothesis-generating nature of the activity, the primary goal of usability testing was to assess caregiver experience, perceived usability, and willingness to engage with the platform rather than quantify adherence or generate performance benchmarks. Subjective caregiver feedback was therefore prioritized as the main data source, consistent with the PPI framing of the activity. Future studies with a formal feasibility or validation design should incorporate objective engagement metrics as predefined end points.

Caregivers who had participated in the survey were invited to take part in usability testing. Given the exploratory nature of the activity, no formal selection criteria were applied beyond prior participation and willingness to engage with a smartphone app for a 2-week period. FSD staff coordinated the recruitment through direct contact.

Feedback Workshop

A final feedback workshop was conducted remotely via video conference to gather in-depth reflections on the usability testing experience. The session was facilitated by members of the FSD and Aparito research teams and followed a semistructured discussion guide based on the findings from the end-of-period user experience survey (Multimedia Appendix 1), covering topics such as task feasibility, seizure diary usability, questionnaire burden, video-recording challenges, and the overall app experience. The session was not formally recorded; notes were taken by a member of the research team during the session. FSD invited all 5 caregivers who had completed usability testing to participate in the feedback workshop via direct email. No additional selection criteria were applied. The meeting lasted 1 hour.

Each stage (Table 1) built on the previous one, allowing iterative refinement based on caregiver feedback. Objective usage metrics, such as task completion rates, submission frequency, or time on task, were not systematically collected during this phase.

Table . Stages of involvement throughout the patient and public involvement activity.

Stage	Activity	Participants	Role and level of involvement	Impact on design
Survey	Identify MAH[a]	50 caregivers	Consultation	Prioritized neuropsychiatric symptoms and independence
Design workshop	Validate priorities and discuss tech	8 caregivers	Collaboration	Selected video tasks and simplified diary
Usability testing	Test prototype app	5 caregivers	Partnership	Requested open-text fields and flexible task list
Feedback workshop	Reflect on experience	2 caregivers	Partnership	Recommended reduced questionnaire frequency

[a]MAH: meaningful aspects of health.

Ethical Considerations

This activity was prospectively designed and conducted as a PPI activity rather than as biomedical research, and it does not constitute biomedical research under Spanish Law 14/2007 on Biomedical Research; therefore, formal research ethics committee approval was not required. No clinical interventions were performed, and no identifiable personal data were collected. All participants provided informed consent prior to participation and were informed about the purpose of the activity, the voluntary nature of their involvement, the types of data collected (including optional video recordings), data storage duration, restricted access procedures, and the intention to disseminate aggregated findings in a peer-reviewed publication. Participants did not receive financial compensation or material incentives. Data handling complied with the European Union General Data Protection Regulation (2016/679) [28] and the Spanish Organic Law 3/2018 on Data Protection and Digital

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Rights [29]. Throughout the activity, ethical principles of transparency, informed consent, proportionality, and data minimization were applied in accordance with the recommendations of the Spanish Code of Good Practices in Health Research (Instituto de Salud Carlos III) [30].

Results

Survey Findings

A caregiver-targeted survey was conducted over a 2-week period in January 2024. The survey included 5 thematic sections: MAH, COI, outcomes to be measured, demonstration of therapeutic benefit, and technology acceptance, incorporating questions adapted from the CTTI Question Bank for Identifying Meaningful Outcome Measures. A total of 50 caregivers responded; however, not all respondents answered every question, as completion of individual items was optional. A summary of the results is provided in Table 2.

Table . Summary of caregiver survey findings (n=50; not all respondents answered every item).

Domain and key finding	Values, n/N (%)
Most impacted areas (patient)	
Neuropsychiatric symptoms	17/48 (35)
Independence	16/48 (33)
Social and leisure activities	15/48 (31)
Most impacted areas (caregiver)	
Loss of independence	19/47 (40)
Reduced social or leisure activities	18/47 (38)
Totally affected (patient)	
Independence	25/48 (52)
Totally affected (caregiver)	
Independence	21/48 (44)
Barriers to daily activities	
Neuropsychiatric symptoms	22/45 (49)
Motor or physical limitations	19/45 (42)
Desired improvements	
Seizure reduction	16/42 (38)
Communication	12/42 (29)
Attention and cognition	11/42 (26)
Priority for judging treatment benefit	
Seizure reduction	35/44 (80)
Neuropsychiatric improvement	16/44 (36)
Technology acceptance	
Digital tools useful for clinical measurement	25/40 (63)
Willingness to use smartphone app	34/42 (81)
Good tolerance of wearables	31/45 (69)

Findings from the survey addressed aim 1 by identifying caregiver-prioritized MAH. Fifty caregivers completed the survey; however, not all respondents answered every item, as completion was optional. Key findings are summarized in Table 2.

Neuropsychiatric symptoms, independence, and social participation emerged as the domains most impacted by DS for both patients and caregivers. Independence was reported as totally affected by more than half of caregiver respondents for their care recipients and by nearly half for themselves. The primary barriers to daily activities were neuropsychiatric symptoms and motor or physical limitations.

Regarding treatment priorities, seizure reduction was overwhelmingly the most valued outcome, followed by neuropsychiatric improvement. When asked what could be measured at home, respondents most frequently selected seizures, the emotional impact on the family, and performance in daily tasks. Technology acceptance was high: the majority of respondents viewed digital tools as useful for clinical measurement, and their willingness to use a smartphone app

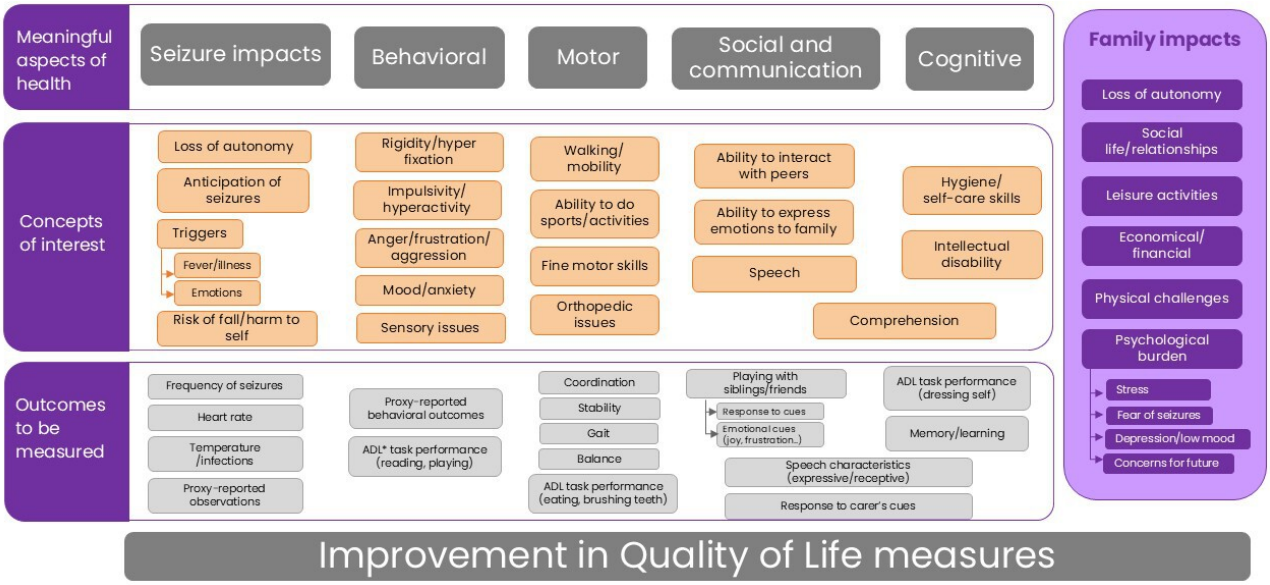
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for symptom reporting was particularly strong. Wearable devices were generally accepted, although concerns about tolerability were noted by a minority of respondents.

Design Workshop

Following the survey, 8 caregivers participated in a workshop to gather qualitative insights, validate the survey findings, and discuss technology preferences. Findings from the design workshop addressed aim 2 by informing the co-design of digital assessment modalities. These findings also contributed to the development of a conceptual framework summarizing key domains of QoL in DS (Figure 1) as a synthesis of the survey results and themes identified during the design workshop. Caregivers highlighted the importance of cognitive issues, although these were noted to fluctuate depending on various factors, such as the patient's age, mood, and time of day. It was also mentioned that cognitive and social afflictions were often accepted as something that cannot be changed. Moreover, caregivers expressed concerns about the onset of puberty, which could cause potential exacerbation of the disease and changes in the child's behavior or cognition due to hormonal changes. A subset of participants expressed a more immediate focus on motor development and speech, given the young age of their children.

Figure 1. Conceptual framework of quality of life in Dravet syndrome (DS) obtained from the literature review, incorporating meaningful aspects of health identified for patients with DS and their families, and responses to the questionnaire and design workshop. ADL: activities of daily living.



Despite these differences, the group converged on a shared set of MAH that was broadly consistent with the domains represented in the conceptual framework of QoL in DS (Figure 1). This convergence was assessed informally: themes were considered to reflect group agreement when raised independently by multiple participants without substantive objection from others, consistent with the exploratory and nonformal nature of this PPI activity.

When asked about their willingness to use digital tools, participants saw value in being able to monitor health variables, especially in the context of DS, which requires a high level of monitoring by caregivers. However, concerns were raised about the practicality of wearing devices, the accuracy of measurements, especially in the case of movement, and the cost-effectiveness of certain products. The idea of using these devices at specific time points, such as during a clinical trial rather than continuous monitoring, was also suggested. Among the tasks and activities that could be valuable to collect in a clinical trial were monitoring sleep patterns during the day and at night, tracking autonomy and movement around the house, and assessing fine motor skills. The ability to walk, and how this varied throughout the day and with mood, was also identified as a potentially valuable measure.

Overall, while participants see the potential benefits of digital tools, they also highlight the need for reliable, accurate, and user-friendly devices and the importance of measuring both physical and cognitive aspects in clinical trials.

During the workshop, attendees provided input on the design features:

- Seizure diary was designed as an in-app feature with a simplified input form that captures whether a seizure occurred (if not, the user can submit and return to the homepage), seizure type (according to the most recently published International League Against Epilepsy seizure classification [25]), duration, mood, location, triggers, event description (in lay terms), and postevent status.
- Task selection and video tasks were designed to capture neuropsychiatric aspects affecting ADLs, such as eating, playing, dressing, and communicating, based on the activities discussed by caregivers during the workshop. The cocreated tasks reflect relevant ADLs for patients with DS across age groups (Table S1 in Multimedia Appendix 1). Video-based assessments may provide a more objective alternative for individuals unable to complete patient-reported outcomes, such as young children or those with severe disabilities [16,31].

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The prototype comprised 4 main modules informed directly by workshop outputs: (1) a screening questionnaire collecting basic demographic information (caregiver gender and age, relationship to the individual with DS, and the patient's age), used to verify eligibility and contextualize responses; (2) a bespoke caregiver QoL questionnaire, administered on a recurring basis, including items rated on 0 to 10 numeric scales (eg, agreement with statements about the patient's condition; perceived change relative to baseline ranging from "much worse" to "much better") and multiple-choice items (eg, seizure frequency over the past 4 weeks: stable, improvement, worsening, or unknown). Items were presented in Spanish; (3) a daily seizure diary, structured as a stepwise form starting with a yes or no question on seizure occurrence, followed by optional fields for seizure type, duration, mood, location, triggers, event description, and postevent status; (4) a video task module, presenting a codeveloped list of ADL tasks from which caregivers could select up to 3 according to the patient's abilities and preferences, with standardized filming instructions provided in Spanish.

The app was configured in Spanish throughout and included an onboarding module, daily push notifications, and a final user-experience survey administered at the end of the 2-week period.

Usability Testing

Findings from the usability testing and the feedback workshop addressed aim 3 by providing preliminary insights into usability and implementation. Usability testing was conducted with 5 caregivers identified by FSD (3 mothers and 2 fathers) over a 2-week user-testing period using a prototype app configured within Atom5.

Four participants completed the survey. The platform received positive feedback regarding the onboarding process, app usability, and the feasibility of using the app at home to collect data. There was some negative feedback regarding task recordings being challenging to get a clear video and requiring 2 people, in addition to not receiving or finding the push notifications to be useful (some testers may not have allowed them when onboarding onto the app accidentally). The general feedback was positive, with 1 participant mentioning that the questionnaire felt a bit repetitive. These points were followed up during the feedback workshop.

Feedback Workshop

The caregivers who tested the app were invited by FSD to participate in a workshop to discuss their experience with the app. Due to scheduling difficulties, only 2 caregivers attended; both were parents of the same adult individual with DS. Feedback from the 2 caregivers highlighted the need for flexibility and adaptability in task design and data entry. Some tasks were perceived as too simple or too brief, whereas others varied in difficulty depending on the individual's cognitive and motor abilities, underscoring the importance of allowing task selection and adaptation. Caregivers valued the ability to modify or switch tasks when activities were neither engaging nor feasible, supporting the need for a broad and customizable task list.

Participants also emphasized flexibility in seizure reporting and requested open-text fields and skip options when predefined categories did not adequately capture seizure characteristics, triggers, or mood changes. Repetitive data entry for frequent or similar seizures was described as burdensome, with suggestions to reduce reporting fatigue through more efficient input options.

Concerns were also raised regarding the questionnaire frequency, with caregivers indicating that overly frequent administration could be tiring and demotivating, particularly given the slow pace of change in QoL. Finally, the recording of video tasks was reported as challenging in some situations due to attention limitations, the need for caregiver assistance, and technical constraints, highlighting the importance of flexible recording requirements and clear guidance [32].

Objective usage metrics, such as task completion rates or submission frequencies, were not systematically collected during this exploratory usability phase.

Impact of PPI on Design

Caregiver input shaped multiple design decisions, including (1) a simplified input form and the addition of open-text fields for atypical triggers in the seizure diary; (2) an expanded task list for video recording to accommodate varying abilities, with the option to substitute tasks; (3) reduced frequency and added customizable intervals to minimize questionnaire burden; and (4) adjusted notification settings based on caregiver feedback about usability. These changes illustrate how PPI moved beyond consultation to active cocreation, ensuring that the prototype reflected real-world needs.

These recommendations are summarized in Table 3. Changes implemented in the initial prototype reflect co-design decisions made during the workshop phase, whereas recommendations arising from usability testing and the feedback workshop are intended to inform the next development iteration.

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Table . Mapping of caregiver feedback to design recommendations across patient and public involvement stages.

Stage	Caregiver feedback	Design recommendation	Status
Design workshop	Need for flexible task selection according to patient age and ability	Codeveloped customizable ADL[a] task list; caregivers select up to 3 tasks	Implemented in prototype
Design workshop	Simplified seizure reporting to reduce burden	Stepwise form with yes/no entry point and optional fields	Implemented in prototype
Usability testing/feedback workshop	Questionnaire frequency perceived as repetitive and tiring	Reduce questionnaire administration frequency; consider quarterly completion	Recommended for next iteration
Usability testing/feedback workshop	Push notifications not received or enabled during onboarding	Review onboarding flow to ensure notification permissions are explicitly requested	Recommended for next iteration
Usability testing/feedback workshop	Video recording challenging without a second person; need for flexibility	Expand task list; allow task substitution; clarify filming instructions	Recommended for next iteration
Usability testing/feedback workshop	Open-text fields needed for atypical seizure triggers	Add free-text option to seizure diary trigger and description fields	Recommended for next iteration

[a]ADL: activities of daily living.

Discussion

Principal Findings

This multistage PPI activity demonstrated that caregivers of individuals with DS can actively contribute to the identification, prioritization, and early design of digital outcome measures intended for home-based use. Across the survey, workshop, and usability testing stages, caregivers consistently emphasized neuropsychiatric symptoms, independence, and daily functioning as meaningful domains, and highlighted the importance of flexibility, reduced reporting burden, and adaptability to the wide variability in abilities, which aligns with recent findings [33,34].

This activity was designed as a hypothesis-generating PPI activity rather than as hypothesis-driven biomedical research, which limits inferential interpretation but is appropriate for early cocreation and feasibility assessment. The Aparito Patient Group Accelerator Program provided the framework for involving patients and caregivers starting from the initial stage of codevelopment for new digital outcome measures, ranging from the identification of the MAH to content design and final user testing [21].

This cocreation approach is particularly relevant for complex conditions such as DS, where patient experiences are highly variable and multifaceted [32]. Involving caregivers from the outset is essential to ensure that the tools developed are meaningful, usable, and aligned with real-world needs. The activity illustrated that the impact of DS on daily life varies considerably across patients and families, reflecting the heterogeneous and multifaceted nature of the condition, and confirming previous results [12,35].

Caregivers' input influenced priorities (neuropsychiatric symptoms and independence), technology choices (video tasks and simplified diaries), and usability features (open-text fields and flexible task lists). Digital tools were perceived positively by participating caregivers, a finding consistent with previously published findings [36,37], although conclusions are limited by the small, self-selected sample [32,35]. The bespoke QoL questionnaires developed in this activity represent the first iteration of a cocreated instrument and were not designed for immediate use as validated end points. Future work should focus on formal psychometric validation, including assessment of content validity, test-retest reliability, and responsiveness to change, with a view to qualifying the instrument as a patient-reported outcome measure suitable for use in clinical trials.

Feedback from the seizure diary component emphasized the importance of flexibility in reporting. Although seizure diaries have been widely used in DS to monitor seizure frequency and duration [38,39], caregivers in our pilot highlighted the limitations of rigid categorization and the need for open-text fields to better capture individualized triggers and seizure types. Regarding QoL assessments, caregivers suggested that quarterly completion would be optimal to avoid fatigue and disengagement.

The feedback gathered underscores the importance of iterative design, caregiver involvement from concept generation to design and testing, and contextual sensitivity in digital health innovation. These findings inform both the future development of digital platforms and clinical trial design and contribute to broader efforts to create meaningful, patient-centered digital outcome measures for rare and complex conditions.

The feasibility of conducting meaningful PPI with caregivers of individuals with DS warrants substantive reflection, as the process itself generated important learnings beyond the design outputs. Recruitment through FSD's established caregiver network facilitated initial engagement and provided a high level of confidence in participant eligibility but also introduced a degree of selection bias toward more engaged and digitally receptive families. Retention across stages declined substantially, from 50 survey respondents to 8 workshop participants, to 5 usability testers, and finally to 2 feedback workshop attendees. This attrition pattern is consistent with

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what has been reported in PPI activities with caregivers of individuals with complex rare conditions, where competing caregiving demands, fatigue, and scheduling constraints are pervasive barriers to sustained participation [40-42]. Caregivers of individuals with DS, in particular, carry substantial psychosocial and practical burdens that may limit their availability for multistage research engagement [43].

Several elements appeared to support engagement in the earlier stages of the activity. The survey format was well suited to this population: it was brief, remote, optional in terms of item completion, and distributed through a trusted advocacy organization. The design workshop benefited from being conducted as a group session, which created a sense of shared experience among participants and facilitated richer discussion than individual interviews might have generated. Caregivers responded positively to seeing their survey results presented back to them at the start of the workshop, which reinforced the sense that their input was valued and acted upon.

However, sustaining engagement across the full multistage process proved challenging. The 2-week usability testing period required a substantial and sustained time commitment from caregivers who already carry high daily burdens. The low attendance at the feedback workshop, despite flexible scheduling and multiple reminders, suggests that even well-intentioned accommodations may be insufficient when competing with the daily realities of caring for an individual with DS. In retrospect, a shorter or asynchronous feedback format, such as a brief structured questionnaire or a recorded video response, might have achieved higher participation at this stage while preserving the depth of feedback needed.

These findings have direct implications for the design of future PPI activities and cocreation studies in this population. We would recommend (1) front-loading the most critical co-design decisions to the earliest, highest-participation stages; (2) offering asynchronous participation options at later stages to reduce scheduling barriers; (3) considering staged incentivization or recognition of caregiver contributions to support retention; and (4) building explicit dropout contingency plans into multistage PPI designs, particularly for final validation or feedback stages. More broadly, the attrition observed across stages should not be interpreted solely as a methodological limitation but also as a substantive finding about the feasibility of sustained PPI engagement in this population that may be transferable to other rare disease contexts with similar caregiver burden profiles.

Limitations

This activity has several limitations. First, participant numbers decreased substantially across stages, with only 2 caregivers attending the final feedback workshop despite all 5 usability testing participants being invited and reminded on multiple occasions. Both attendees were parents of the same adult individual with DS, which limits the diversity of perspectives captured at this stage and introduces a risk of homogeneity bias in the final feedback. This attrition likely reflects the considerable competing demands faced by caregivers of individuals with complex conditions, for whom participation in multistage research activities can be difficult to sustain over time. Proactively addressing these barriers, for example through shorter or asynchronous feedback formats, more flexible scheduling, or dedicated caregiver support, will be important in future cocreation studies with this population. The limited and homogeneous participation in the feedback workshop should be considered when interpreting the design recommendations that emerged from this stage. Second, caregiver status was based on self-report and recruitment through FSD rather than independent clinical verification, which may introduce selection bias toward more engaged or digitally receptive caregivers. The sample, therefore, probably does not represent the full spectrum of DS caregivers, and findings on acceptability and usability may be more optimistic than would be observed in a broader or less self-selected population. Third, usability testing was short in duration and did not include objective usage metrics, such as task completion rates or adherence over time, as this was not the purpose of the testing. Finally, the activity was conducted in a single language and geographic context, which may limit cultural transferability.

Participant demographic and clinical characteristics were not systematically collected across all stages of the activity, in line with the data minimization principles applied throughout. As a result, it is not possible to characterize the sample in terms of caregiver relationship, patient age range, or digital familiarity, which limits readers' ability to contextualize the findings and assess their broader applicability. Future cocreation studies with this population should consider collecting a minimal set of anonymized descriptors, such as caregiver relationship, broad patient age group, and self-reported digital experience, to strengthen interpretability without imposing undue burden on participants.

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Conclusions

This PPI activity suggests preliminary feasibility and the potential value of codeveloping digital outcome measures for DS through the active involvement of caregivers and patient advocates. By leveraging insights from the conceptual framework, we identified digital options to capture seizures, daily functional abilities, and QoL in the home environment. We addressed important gaps in current assessment tools, particularly the limited ability of clinic-based evaluations to reflect the real-world impact of neurodevelopmental and behavioral comorbidities. With this activity, video-based tasks have been identified as a promising approach to remotely observe motor, cognitive, and social behaviors that may not be easily measured using traditional scales or in the clinical environment.

This PPI activity contributes (1) a cocreated concept set of outcomes and home-based assessment modalities prioritized by caregivers; (2) usability and acceptability insights that translate caregiver preferences into concrete design requirements (eg, flexible task lists, open-text fields, and reduced reporting burden); and (3) a pathway for trial readiness, specifying how cocreated measures may be iteratively refined and prepared for future psychometric validation and regulatory alignment.

Future work should focus on iterative refinement of the tools and rigorous validation of digital end points in longitudinal

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studies and clinical trials. Ultimately, integrating cocreated digital measures into clinical research and care pathways may support a more comprehensive evaluation of emerging therapies by capturing changes that truly matter to individuals with DS and their families.

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Data Availability

The anonymized data generated during this patient and public involvement activity are available from the corresponding author upon reasonable request.

Authors' Contributions

NS, EFM, JAA and SG conceptualized the design of the patient and public involvement activity. JAA, SG, ACM, and NSM coordinated caregiver engagement and data collection. EFM and NS developed the digital platform prototype. SG and NS drafted the manuscript with input from all authors. All authors reviewed and approved the final version.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Timeline, survey, and interview guide.
[DOCX File, 71 KB - jopm_v18i1e92512_app1.docx]

Checklist 1
DANCE checklist.
[DOCX File, 61 KB - jopm_v18i1e92512_app2.docx]

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Abbreviations

ADL: activities of daily living
COI: concepts of interest
CTTI: Clinical Trials Transformation Initiative
DANCE: Dravet Syndrome-Associated Neuropsychiatric Comorbidities Evaluation
DS: Dravet syndrome
EQ-5D-5L: EuroQol 5-dimension 5-level
FSD: Fundación Síndrome de Dravet
MAH: meaningful aspects of health
PPI: patient and public involvement
QoL: quality of life

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Developing a Health App Quality Report for CEN-ISO/TS 82304-2 to Satisfy Health Care Professionals' Information Needs on the Quality of Health Apps: Participatory Design Study

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Abstract

Background: Health apps, which comprise medical and wellness apps, hold potential to improve prevention, diagnosis, treatment, and management of disease. Yet, recommendation and prescription rates by health care professionals (HCPs) are low. Trusted standardized health app quality reports providing the information HCPs need to recommend or prescribe a specific app for an individual patient and guidelines from medical societies are considered crucial to enable this digital transformation of medicine. The CEN-ISO 82304‐2 (hereinafter "82304‐2") Technical Specification, an initiative of the European Commission, includes a research-based health app quality assessment framework comprising 81 quality requirements. Results of 82304‐2 app assessments are summarized in an intuitive "health app quality label." The 82304‐2 quality label's potential to increase HCP willingness to recommend health apps was recently confirmed. To adequately enable decision-making and thus app recommendations, 82304‐2 proposes a more detailed "health app quality report" to complement the 82304‐2 quality label.

Objective: This study aimed to design the 82304‐2 health app quality report that satisfies the information needs of individual HCPs in decision-making on an individual health app for an individual patient.

Methods: A participatory design approach was applied. In an 18-month process of participatory prototyping with 9 HCPs with digital health expertise, the 82304‐2 quality report was iteratively designed. A convenience sample of 31 HCPs indicated the priority 82304‐2 quality requirements they considered useful in decision-making on recommending an app, and thus needed detailed quality information. Final feedback meetings with the 9 HCPs and 8 medical societies were used to finalize the 82304‐2 quality report design. Web-based questions in these meetings, feedback from the Dutch Patient Federation, and a comparative content analysis and the Health Education Materials Assessment Tool were used to evolve to and evaluate the final 82304‐2 quality report design.

Results: In total, 37% (30/81) of the 82304‐2 quality requirements were prioritized by >50% of the HCPs. The final 82304‐2 quality report design provides detailed information for 90% (27/30) of the prioritized quality requirements. The reporting detail for 2 quality requirements requires more research. The final feedback meetings, the Patient Federation feedback, comparative content analysis, and Health Education Materials Assessment Tool provide indicative proof of the usefulness and usability of the quality report design.

Conclusions: We succeeded in our aim to design the 82304‐2 health app quality report and found promising potential for its distinctive usefulness for HCPs and patients in recommending and considering a health app, respectively, and for medical societies in creating guidance. Further efforts are needed to test its effectiveness, fine-tune multistakeholder and intercontinental usefulness and usability, support medical societies in providing guidance and potentially training on recommending health apps, and advance from the current design to a scalable fully functional version of the quality report and associated open access database.

(J Particip Med 2026;18:e86473) doi:10.2196/86473

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KEYWORDS

health app; digital health; health care providers; medical societies; information needs; participatory design

Introduction

Within the broader field of digital health technologies, health apps are defined as software applications that can be executed on a computing platform, intended specifically for managing, maintaining, or improving the health of individual persons or the delivery of health care [1]. Health apps comprise both apps that can be used for medical purposes and wellness apps [2]. Patients' willingness to use health apps is high [3]. Recommendations provided by their health care professionals (HCPs) positively affect patients' trust in and willingness to use, pay for, and download a health app, and matter especially for those with lower digital literacy [4-8]. Only some countries have already implemented reimbursement mechanisms for health apps that require app prescriptions by HCPs [9,10]. Germany, France, and Belgium are recognized front-runners [9]. Germany now reimburses 57 apps via its "DiGA" fast-track and France 4 apps via its "PECAN" initiative [11]. Belgium has exchanged its individual app ("validation pyramid") approach for a care pathway approach where participating hospitals individually identify, evaluate, select, and, if applicable, procure the type of apps described in their contract with the funding agency. The first care pathway (telemonitoring after hospitalization for heart failure) is now approved [11]. Of these 3 countries, Germany is the only one to provide HCPs with a directory with detailed information on the prescribable reimbursed health apps [11], all of which are evidence-validated digital medical devices, referred to in German as "Digitale Gesundheitsanwendungen" or "DiGA" [12].

German prescription behavior studies indicate that HCPs increasingly observe benefits of these apps, such as health promotion, mobility, prevention, empowerment, health literacy, improved adherence, disease self-management, health benefits, and better access to care. Yet, intent to prescribe or recommend them and the number of actual prescriptions are low and differ per medical specialty [13-18]. Over the course of 5 years on a population of 73 million in statutory health insurance, in total 1.6 million app prescriptions have been issued by German HCPs, predominantly (51%) by general practitioners (GPs) [19,20]. Yet, as a recent study with German GPs (n=5868) shows, even within this group, confidence in ability to give patients capable advice on DiGA is low. Especially, GPs from rural areas report a lack of this confidence (urban 42% and rural 9%). They also report less often a favorable opinion of apps (urban 92% and rural 29%) and confidence in the DiGA directory (92% urban and 30% rural). Overall, 14% of GPs had prescribed DiGA (21% urban and 5% rural), and 13% planned to prescribe them in the near future [18]. For Belgium and France neither prescription numbers nor prescription behavior studies were found [11].

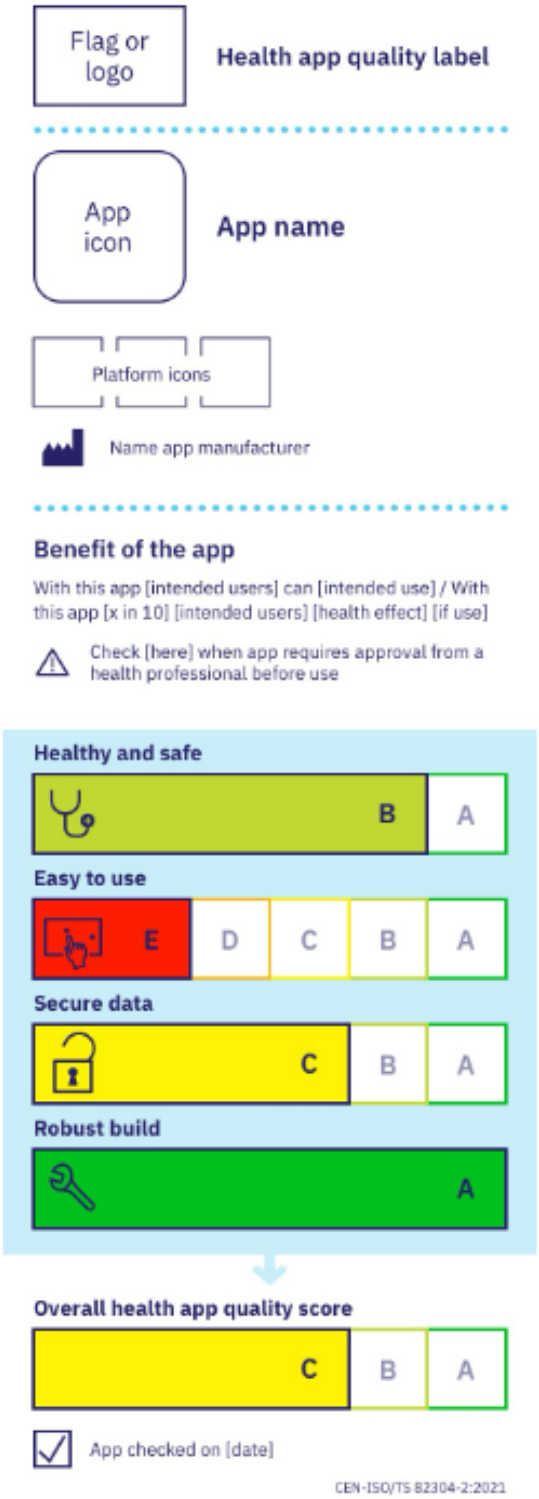
A recent systematic review demonstrated the potential of interventions to encourage app prescriptions by HCPs, with 91% of studies (10/11) reporting positive results, although sample sizes and follow-up were generally limited [21]. The range of interventions studied did not include structured reports on the quality of a given health app, nor guidelines from medical professional societies (hereinafter "medical societies"), despite a distinct need for and benefit of this type of information and guidance [3,7,13,14,16-18,22]. For example, Canadian HCPs (n=117) prioritized a health app quality report ("unbiased standardized review by experts") (80/117, 68%) and guidelines (72/117, 62%) as sources of information for recommending or prescribing apps [5]. German diabetes HCPs (n=538) expressed a willingness to include apps in their type 2 diabetes prevention, monitoring, and management far more (26%) or rather more (54%) if the national guideline would address the use of apps in these areas [16]. The European Society of Cardiology recently confirmed a need for accepted criteria for uptake of apps in guidelines and for standardized assessment, referencing CEN-ISO/TS 82304‐2 for its potential to become a widely used and efficient tool to help drive health app recommendations internationally [23].

CEN-ISO/TS 82304-2:2021 Health software Part 2: Health and wellness apps—Quality and reliability [1] (hereinafter "82304‐2") was an assignment from the European Commission to the European Committee for Standardization (CEN). The initiative became a global standardization effort due to its collaboration with the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC). 82304‐2 provides a health app quality assessment framework and a health app quality label. The quality assessment framework was built on a Delphi study with 83 experts from 8 stakeholder groups, including HCPs and medical organizations, and consists of 81 health app quality requirements [24]. Sixty-seven of these impact 4 overarching scores, which were named "Healthy and safe," "Easy to use," "Secure data," and "Robust build" after testing with persons with low health literacy. The 82304‐2 quality label summarizes the results of an 82304‐2 quality assessment for an individual app in these 4 scores in a simple and intuitive way, with comparative discrete A-E scales, traffic light color coding, and score bar length.

82304‐2 also introduces a health app quality report. While the label displays the results of the 4 overarching scores, the report is described as the set of answers to all 81 quality requirements and by its aims to enable multistakeholder informed decision-making on the quality-assessed app. Whereas the label is specified in detail (Figure 1), 82304-2 does not provide a design of the quality report, nor a specification of the granularity of information within it [1].

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Figure 1. CEN-ISO/TS 82304 - 2 health app quality label design.



An experimental vignette study (n=116) confirmed the potential of the 82304 - 2 quality label to increase HCP willingness to recommend a range of health apps (prevention, self-management, and health care related) to a range of patients (low and high socioeconomic status). Moreover, the label positively affected "Acceptability," the criterion most strongly correlated to willingness to recommend health apps. The study underlined that once developed, the more detailed 82304 - 2 quality report may further increase HCP willingness to recommend high-quality apps [25]. A follow-up study (n=290) explored what HCPs would need beyond the 82304 - 2 quality label and found that increasing knowledge, boosting confidence, and forming habits had the highest potential for change in HCP health app recommendation behavior [26]. Unfortunately, the research method did not provide a specification of "knowledge" and as such direction for the type of information and granularity HCPs would need in the 82304 - 2 health app quality report. With regard to citizens (patients), separate yet to be published

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studies found a positive effect of the 82304‐2 quality label on their intent to download a health app (n=1105) and their ability to choose “the right app” with the label and a short educational video to explain the label (n=789). Both studies took measures to ensure inclusion of persons with low health literacy.

To our knowledge, literature on the information detail that individual HCPs would need to make informed decisions about recommending the right health app to the right patient and report designs that support such decision-making is scarce. The only sources we found indicated that even the detailed information provided by Germany’s national directory of certified DiGA [12] was perceived as not detailed enough and lacking well-founded reliable information [17,18]. Especially information on functionalities and (research about) benefits and risks was considered not sufficient [22]. A user survey and routine data analysis by a German insurer proposed to improve the DiGA directory by adding sufficiently detailed information about the range of indications and contraindications, including age and gender, and a brief uniform understandable explanation of the app content and key functionalities within a few clicks [27].

Given the importance of HCPs for decision-making by their patients, the objective of this study is to design the 82304‐2 quality report that satisfies the information needs of individual HCPs in decision-making on recommending the app covered by the quality report to an individual patient. We aim to uncover which 82304‐2 quality requirements need which specific information in which granularity, and which graphical design is expected to support HCP decision-making best, effectively pursuing usefulness and usability and, as such, use of the 82304‐2 quality report by HCPs. Although our aim is to expand the usefulness and usability of the quality report to more stakeholders over time, our focus in this study is limited to HCPs and the potential compatibility of the resulting quality report with the information needs of medical societies and patients.

Methods

Participatory Design

Participatory design (PD) is a user-centered design method that actively involves future users as co-designers in generally an iterative design process in which changes to the design based on feedback by users are applied between design sessions [28-30]. This user involvement increases the likelihood that the design fits user needs and will be adopted and used as intended [30]. PD is particularly helpful for developing health information visualizations, that is, text and images with a communicative intent that aim to improve health outcomes by means of improved comprehension, communication, or engagement, and subsequent behavior changes [28]. PD is frequently used in health informatics and has been proven capable of changing clinical practice [28,31]. Since its inception in the late 1970s in Scandinavia in the computer science field, PD has evolved significantly. A recent systematic review showed that users are generally involved throughout a design process in which multiple techniques are used. The techniques can either be predetermined or emergent [29]. Our approach was emergent.

Methodological Elements and Principles

Overview

PD methods are typically tailored to the project-specific context [32]. Methodological elements that play a key role in PD research are (1) recruitment and management of stakeholders, (2) the use of tools and techniques, and (3) outcome measures [29,33]. PD principles that can aid in methodological decision-making include (1) democracy, the aim to involve all stakeholders including nondesigners and future users to achieve diversity of experience, values, and knowledge; (2) mutual learning; (3) tacit or latent needs assessment, transcending the easily detectable needs; and (4) collective creativity, in which values emerge and become inscribed in the product [33]. To achieve a comprehensive, useful, and usable 82304‐2 quality report, these methodological elements were tailored—aided by the PD principles—as follows.

Recruitment and Management of Stakeholders

For the project as a whole, the Label2Enable HCP Advisory Board (in short, HCP Advisory Board) was set up to ensure a comprehensive representation of HCPs, contributing to the effectiveness and impact of several project tasks, yet with a focus on being co-designers in this design study. A committee of user representatives is one of the PD techniques identified by Wacnik et al [29]. According to the grant agreement, the HCP Advisory Board was to consist of individuals representing different specialties, medical organizations, clinical settings, age groups, and nationalities to ensure sufficient diversity. To ultimately achieve the PD principle “collective creativity,” AM and KZ added as a requirement digital health expertise. Expertise and diversity are recognized to positively affect PD [33]. Recruitment was achieved by purposive sampling, using existing networks, and identifying and contacting European medical societies via email. Eleven HCPs with expertise were shortlisted, and 9 agreed to join the HCP Advisory Board. See Multimedia Appendix 1 for the HCP Advisory Board. The size of the HCP Advisory Board resulted from our aims to achieve sufficient expertise and diversity while fostering engagement [28]. All the HCP Advisory Board meetings were in English and online, given the various native languages and geographic locations. Members of the HCP Advisory Board received symbolic remuneration for their efforts. A diverse representation of medical societies was invited to assist in connecting to the medical community at large and ultimately to participate in final feedback meetings. The Label2Enable Patient Advisory Board was consulted once during the PD process and 2 employees of the Dutch Patient Federation provided feedback from a patient perspective on the final design of the health app quality report.

Tools and Techniques

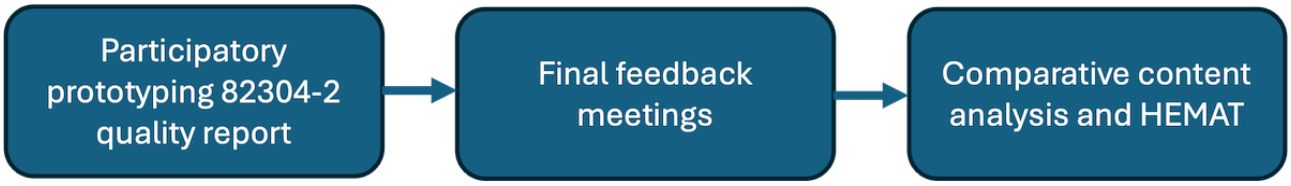
Overview

According to Vandekerckhove et al [33], depending on the aim of PD, tools can be used to (1) inspire ideas, (2) immerse participants in a domain, (3) gain an understanding, and (4) generate new ideas. The tools used in this study were participatory prototyping, final feedback meetings, a comparative content analysis, and the Health Education Materials Assessment Tool (HEMAT) (Figure 2). Their purpose,

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as distinguished by Vandekerckhove et al [33], and the PD techniques used, as classified by Wacnik et al [29], are further detailed in the following paragraphs . Although Wacnik et al [29] provided high-level definitions for the PD techniques distinguished, the authors stressed that techniques can, and in the spirit of adaptability should, stray from these definitions.

Figure 2. Graphic overview of the iterative stages of this participatory design study. HEMAT: Health Education Materials Assessment Tool.



Participatory Prototyping 82304‐2 Quality Report

First, to inspire ideas, PH searched online for designs of what could be described as quality reports for health apps and other products that HCPs and other stakeholder groups may be familiar with in the European context (PD technique: competitive benchmarking). This aligns with the Data-Frame Theory of Sensemaking, which suggests that people make sense of data by comparing them with frames from prior lived experiences, easing sensemaking. Stoplight colors to convey value judgments are a well-known example [28]. The quality reports analyzed, with in-between brackets the type of products they report on, included the European Product Registry for Energy Labelling database (European Union [EU] energy-labeled products) [34], the German DiGA directory (digital health applications) [12], the Finnish Digi-HTA directory (digital products and services for social and health care and well-being) [35], and the Summary of Product Characteristics, commonly known as SmPC (medicinal products) [36]. Later, additionally, the AppGuide (all health and wellness apps in the App Store and Google Play Store) [37], the European Database on Medical Devices [38], and the International HTA database (Health Technology Assessments from 53 HTA agencies from 33 countries around the globe) [39] were examined. These quality reports were where considered relevant evaluated with AM and graphic designer Oscar Smeulders and inspired the 82304‐2 quality report prototyping, similar to how the designs of the EU energy label [40] and Nutri-Score front-of-pack nutrition label [41], and the content of the United States Food and Drug Administration over-the-counter medicine label [42] inspired the 82304‐2 quality label design and content.

Second, to immerse participants, PH used a PowerPoint presentation to make the HCP Advisory Board acquainted with the 82304‐2 quality assessment framework and quality label and exemplary quality report designs found in the online search to provide a sense of direction for this study (PD technique: participatory workshop). Initial stimuli to respond to are found to be more effective in PD than presenting a blank slate [28]. While the exemplary quality reports provided direction for usability of the design for the quality report, they provided less so for the content of the quality report.

Third, to gain a better understanding and guide decision-making which 82304‐2 quality requirements would benefit from detailed information, the HCP Advisory Board proposed and AM organized a web-based survey (PD technique: stakeholder survey). The survey—in English only—aimed to evaluate which 82304‐2 quality requirements are considered most useful or, put otherwise, have most “use value” [43] in HCP decision-making on recommending a health app. PD methods intend to facilitate a design process in which *values*, in this case related to HCP information needs, emerge and become inscribed in a prototype, aiming for a final prototype (ie, design) that fits its intended future users’ values [30]. Medical societies assisted in recruiting a convenience sample of HCPs via email. No further inclusion or exclusion criteria were applied. Thirty-one HCPs participated. They were asked to provide demographics (age, gender, and country of origin), individually tick in an Excel sheet only those 82304‐2 quality requirements that they believed provided information valuable for HCPs in their decision-making on recommending a health app, and return their responses within 2 weeks. The survey was not piloted. Descriptive statistics (mean, SD, percentages) were used to summarize the results and identify the 82304‐2 quality requirements considered relevant by at least 50% of the respondents.

Fourth, to generate new ideas and arrive at the 82304‐2 quality report design, participatory prototyping, one of the most important methods used in PD [30], was applied (PD technique: prototyping with stakeholders). In participatory prototyping, participant values are translated into design requirements (here referred to as key design decisions to avoid confusion with the 82304‐2 quality requirements) [28], which iteratively materialize in what is intended to be a high-fidelity prototype (ie, design) as a result of interactions between designers, co-designers, and material objects (mock-ups, prototypes, etc) [30]. Prototyping has been found to support PD principles “mutual learning” and “tacit or latent needs assessment” [44]. PH, designer and researcher of the 82304‐2 quality label, trained and experienced as an industrial engineer and change manager, based in the Netherlands, translated the participant values, key design decisions that emerged, and own handwritten notes from the HCP Advisory Board meetings in iterative 82304‐2 quality report prototypes. Postmeeting, premeeting, and prototyping reflections by PH and AM, medical professional based in Lithuania, past–vice president of the European Junior Doctors Association, an organization for which digital health, including training, pan-European standards, guidelines, and research, is a key pillar, helped shape the iterative prototypes and determined timing and agenda for the next HCP Advisor Board meetings. This researcher role can be understood as that of a main participant directly participating as a designer in the design of a product [45]. PH consulted when needed lead app assessors from the Organisation for the Review of Care and Health Apps (ORCHA) based in England to ensure new

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iterations of the quality report prototypes could realistically be produced in the future. PH initiated and maintained a Word document which specified for each of the 82304‐2 quality requirements what information would be included in the quality report if the requirement was met, not met, or not applicable. This content was informed by parallel project tasks which resulted in a handbook app assessment for 82304‐2 aligned with EU-level legislation. PH kept Oscar Smeulders, graphic designer of the 82304‐2 quality label, also based in the Netherlands, informed about updates in the Word document. Oscar Smeulders proposed and used as a material object a FIGMA graphical design software visualization for the graphical design of the 82304‐2 quality report.

Final Feedback Meetings

Three separate final feedback meetings were organized to enable all 9 members of the HCP Advisory Board to provide their final remarks. Another 2 separate final feedback meetings were organized to gather feedback from in total 8 medical societies. In these final feedback meetings, PH and AM presented the final 82304‐2 quality report design prototype (the FIGMA visualization) and the detailed information in it (the Word document). Questions from the participants were answered, and feedback captured in notes by PH, AM, and PAP. PAP compiled and presented at the end of these meetings the web-based questions (PD technique: stakeholder survey) which were used to assess readiness of the final design prototype for evaluation in a future effectiveness study ("design saturation") [28]. These questions also indicatively assessed the quality report's potential usefulness for medical societies in providing guidance on recommending health apps. See Multimedia Appendix 2 for the web-based questions, which were inspired by the Theoretical Domains Framework (TDF), previously employed by Biliunaite et al [26] to investigate barriers to HCP health app recommendation behavior. Horizontally stacked bar charts were used to summarize the results. Responses to a final open question and the feedback in the meetings informed the final design of the 82304‐2 quality report. This final version of the health app quality report was shared with 2 employees with a focus on digital health of the Dutch Patient Federation to gather their feedback on usefulness and usability of the quality report for patients. To support their adequate understanding and enable valuable feedback, all their written questions were answered in writing in 2 consecutive rounds.

Comparative Content Analysis and HEMAT

A comparative content analysis and the 8-item HEMAT were used to evaluate the content and understandability of 4 health app quality reports (PD technique: competitive benchmarking). HEMAT was created by the United States National Library of Medicine and is based on the understandability items from the Patient Education Materials Assessment Tool for Printable Materials developed by the United States Agency for Healthcare Research and Quality [46]. Heatmaps were used to visualize the results. Rationale for the focus on content and understandability derives from the identified need for more well-founded detailed information than the DiGA directory [17,18] and a brief uniform understandable explanation within a few clicks [27]. The 4 quality reports included (1) the final FIGMA design of the 82304‐2 quality report, (2) the German DiGA directory [12], (3) the Finnish Digi-HTA directory [35], and (4) AppGuide, a private Canadian initiative [37]. For the comparative content analysis, PH and AM examined the type of detailed information available and the number of clicks required to access the detailed information. PH, AM, and an understandability expert from Pharos, the Dutch Center of Expertise on Health Disparities, who is a GP by background, completed the HEMAT (Textbox 1). To assess HEMAT item 2 , the literature on the type of information HCPs need [17,18,22,27] was used. To add nuance, the regular yes/no scoring for HEMAT was enhanced to yes/in part/no.

Textbox 1. The 8 items of the Health Education Materials Assessment Tool.

1. An obvious main message near the top to make the purpose of the report evident.
2. All the relevant information readers need to take action, excluding information that may distract or overwhelm users unfamiliar with the topic.
3. Common, everyday language; necessary medical terms are explained if used.
4. For the most part, active voice (eg, x does y instead of y is done by x).
5. Short sections with headings to easily do a quick scan and find needed information.
6. Selective use of visual cues (eg, font size, arrows, boxes, bullets, and highlighting) to draw attention to key takeaways before reading the words.
7. Visual aids (eg, photos, illustrations, and graphics) to support the main message.
8. Numbers are easy to understand (eg, whole numbers instead of decimals, 3 out of 10 instead of 30%, 3rd instead of third, and no need for readers to make calculations).

Outcome Measures

Outcome measures for PD can range (1) development (eg, ideas developed), (2) quality (eg, understandability), and (3) user outcomes of the quality report (eg, intent to prescribe or actual prescriptions) [33]. In this study, the key design decisions that emerged during participatory prototyping are the development outcome measures. The web-based questions in the final feedback meetings (PD technique: stakeholder survey), the comparative content analysis (PD technique: competitive benchmarking), and the HEMAT (PD technique: competitive benchmarking) are the quality outcome measures. A proposal for an effectiveness study has been submitted to assess user outcomes, results of which, if funded, will be reported separately. The proposed study will include both HCPs that are known to have more affinity with health apps (young urban

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HCPs) and HCPs that are known to be more reluctant (older rural HCPs) and will use widely applicable clinical situations ("vignettes") to approximate real-life HCP scenarios [18].

Ethical Considerations

The study followed a participatory and emergent research approach conducted within the framework of an EU-funded project. Due to the exploratory and iterative nature of the activities, formal ethics committee approval was not obtained prior to the study. However, ethical considerations were integrated throughout the research process and participant rights were actively protected. Participation in the HCP Advisory Board, the prioritization survey, and final feedback meetings was entirely voluntary, and participants could discontinue participation at any stage. Participants in the HCP Advisory Board confirmed their willingness to participate via email communication and were informed at the beginning of meetings about the purpose of the discussions, the intended use of the collected information, and their right to withdraw or decline to contribute without any consequences. For the survey-based data collection, participants were informed about the purpose of the study and provided consent through the Google Forms interface prior to participation. Participants in the feedback meetings were informed that they could leave the meeting at any time if they did not wish their opinions to be included in the research. The employees of the Dutch Patient Federation who provided feedback signed an informed consent form. The study did not involve vulnerable populations, medical interventions, or the collection of highly sensitive personal data. Data collection focused on professional experiences and perspectives relevant to the project activities. All collected information was handled in accordance with applicable data protection and confidentiality principles within the EU project framework. All members of the HCP Advisory Board received and reviewed the final version of this manuscript and agreed to its publication. See Multimedia Appendix 3 for the reporting guideline for health research involving design [47].

Results

Participatory Prototyping 82304-2 Quality Report

The HCP Advisory Board met 12 times over the course of 18 months (December 8, 2022, to May 29, 2024). The recommended group size of 4-8 [28] was achieved in the iterative meetings, which lasted in between 1 and 1.5 hours. The survey to evaluate the usefulness of the 82304‐2 requirements in decision-making on recommending a health app revealed that in total 37% (30/81) of 82304‐2 requirements were prioritized by at least 50% of the participating 31 HCPs. The medical societies that were contacted to support recruitment, the demographics of the 31 HCPs, and the 30 prioritized 82304‐2 requirements are included in Multimedia Appendix 4. The most prioritized 82304‐2 quality requirement, endorsed by 87% (27/31) of the participating HCPs, was "Peer-reviewed scientific literature used in the development of the app." The second most prioritized 82304‐2 quality requirements were "Health issues targeted," "HCPs involved in the development of the app." "Potential customers and users made aware of health risks," "Health benefit evidence," and "Appropriate evidence level for the health benefit," which were all selected by 80% (25/31) of the participating HCPs. The key design decisions ("development outcomes") that emerged in the participative prototyping of the 82304‐2 quality report are shown in Textbox 2.

Textbox 2. Key design decisions.

1. If feasible, have the 82304‐2 quality report satisfy both health care professionals' (HCPs') and patients' information needs instead of a separate version of the report for HCPs and another version for patients ("there are very experienced patients and very unexperienced HCPs and it's good if they speak the same language").
2. A design that aligns with the 82304‐2 quality label design.
3. Maintaining the 82304‐2 quality assessment framework structure including the scores of "Healthy and safe," "Easy to use," "Secure data," and "Robust build."
4. Within a few clicks ("everything is important but not all at once") access to an increasing detail of information.
5. An in one glance overview of the assessment results (requirement met, not met, or not applicable) for the 67 score-impacting 82304‐2 quality requirements using color-coding and abbreviated standardized accessible text.
6. More information detail beyond if the 82304‐2 quality requirement was met, not met, or not applicable where considered value adding based on the prioritization survey and HCP Advisory Board feedback.

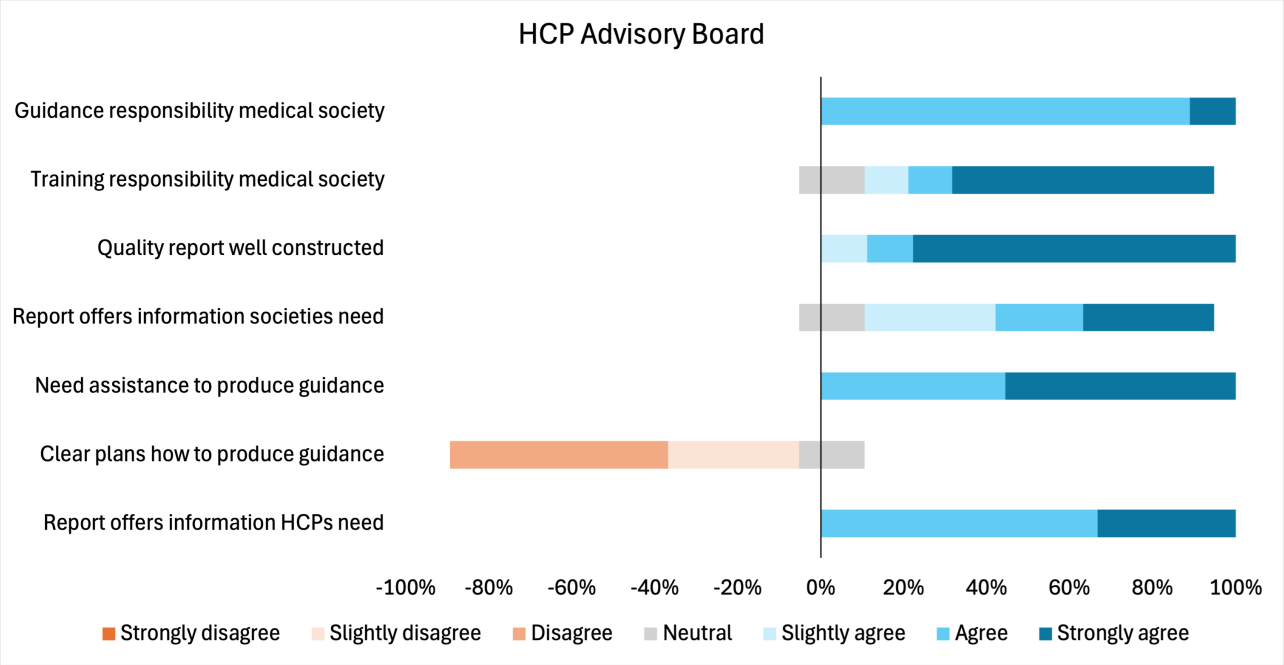
Final Feedback Meetings

The responses from the HCP Advisory Board to the web-based questions inspired by the TDF (Figure 3) revealed that the HCP Advisory Board members were very positive about the 82304‐2 quality report final prototype: 89% (8/9) agreed or strongly agreed that it was well constructed and 100% (9/9) agreed or strongly agreed that it offered all information and materials that HCPs need to recommend high-quality apps to their patients. In total, 100% (9/9) of the HCP Advisory Board members agreed or strongly agreed to medical societies or organizations having a responsibility to produce guidance on recommending high-quality health apps, while 78% (7/9) agreed or strongly agreed to medical societies having a responsibility in providing training on recommending high-quality health apps. Although the 82304‐2 quality report design was not built with this purpose in mind, 56% (5/9) agreed or strongly agreed that the final prototype nonetheless offered all information and materials for medical societies to produce guidance. The Board members confirmed a perceived need for assistance for medical societies in producing guidance: 100% (9/9) agreed or strongly agreed. Relatedly, 56% (5/9) disagreed with medical societies

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having clear plans to produce guidance on recommending high-quality apps.

Figure 3. Responses of the 9 HCP Advisory Board members to the 7 questions inspired by the Theoretical Domains Framework. HCP: health care professional.

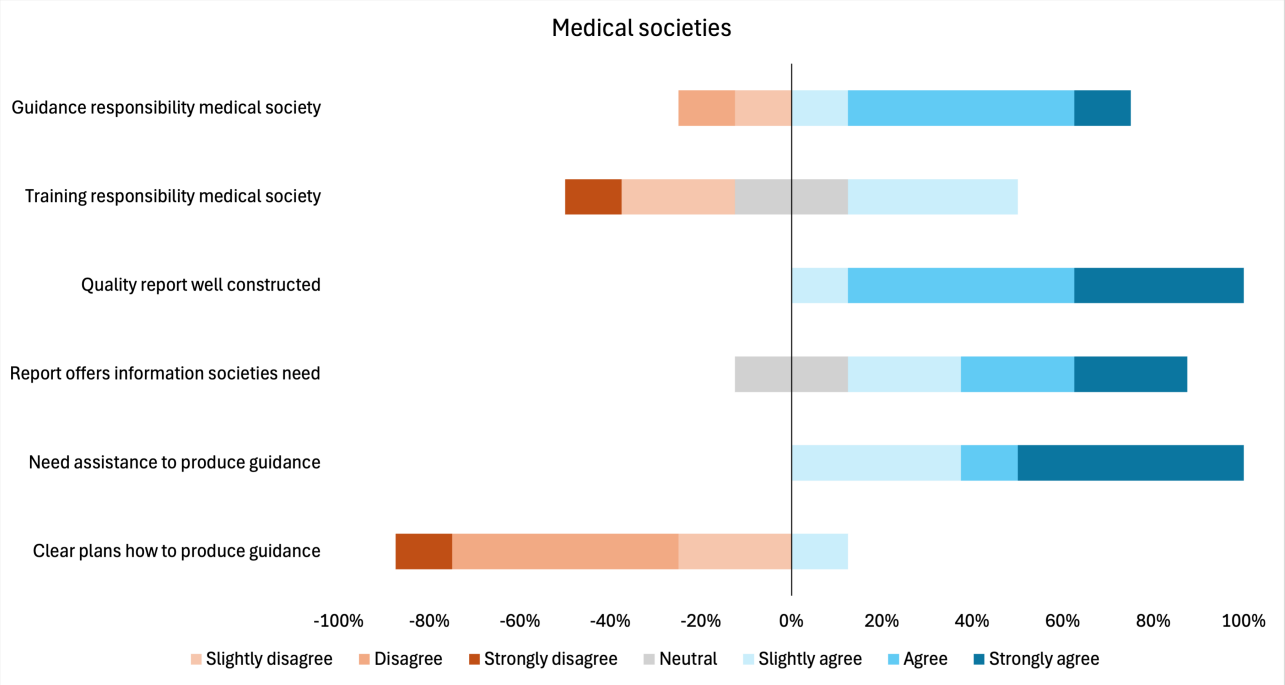


The responses from the medical societies to the web-based questions inspired by the TDF (Figure 4) revealed that the medical societies were also positive about the 82304 - 2 quality report final prototype: 88% (7/8) agreed or strongly agreed that it was well constructed. Although the report was not designed with medical societies in mind, 50% (4/8) agreed or strongly agreed that it offered all information and materials for medical societies to create guidance. The results indicated mixed to positive perceptions regarding medical societies' responsibility to produce guidance on recommending high-quality health apps: 63% (5/8) agreed or strongly agreed and 25% (2/8) slightly disagreed or disagreed. Responses were more reluctant to negative about providing training: 0% (0/8) agreed or strongly agreed, 38% (3/8) slightly agreed, and 38% (3/8) disagreed or strongly disagreed. The results confirmed that medical societies need assistance in developing guidance on recommending high-quality apps to members: 63% (5/8) agreed or strongly agreed. This need was reflected in the negative responses to having clear plans for producing such guidance: 63% (5/8) disagreed or strongly disagreed.

The final remarks, related follow-up to transform the final prototype into the final 82304 - 2 quality report design, and the medical societies that participated in the final feedback meetings are included as Multimedia Appendix 5. Two items related to the concept that "an app is not a pill" require further research. These concern a taxonomy of health interventions or health app functionalities and sufficient level of evidence (accepted study design) for different intended uses.

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Figure 4. Responses of the 8 representatives of the medical societies to the 6 questions inspired by the Theoretical Domains Framework.



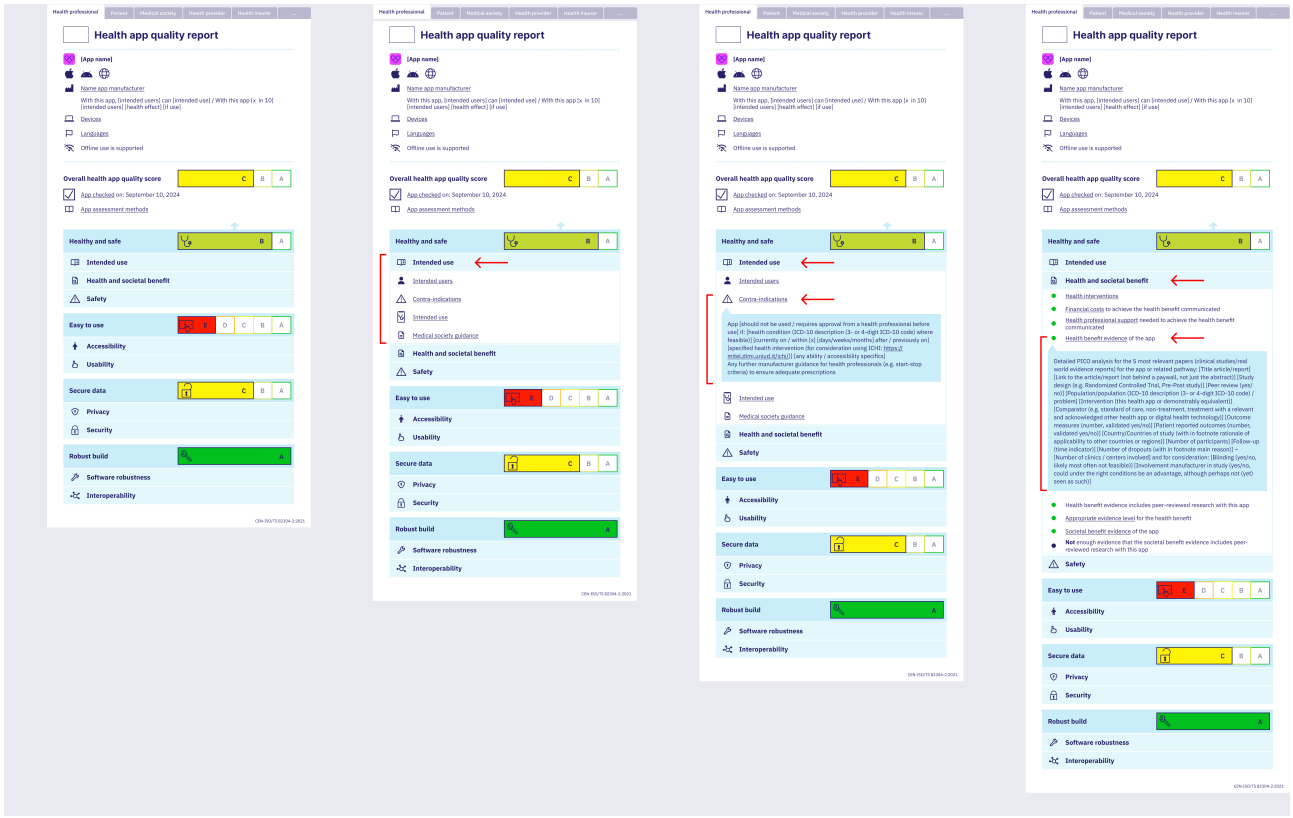
82304-2 Quality Report Design

The final FIGMA graphical design software visualization of the design of the 82304 - 2 quality report, scrollable and in part clickable to visualize access to the more detailed information, is included in Multimedia Appendix 6. See Figure 5 for screenshots of the FIGMA. The final version of the Word document, which specifies for each of the 82304 - 2 quality requirements what information will be included in the 82304 - 2 quality report if the requirement is met, not met, or not applicable, is included in Multimedia Appendix 7.

All key design decisions were adhered to (Textbox 3).

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Figure 5. Screenshots of the design of the CEN-ISO/TS 82304 - 2 health app quality report (FIGMA graphical design software visualization). The red arrows were added to indicate what has been clicked; in the second screenshot subcategory “Intended use”; in the third screenshot subcategory “Intended use” and the 82304 - 2 health app quality requirement regarding “Contra-indications”; and in the fourth screenshot subcategory “Health and societal benefit” and the 82304 - 2 requirement regarding “Health benefit evidence.” The red vertical lines were added to indicate what has opened with the last click. The fourth screenshot also displays the colored dots (green/dark blue/grey) that indicate whether an 82304 - 2 requirement is met (yes/no/not applicable). Only subcategories (“Intended use,” “Health and societal benefit,” etc) and underlined quality requirements can be clicked to provide access to more detailed information. The square on top is intended to display a flag (eg, the EU flag, similar to the EU energy label) if endorsed by a regional or national authority. The necessity for stakeholder-specific versions of the 82304 - 2 quality report and related need for the separate tabs at the top (health professional, patient, etc) is to be established in follow-up research.



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Textbox 3. Adherence to key design decisions.

1. A consultation of the Label2Enable Patient Advisory Board, established and chaired by the European Patients' Forum, indicated that patients' information needs with regard to health app decision-making were quite similar to health care professional (HCP) information needs. To accommodate potential different versions of the quality report targeted at meeting different stakeholder information needs over time, tabs were added at the top of the quality report design. Feedback from the Dutch Patient Federation confirmed the value of the content of the final version of the quality report for patients, and the importance of design decisions such as the use of color-coding and abbreviated standardized text for understandability. Minor changes were made, in particular, the suggestion to explain to patients what to expect from "Medical society guidance."
2. The quality report design aligns with the 82304 - 2 quality label design, using similar colors and fonts.
3. The quality report maintains the 82304 - 2 assessment framework structure, including the scores for the quality aspects "Healthy and safe," "Easy to use," "Secure data," and "Robust build." Details immediately visible in the quality report which are not included in the quality label include which devices are supported (computer, tablet, smartphone, smartwatch, and other), languages in which the app is available, whether offline use is supported, a link to the assessment methods, and subcategories within scores to facilitate focused access. The 5 subcategories within "Healthy and safe" in the 82304 - 2 framework were reduced to 3 and phrased "Intended use," "Health and societal benefit," and "Safety," priority categories in the literature, as well as in discussions in the HCP Advisory Board following the use value evaluation. "Technical robustness" was rephrased "Robustness." Other subcategories remained as is.
4. Detailed information on an 82304 - 2 quality requirement level is accessible in 2 clicks.
5. With 1 click on a subcategory, the quality report provides a quick overview of the assessment results of all score-impacting 82304 - 2 quality requirements within that subcategory using color-coded dots. A green dot ahead of a quality requirement indicates that the requirement is met, dark blue indicates that the quality requirement is not met, and gray indicates that the quality requirement is not applicable. Standardized short simple texts are used to ensure adequate interpretation of the colored dots. For example, a requirement that is not met starts with **Not** enough evidence, with Not in bold.
6. With a second click on a quality requirement that is met (green dot) and underlined (indicating a hyperlink), the quality report provides access to more detailed concise factual information on that individual quality requirement. Detailed information is available for 90% (27/30) of the 82304 - 2 quality requirements that were prioritized by at least 50% of the convenience sample of HCPs. Adding detail for the remaining 10% (3/30) quality requirements, of which 1 had 55% and 2 had 52% endorsement, was carefully considered with the HCP Advisory Board but judged not to add value. Even if this level of detail would not be accessed 99 out of 100 times by an individual HCP deciding on an app, the HCP Advisory Board considered this detailed information vital to be included for the 1 out of 100 times, to avoid a duplication of assessment efforts and to add to trust.

Comparative Content Analysis

The results of the comparative content analysis are included in Multimedia Appendix 8. Except for AppGuide (4 clicks), all reports provided detailed information in at most 2 clicks. The 82304 - 2 quality report provides detailed factual information for more quality requirements than DiGA, Digi-HTA, and AppGuide, and with a few exceptions in equal or fewer clicks. Of note, our design effort did not include a directory that provides access to multiple health app quality reports, which might add a click. DiGA differed in having a separate section for HCPs ("Information für Fachkreise"), in not providing (color-coded) quality scores, and in having products either permanently or provisionally listed or not listed anymore, indicating whether funding by statutory health insurance funds is provided. DiGA did provide search options (medical specialty, platform, ICD [International Classification of Diseases] indication, status of the app [permanently included, provisionally, and removed], age [12 - 17 years, 18 - 65 years, and older than 65 years], gender, language, additional costs, and additional devices [no, included, optional, and necessary]). As the supply of DiGA grows, choosing between DiGA with the same intended use and intended users may become challenging without (color coded) quality scores [48]. To indicate whether individual health app quality requirements were met, AppGuide and 82304 - 2 used color coding and standardized text, DiGA-only standardized text, and Digi-HTA descriptive information.

HEMAT

The HEMAT understandability results are included in Multimedia Appendix 9. The 82304 - 2 quality report scored highest with 63% (5/8) of items scored yes and 25% (2/8) in part, AppGuide scored second with 57% (4/7) yes and 14% (1/7) in part, Digi-HTA scored 13% (1/8) yes and 25% (2/8) in part, and DiGA scored 13% (1/8) yes and 13% (1/8) in part. Of note, DiGA and 82304 - 2 scored best on providing all the information HCPs need, with details including indications and contraindications using ICD-10 (International Classification of Diseases, 10th Revision), functionalities, a standardized granular overview of privacy measures met and not met, and a PICO (Patient or Problem, Intervention, Comparison, Outcome) analysis for clinical evidence. However, DiGA did not score on "excluding information that may distract or overwhelm users unfamiliar with the topic." AppGuide and 82304 - 2 both provide access to detailed information per individual requirement, whereas DiGA and Digi-HTA provide this access to findings for a range of quality requirements within a category. Especially for DiGA, this results in long text documents, which makes finding needed information more challenging. Digi-HTA and AppGuide did not provide this information, or not in the needed granularity. Digi-HTA assesses "suitability of an app for use in healthcare" in general and, as such, does not seem to tailor to the information needs of HCPs in their decision-making for individual patients. AppGuide was distinctive in information on all (322.020) health and wellness apps in the app stores, providing HCPs with a source of information to respond to questions from patients who have come across a health app themselves.

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Discussion

Principal Findings in Perspective

In this study, we used PD techniques to design the 82304‐2 quality report, with an aim to support decision-making on recommending an individual health app to an individual patient by providing HCPs in a user-friendly way the information on the quality of a health app that fits their needs and competences. We managed to engage the Label2Enable HCP Advisory Board, a diverse group of 9 HCPs with expertise in digital health, in participatory prototyping over the course of 18 months, supplemented by 8 medical societies in a final feedback meeting. This resulted in a final 82304‐2 quality report design with detailed information for 90% (27/30) of the 82304‐2 quality requirements HCPs (n=31) perceived of most use value in individual HCP decision-making on recommending a health app. A comparative content analysis and the HEMAT indicated that the quality report design was generally comprehensive and understandable. Final feedback from the 9 HCPs and 8 medical societies was limited, and responses to our web-based questions on the final prototype confirmed promising potential in meeting HCP information needs ("design saturation"). Although the quality report was not designed with the needs of medical societies in creating guidance on recommending high-quality health apps in mind, the quality report design did show potential in also meeting medical societies' information needs. Feedback from the Dutch Patient Federation indicatively confirmed the usefulness and usability of the quality report for patients. Two items in the quality report related to "an app is not a pill" require further research. These are a taxonomy for health app functional components and, on a more granular intended use level, which study designs are considered adequate evidence.

The recent mapping of HCP information needs and the 82304‐2 quality assessment framework created with the European Society of Cardiology Regulatory Affairs Committee [23] affirms the potential of 82304‐2 to satisfy HCP and potentially also medical society information needs with regard to recommending health apps. More conclusive evaluation of the usefulness and usability of 82304‐2 quality reports by HCPs is recommended, also considering guidance that formal evaluations such as testing comprehension, usability, behavioral intention, or behavior change should follow PD's preliminary evidence of meeting objectives [28], and the few interventional studies to enhance HCP health app recommendations to date and their limitations [21]. These evaluations should make use of 82304‐2 quality reports with the results of actual app assessments instead of dummy content. The assessed apps should have target users that fit the patient characteristics of the participating HCPs. A particular focus on reluctant and less experienced HCPs should be considered to ensure that the quality report effectively meets the information needs of both HCPs who have and those who have not yet been willing and able to recommend health apps. Both German and French research suggest 3 types of HCPs, being those with positive attitudes toward health apps based on perceived benefits (eg, facilitating and complementing care provision and behavioral effects for patients), those carefully considering benefits (eg, effectiveness and efficiency) and risks (eg, overuse and misuse) for patients and HCPs, and those with negative attitudes (eg, concerns about data privacy, liabilities, actionability of app data, and adverse effects on patient-doctor relationship) [3,16]. Additionally, further research efforts with medical societies and other stakeholders will have to prove the multistakeholder and intercontinental value of the 82304‐2 quality report and related potential in avoiding a duplication of assessment efforts. Such evaluations are expected to enhance the compatibility of the report with the needs of a wide range of HCPs, their medical societies, and with extended efforts potentially more stakeholders that matter to HCPs, such as patients, hospitals, insurers, and HTA bodies. Nontraditional stakeholders (eg, new market entrants such as a telecom company or supermarket that recommends prevention-related apps) may also be considered [49-51].

Medical societies were more ambivalent to negative about their role in providing guidance and training on recommending high-quality health apps than we expected based on medical societies' common roles in guidance and training and the literature on HCP needs as to medical society guidance with regard to recommending health apps. The perceived need of medical societies for more assistance in creating this type of guidance seems to indicate the lack of clear plans, and perhaps also the ambivalence may be more related to a lack of know-how than a lack of interest. The particularly negative score for training may be due to difficulties designing a training if guidance lacks. Further research and support for medical societies to develop effective guidance and related training seem warranted, ideally without each and every medical society having to invent or reinvent the wheel. We expect that an effort with a limited number of medical societies will reveal that guidance will be only to a limited extent health issue specific. This finding would prove directional to further medical societies and provide a basis for creating guidance and training material (eg, Massive Open Online Courses) for both the medical societies involved and their not directly involved peers. Potential new medical societies such as the German Medical Society of Digital Medicine [52] can be involved in the future—in addition to more industry-guided societies of health app manufacturers.

This study was part of the Horizon Europe Label2Enable project. Another task in this project examined the EU label legislations for energy, food, and medication. All these labels were found to be accompanied by more detailed quality reports. These reports were made available in a database, as were the 3 quality reports we compared with in this study. Although there are many health and wellness apps, their numbers are limited compared with, for example, the number of household appliances in the European Product Registry for Energy Labelling and medical devices in the European Database on Medical Devices. In this research, we created a design for the 82304‐2 quality report. A working scalable version of the 82304‐2 quality report, also referred to as "proof of process" and "proof of production" [44], as well as the related open access database, requires additional funding and yet could build on the learnings with the energy, food, and medication labels, and perhaps even on their existing (EU) platforms or the yet to be established EU database for registration of electronic health record systems and wellness applications described in Article

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49 of the European Health Data Space regulation. Having the designated platform connect to routinely used trusted platforms, such as those of medical societies, may be further explored, benefiting from experiences in, for instance, Australia [7], and findings in research in Germany [16,18], where, for example, 73% of diabetes HCPs obtained information on apps from their medical society versus 13% from the DiGA directory and 7% from the national health portal [16].

Strengths and Limitations

To our knowledge, this is the first extensive PD study to arrive at a design for a health app quality report with indicative proof of satisfying the information needs of HCPs and potentially other stakeholders, in particular, medical societies and patients. The perceived potential alongside complementary interventions toward making recommending high-quality apps a habit and building HCP confidence in this new skill [26] holds promise in addressing the current lack of high-quality health app recommendations and achieving the related health and societal benefit. Although 82304‐2 is a standard with global applicability, and the 81 global quality requirements were the basis of the 82304‐2 quality report, the information provided including granularity may be specific to information needs of European HCPs. In total, 89% (8/9) of HCPs and all medical and patient societies involved were European. Some of the detailed information in the quality report was adapted to the EU regulatory context (eg, referring to the EU Medical Device Regulation and the [soon to be implemented] European electronic health record exchange format), as was some of the wording (eg, personal data instead of personally identifiable information, and data protection officer instead of person responsible for legal and regulatory compliance of processing of personally identifiable information, following terminology used in the EU General Data Protection Regulation). Differences may also be attributable to health system specifics and context-specific additional quality requirements [53]. We acknowledge that in the aftermath of the COVID-19 pandemic the number of HCPs who evaluated the use value of individual 82304‐2 requirements (n=31) as well as the number of participants in the final feedback meetings (n=17) was limited, and that the HCP Advisory Board consisted largely of HCPs with experience in the field and interest in the topic, who were also involved in the participatory prototyping. This likely had an effect on the responses to our questions based on the TDF with regard to the quality report being well constructed and offering the information that HCPs need. On the other hand, the 8 medical societies that participated in the final feedback meetings were not involved in this design effort and agreed with the quality report being well constructed. We recognize that our current work concerned prototyping and not real-life deployment. We recommend more conclusive evaluation of usefulness, usability, and use of the 82304‐2 quality report by HCPs in a demonstrator phase or effectiveness study, with particular effort to also include reluctant and less experienced HCPs and other relevant stakeholders. This phase would also enable next stages of the design process, progressing from “proof of concept” and “proof of product” to “proof of process” and “proof of production” [44], beyond the current indicative assessments of ORCHA lead app assessors as to feasibility to produce and scale production of the 82304‐2 quality report.

Conclusions

We succeeded in our aim to design the 82304‐2 quality report including its information detail and found promising potential for its distinctive usefulness for HCPs in recommending health apps, complementing the 82304‐2 quality label for which an effect on willingness to recommend apps was previously found. Additionally, initial feedback on the potential compatibility of the quality report for medical societies in creating guidance and for patients in considering a health app was positive. Further efforts are needed to test and fine-tune the HCP, multistakeholder and intercontinental usefulness, usability, and use of the 82304‐2 quality report; to support medical societies in providing guidance and training; and to evolve from the current FIGMA design to a working scalable version of the 82304‐2 quality report and related open access database.

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Data Availability

All data generated or analyzed during this study are included in this published article and its supplementary information files.

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Authors' Contributions

Conceptualization: PH, AM
Data curation: PH, AM, PAP
Formal analysis: PH, AM, PAP
Funding acquisition: PH
Investigation: PH, AM, KZ, PAP
Methodology: PH, AM
Project administration: PH, AM, KZ
Supervision: PH, AM, JK
Visualization: PH, Oscar Smeulders, PAP
Writing – original draft: PH, AM, PAP
Writing – review and editing: PH, AM, KZ, PAP, MVQ, NHC, MK, JK

Conflicts of Interest

None declared.

Multimedia Appendix 1
HCP Advisory Board.
[PDF File, 28 KB - jopm_v18i1e86473_app1.pdf]

Multimedia Appendix 2
Questions final feedback meeting.
[PDF File, 19 KB - jopm_v18i1e86473_app2.pdf]

Multimedia Appendix 3
Reporting guideline for health research involving design.
[PDF File, 69 KB - jopm_v18i1e86473_app3.pdf]

Multimedia Appendix 4
Priority 82304-2 requirements survey.
[PDF File, 66 KB - jopm_v18i1e86473_app4.pdf]

Multimedia Appendix 5
Follow-up final feedback.
[PDF File, 40 KB - jopm_v18i1e86473_app5.pdf]

Multimedia Appendix 6
82304-2 quality report design (“FIGMA”).
[PDF File, 12 KB - jopm_v18i1e86473_app6.pdf]

Multimedia Appendix 7
82304-2 quality report information detail (“Word document”).
[PDF File, 1323 KB - jopm_v18i1e86473_app7.pdf]

Multimedia Appendix 8
Comparative content analysis.
[PDF File, 68 KB - jopm_v18i1e86473_app8.pdf]

Multimedia Appendix 9
Health Education Materials Assessment Tool results.
[PDF File, 24 KB - jopm_v18i1e86473_app9.pdf]

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Abbreviations

82304-2: CEN-ISO/TS 82304-2
CEN : European Committee for Standardization
DiGA : Digitale Gesundheitsanwendungen (Digital Health Applications)
EHR : electronic health record
EMA : European Medicines Agency
EU: European Union
FIGMA: graphical design software
GP: general practitioner
HCP: health care professional
HEMAT: Health Education Materials Assessment Tool
HTA: Health Technology Assessment
ICD: International Classification of Diseases
ICD-10: International Classification of Diseases, 10th Revision
ORCHA: Organisation for the Review of Care and Health Apps
PD: participatory design
PICO: Patient or Problem, Intervention, Comparison, Outcome
SmPC: Summary of Product Characteristics
TDF: Theoretical Domains Framework

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The Patient Monitoring Roundtable as Catalyst for Health Care Innovation: Case Study

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Abstract

Background: In the field of patient monitoring, there often remains a gap between clinical needs and the monitoring technologies available from industry. To conquer this, the Patient Monitoring Roundtable (PMRT) live event series offers a sustainable and structured platform for innovation through focused small-group discussions, prioritizing deep engagement among stakeholders. By establishing a dynamic, low-barrier forum, the PMRT aims to serve as a thought leadership platform in patient monitoring and digital health, driving continuous improvement and shaping the future of health care technology.

Objective: This paper pursues 2 main objectives: first, to describe the concept, implementation, and practical insights of the PMRT as a novel format for transdisciplinary collaboration in digital health; second, to evaluate its perceived impact and reception among participants.

Methods: The concept and implementation of the format were described using internal planning documents, event materials, and communication records. To evaluate participant reception and perceived impact, a cross-sectional online survey was conducted between October 2024 and January 2025. The questionnaire was distributed at PMRT events and via digital channels, including the PMRT newsletter and LinkedIn.

Results: The PMRT was conducted 29 times between January 2022 and June 2025. It is usually structured in a keynote, followed by interactive small group workshops and a consecutive group discussion, and concluded by a networking session. Examples of topics include alarm management, tele-surveillance and care, user testing of monitoring devices, implementation science, data protection and cybersecurity, artificial intelligence in medicine, and interoperability. Following each event, a structured set of postevent activities ensures continued engagement and knowledge dissemination. A total of 47 responses were included in the survey analysis. The 2 most represented professional backgrounds were industry representatives and physicians. Other participants came from nursing, research, or other fields. Most respondents reported having experience in patient monitoring and digital health, with no notable differences across professional backgrounds or gender. More than half had attended several PMRT events. Formats such as small group discussions and workshops were viewed as highly effective in fostering dialogue. Most participants felt they were part of a professional community, and some reported having established new collaborations. Informal exchanges and interactive workshops were seen as the most valuable aspects of the event.

Conclusions: The PMRT presents a novel, structured, low-threshold platform for clinical-centered transdisciplinary dialogue, professional networking, and knowledge exchange in the field of digital health. Participant reception confirms high acceptance and perceived impact, with many reporting strengthened community ties and new collaborations and valuing the interactive workshop format. These findings demonstrate that the PMRT can serve both as an innovative collaboration model and as a platform with tangible benefits for its attendees.

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KEYWORDS

digital health; transdisciplinary research; patient-centered care; health care innovation; medtech; ehealth

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Introduction

Patient monitoring systems are essential for the continuous assessment of patients' physiological status in high-acuity environments such as intensive care units, operating theaters, and emergency departments and are increasingly used on general wards to enable early detection of patient deterioration [1,2]. Over the past decades, advances in sensor technology, data integration, and analytic capabilities have expanded the scope and complexity of monitoring. Nevertheless, there is often a gap between clinical needs and the technologies available from industry [3-5]. Common challenges include alarm fatigue from excessive and often nonactionable alerts, fragmented device ecosystems lacking interoperability, and usability issues that hinder integration into clinical workflows [6-8]. Addressing user needs is critical for the successful adoption of medicotechnical innovations, as misaligned solutions often remain unused or create barriers in daily workflows [9-14]. Early and continuous user involvement is therefore essential to achieving real-world impact.

Hackathons have the potential to address this gap by fostering early, collaborative problem-solving among stakeholders while accelerating innovation and fostering transdisciplinary collaboration. Originating in the tech industry, these events unite clinicians, engineers, designers, industry representatives, and patients to co-create practical solutions [15]. However, prior research shows that hackathons demand substantial resources and frequently struggle to sustain momentum or translate ideas into long-term impact [16-19].

Building on the collaborative, user-centered, and solution-oriented spirit while addressing their limitations in sustainability and follow-up, we developed the Patient Monitoring Roundtable (PMRT). In the context of the PMRT, "patient monitoring" encompasses both established clinical monitoring systems, including traditional bedside monitoring of vital signs, and emerging digital health technologies and data-driven tools that collect, integrate, and interpret physiological and clinical information to inform care practices and workflows. The PMRT in the form of a live event series offers a sustainable and regular platform for innovation through focused, small-group discussions, prioritizing deep engagement among stakeholders. By establishing a dynamic, low-barrier forum, PMRTs aim to create a community of like-minded experts, driving continuous improvement and shaping the future of patient monitoring and digital health.

Against this background, this paper pursues 2 objectives. First, it describes the concept, implementation, practical insights, and outcomes of the PMRT events as a novel format for interdisciplinary collaboration in digital health. Second, it presents findings from a participant survey that evaluated the perceived impact and reception of the PMRT, acknowledging the challenges of measuring open exchange formats. Through this initiative, we aim to advance health care innovation in a manner that is both impactful and sustainable.

Methods

Origin

The PMRT was initiated under the framework of Hacking Health, a global initiative aimed at fostering innovation in health care by bringing together diverse stakeholders, such as clinicians, industry representatives, and researchers, to collaborate on solving pressing medical challenges through hackathons, workshops, and community events. The Berlin branch of Hacking Health was founded in 2014, supported by Hacking Health Canada [16]. As part of its efforts to promote user-driven innovation, the Berlin branch organized its first health hackathon in February 2017. Over the course of 2 days, participants worked in transdisciplinary teams to develop digital health solutions, while researchers conducted a field study to capture insights on collaboration dynamics and innovation processes. Building on this experience, two additional health care hackathons were conducted in December 2017 and November 2018.

Development of the PMRT

In a series of interdisciplinary meetings, a group of researchers and students consisting of ASP, MS, JW, and LA-M-S created the concept of the first PMRT, drawing on lessons from prior hackathon experiences. In January 2022, the first event was conducted, and the series was established to promote an ongoing low-threshold exchange of pain points, ideas, and feedback with a focus on the topics of patient monitoring and digital health. Since then, the PMRT has evolved into a structured event series supported by a network of sponsors such as Masimo [20], Dräger [21], and Philips [22] and partners such as HealthCapital [23], the Berlin Institute of Health (BIH) [24], and the Einstein Center for Digital Future (ECDF) [25].

The target audience encompasses individuals from a variety of professional backgrounds, mainly including clinicians such as nurses and physicians; hospital IT staff and industry representatives; but also patient representatives, scientists, and students. A special focus lies on the exchange between the clinical practice and patient monitoring device manufacturers.

As of June 2025, a total of 29 roundtable events have been conducted in Berlin, Germany, and partly via an online approach. The organizing team eventually expanded to 5 members, all of whom were part of the nonprofit organization Initiative for Innovation and Collaboration in Healthcare (INCH) e.V., as a successor of Hacking Health Berlin.

While the PMRT is supported by industry sponsors, the format is designed as a co-creative platform involving multiple stakeholder groups. Industry partners may propose topics and contribute to the co-design of selected events, with final selection made by mutual agreement. As part of the governance framework, sponsoring partners are explicitly instructed to limit promotional content and to ensure that their contributions are framed in a way that provides clear value for clinical participants. Final decisions regarding topic selection, agenda structure, and workshop formats rest with the organizing team. Sessions are primarily moderated by members of the organizing team or independent experts, for example, with affiliations to

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universities or professional societies. In rare cases, industry experts have contributed to moderation within the same governance framework. In addition, some PMRT events have included clearly delineated, product-focused sessions. These sessions were embedded within a broader clinical and methodological discussion and did not constitute the dominant format of the event.

Data Collection and Analysis

The structure, development, and implementation of the PMRT format were reconstructed and documented using multiple internal sources, including planning documents (eg, agendas, timelines, and stakeholder lists), event materials (eg, programs, presentations, and workshop templates), and communication records (eg, meeting notes and email correspondence).

To evaluate the impact and reception of the PMRT, a cross-sectional online survey was conducted using an online questionnaire (Multimedia Appendix 1). The survey instrument was designed as a pragmatic evaluation tool to assess participant experiences and the perceived impact of the PMRT format. Item generation was informed by the objectives of the roundtable series and recurring themes from prior events. The questionnaire was reviewed internally by the organizing team to ensure clarity and relevance prior to use. Minor refinements were made iteratively based on this early feedback. No formal psychometric validation procedures (eg, test-retest reliability or construct validation) were conducted prior to deployment. Potential participants were defined as people who have attended at least one roundtable event and are not involved in its organization or conduction. The questionnaire was administered during 3 roundtable events; distributed via the PMRT newsletter, which had 289 subscribers as of July 7, 2025; and a call for participation on LinkedIn (Microsoft Corp). It was accessible for submission between October 15, 2024, and January 31, 2025.

Data were collected regarding the participants' professional background, experience and satisfaction, results and impact, criticism, and suggestions in regard to the PMRT. Answer formats included nominal scales, ranked-order questions, 5-point Likert scales (5="very applicable," 4="rather applicable," 3=neutral, 2="rather not applicable," 1="not applicable at all") and free-text responses. In cases of incomplete questionnaires, only the answered items were considered for analysis. Results were analyzed using Microsoft Forms and IBM SPSS Statistics (version 29.0.2.0). Absolute and relative frequencies were calculated, and the median was reported for ordinal-scaled questions. Additionally, correlations between responses and professional groups were examined for selected questions using the Fisher exact test, given the small sample size and the categorical nature of the data with low expected frequencies. All reported *P* values refer to this test. The survey instrument was developed, administered, and analyzed independently by the organizing team. Sponsors had no access to raw survey data and no influence on data analysis or interpretation.

Ethical Considerations

The study received approval from the institutional ethics committee of Charité–Universitätsmedizin Berlin (EA1_055_25). Participants received information about the study prior to participation and provided informed consent before taking part. Participation was voluntary, and no financial compensation was provided. All data were collected, stored, and processed in accordance with institutional guidelines and the General Data Protection Regulation (GDPR). Only pseudonymized data were used for analysis.

Results

The following results section comprises 2 parts, first, a description of the concept, implementation, and practical insights of the PMRT live event; and second, findings from an online survey evaluating its perceived impact and reception among participants.

Patient Monitoring Roundtable Live-Event

Roundtable Preparation

The successful execution of each roundtable requires a thoroughly coordinated preparation phase, encompassing the scheduling of dates and venues, the selection of relevant topics, the application for continued education points, and the implementation of a targeted promotional strategy. These processes are described in detail in the following section.

Scheduling

The roundtables are scheduled 8 times annually, evenly distributed across the calendar year. A key lesson learned was that no events should be scheduled in July, August, or December, as the summer and Christmas holiday periods significantly reduce participant availability. At participants' request, event dates are planned at the end of the preceding year and are then confirmed 3 months in advance to accommodate the scheduling constraints of clinicians and other participants. Each roundtable is held on a weekday evening and lasts 2.5 hours (6:00 PM-8:30 PM).

Location

To facilitate accessibility and encourage attendance, events are hosted at centrally located venues in Berlin close to hospital facilities, with locations varying across events depending on availability and suitability for the planned format. Requirements for venues include a projector and a larger room for keynotes and group discussion, smaller rooms for breakout sessions, and Wi-Fi for hybrid sessions.

Topic Selection

Over the course of the PMRT events, it became evident that topic selection is most effective when combining several sources, including suggestions from participants grounded in their day-to-day experience with patient monitoring, emerging trends in scientific research, input from industry partners, and the expertise of potential keynote speakers. These inputs are jointly reviewed and prioritized by the organizing team to ensure that each event addresses challenges and developments of direct relevance to the audience.

Continuing Education Points for Nurses and Physicians

In Germany, proof of continued training is mandatory for medical specialists, and a certain number of so-called Continuing Medical Education points [26] must be collected. Since January

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2025, we have applied and received Continuing Medical Education certification for each roundtable. A similar system exists for nursing staff, who are required to collect so-called nursing points to continue their facultative registration [27]. Since April 2025, we have also applied regularly for these certifications.

Promotion and Registration

A comprehensive promotional strategy was implemented, using the PMRT's official website [28] and newsletter, partner organizations' online platforms, and social media channels such as LinkedIn and Instagram (Meta Platforms). Event registrations are available free of charge and are managed through Eventbrite (Eventbrite Inc) [29], a global platform for ticketing and event organization. The number of registrations, that is, tickets, available mainly depends on the capacity of the event location and the intended agenda. A lesson learned in 2025 was to introduce separate registration contingents for clinicians and other professionals to ensure balanced representation of both groups. No systematic tracking of outreach channel effectiveness for event registrations (eg, referral links or click-through analytics) was conducted; based on organizer observations, most registrations appeared to follow newsletter announcements, and intranet postings often prompted registrations among clinical participants.

Roundtable Event

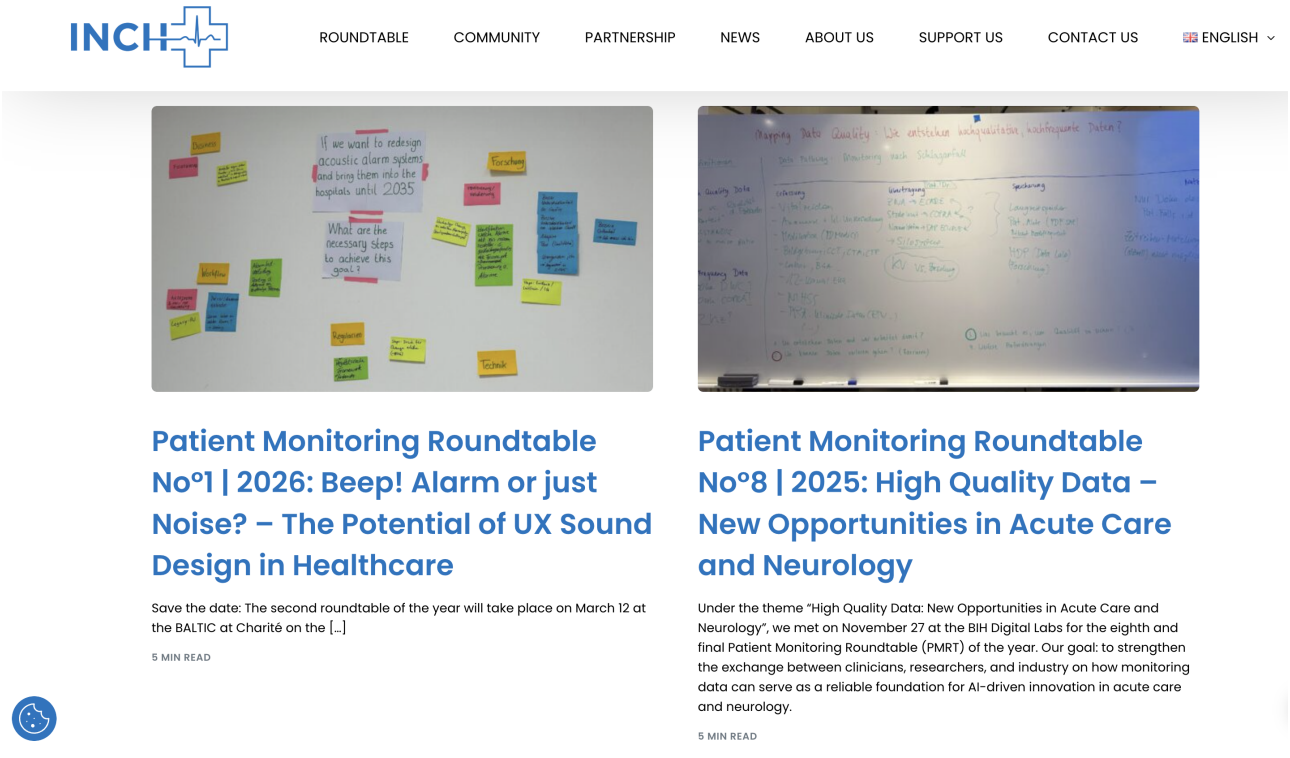
Topics and Participants' Interests

Depending on the topic, each PMRT event is co-designed and co-conducted with renowned experts in the respective field to ensure relevance, depth, and practical impact. Examples of topics include alarm management, tele-surveillance and -care, user testing of monitoring devices and medical smartwatches, user experience design in alarm management, monitoring in weightlessness, implementation science, data protection, and cybersecurity, artificial intelligence in medicine, and interoperability. Experience has shown that participants are especially interested in topics that are prominently discussed in general societal discussion, such as artificial intelligence and cybersecurity or are directly linked to their daily professional life, such as alarm management and monitoring devices. A complete list of topics, formats, and estimated number of participants can be found in Multimedia Appendix 2.

Event Structure

From the outset, each roundtable has used a variety of formats, including keynote presentations, panel discussions, World Cafes [30], small group discussions, and hands-on workshops. Especially the combination of starting the event with an introductory keynote followed by interactive workshops in small groups has been established. Sessions conclude with a group discussion followed by a networking session, providing participants with the opportunity to establish and strengthen professional connections. The contribution of expertise and personal experience is strongly encouraged to promote meaningful dialogue and cross-sector collaboration in problem-solving. Keynotes are recorded using smartphones and clip-on microphones. Since 2025, a hybrid event solution with Microsoft Teams has been introduced, where possible, to accommodate virtual attendees and enhance accessibility. Online participants have the opportunity to submit questions via the chat function. Following the keynote, an additional online workshop is held in parallel to the in-person breakout groups. During the final group discussion, online participants can again contribute via the chat. A typical agenda is displayed in Figure 1 [31].

Figure 1. An example of 2 blog posts summarizing recent Patient Monitoring Roundtable (PMRT) events on the Initiative for Innovation and Collaboration in Healthcare (INCH) website [31].



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Moderation

Each event starts with opening words by the PMRT team, introducing the topic, today's agenda, and potential keynote speakers. Depending on the content and the experts involved, the workshops are led either by the PMRT team or by external experts. The discussion in the large group format and concluding remarks are again facilitated by the PMRT team. While most events are held in German, the roundtable is occasionally conducted in English, depending on the language preferences of the experts and the language profile of the audience.

Postevent Activities

Overview

Following each event, a structured set of postevent activities ensures continued engagement and knowledge dissemination. A newsletter summarizing the event, including a brief description, key takeaways, and a link to the keynote video, and an announcement for the next roundtable are distributed across multiple channels. This includes email newsletters and social media platforms such as LinkedIn and Instagram, as well as institutional communication channels such as the Charité intranet and the websites of the Institute of Medical Informatics at Charité-Universitätsmedizin Berlin [32] as well as INCH e.V [28] (Figure 2).

Figure 2. A typical agenda of the Patient Monitoring Roundtable (PMRT) starts with a short introduction and keynote at 6 PM, followed by an extensive workshop session and subsequent discussion lasting about 2 hours, concluded by a networking session. PMRT: Patient Monitoring Roundtable.



Participant Engagement and Event Attendance Trends

Participants of the first 6 events in 2022 were invited exclusively via email, primarily targeting industry representatives, clinicians (including nurses and physicians), and researchers with direct or indirect connections to the organizing team. Over time, as the event series became more established, personal invitations via email decreased in favor of registrations through Eventbrite. Registration data are available starting from September 2022. For the 2 recorded events that year, an average of 20 registrations was recorded. In 2023, this average increased to 27 in the first half and 29 in the second half. The upward trend

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continued in 2024, with the first 4 roundtables averaging 38 registered participants and the following 4 averaging 61. In 2025, the first 5 roundtables recorded an average of 54 in-person registrations and 17 online registrations, reflecting the continued growth and hybrid nature of the format. Total attendance was not consistently recorded across all events.

Survey Results

Study Population Characteristics

As the survey was distributed via QR code during PMRT events and shared on LinkedIn, no exact response rate can be determined. However, considering that each event typically attracts around 40 participants on site, the number of responses represents a substantial share of the actively engaged audience.

Regarding demographics, the majority of participants identified as male, with most respondents falling into the 30 - 39 years and 50 - 59 years age groups. Industry representatives and physicians were the largest professional groups, making up nearly half and a quarter of the sample, respectively. Smaller proportions included nurses, researchers, and specialists from fields such as information technology, user experience research, and innovation management (see Table 1).

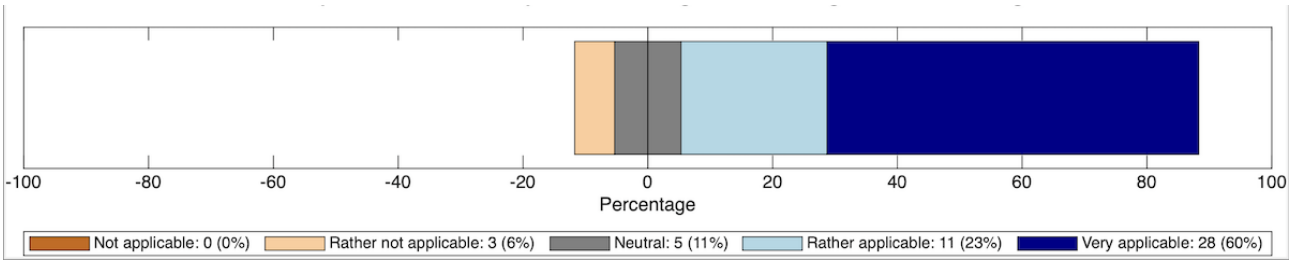
The majority of participants reported having experience in patient monitoring and/or other digital health technologies, with the median response to the statement, "I have experience in the field of patient monitoring and/or other digital health technologies," being "very applicable" on a 5-point Likert scale (Figure 3). Further analysis by professional group (clinical vs industry vs other) showed no statistically significant differences (Fisher exact test, P=.11). Similarly, no significant differences were found when analyzing responses by gender (Fisher exact test, P=.15).

Table . Study population characteristics.

Characteristic	Values, n (%)
Gender	
Man	31 (66)
Woman	15 (32)
Not disclosed	1 (2)
Age group (years)	
18 - 29	7 (15)
30 - 39	19 (40)
40 - 49	9 (19)
50 - 59	11 (23)
>60	1 (2)
Professional background	
Industry representatives	21 (45)
Physicians	11 (23)
Health and nursing professionals	4 (9)
Researchers	5 (11)
Other[a]	6 (13)

[a]Includes hospital information technology specialists, user experience researchers for medical hardware and software, cofounders with a focus on user experience research, innovation managers, designers, and physician-scientists.

Figure 3. Distribution of participants' responses to the statement "I have experience in the field of patient monitoring and/or other digital health technologies." Percentages indicate the proportions of answers given per Likert item (eg, "rather applicable"); n=47. PMRT: Patient Monitoring Roundtable.



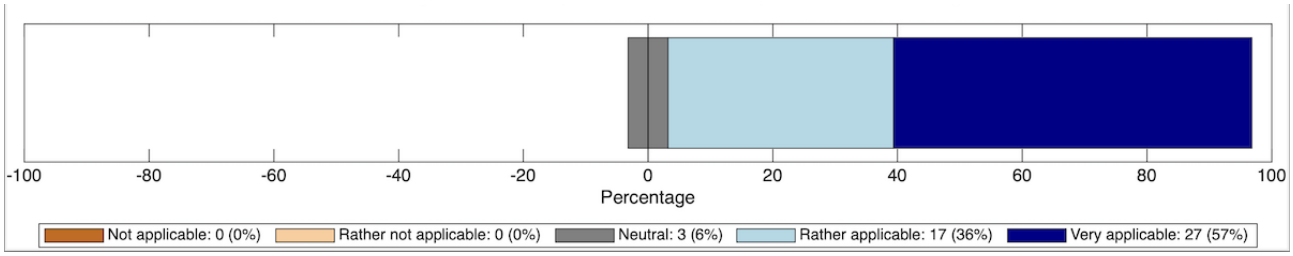
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Engagement With PMRT Events

More than half of the respondents (25/47, 53%) reported having attended four or more PMRT events, 9 out of 47 participants (19%) have attended 2 - 3 events, while 13 out of 47 (27%) have participated in the roundtable only once. There is no significant correlation between the professional background and the number of attended events (*P*=.19).

Around 44 (94%) out of 47 respondents indicated that it would be very likely or rather likely that they would recommend the PMRT to colleagues. A total of 3 out of 47 (6%) remained neutral (Figure 4). Analyzing the responses by professional group did not yield statistically significant differences (*P*=.08).

Figure 4. Distribution of participants' responses to the statement "I have already recommended, or would recommend, the PMRT to a colleague" (n=47). Percentages indicate the proportions of answers given per Likert item (eg, "rather applicable"). Percentages may not sum to 100 due to rounding. PMRT: Patient Monitoring Roundtable.



Relevance and Impact of PMRT Events

Regarding the relevance of the event content, the majority of participants found the PMRT content very or rather applicable to their professional interests (46/47, 98%). One respondent stated that the content was not relevant. The median response was "very applicable" (Figure 5). An analysis by a professional group showed no statistically significant differences (*P*=.95), indicating no systematic difference in responses across different professional backgrounds.

Similarly, the event formats, such as small group discussions and workshops, are widely regarded as effective in promoting dialogue among participants. Around 43 out of 47 attendees (93%) rated them as very effective or rather effective, 3 remained neutral, and one did not answer (Figure 6).

Many respondents reported feeling connected to like-minded colleagues, with most describing this as very or rather applicable (42/47, 89%). A smaller number of participants expressed neutrality on this point (5/47, 11%). The median response was "rather applicable" (Figure 7).

Figure 5. Distribution of participants' responses to the statement "The content of the PMRT events I have attended is relevant to my professional interests" (n=47). Percentages indicate the proportions of answers given per Likert item (eg, "rather applicable"). PMRT: Patient Monitoring Roundtable.

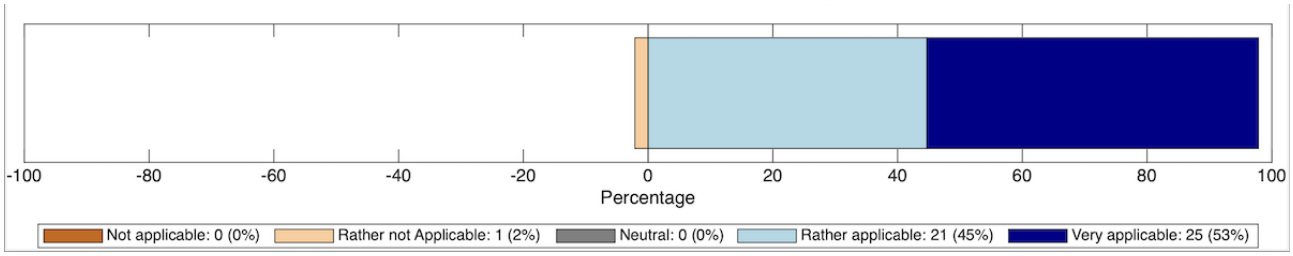
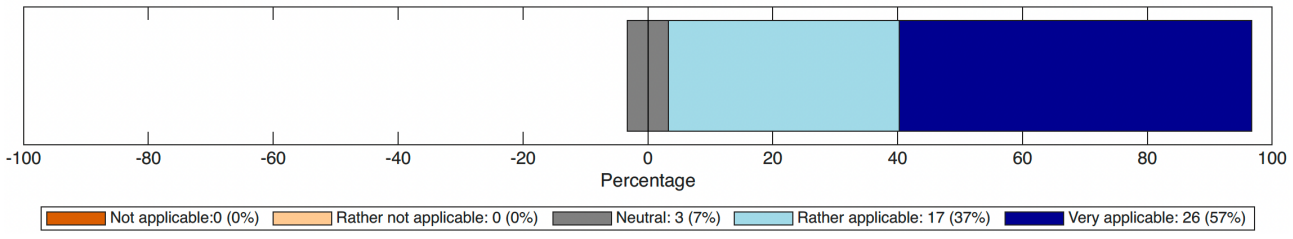
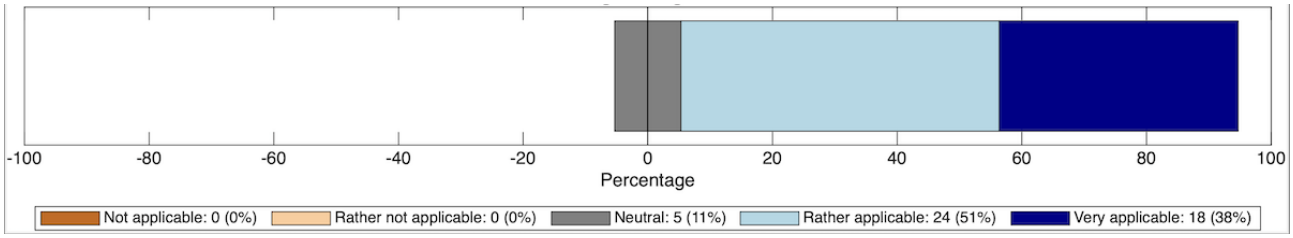


Figure 6. Distribution of participants' responses to the statement "The formats of the PMRT events (eg, small group discussions and workshops) effectively promote dialogue among participants" (n=46). Percentages indicate the proportions of answers given per Likert item (eg, "rather applicable"). Percentages may not sum to 100 due to rounding. PMRT: Patient Monitoring Roundtable.



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Figure 7. Distribution of participants' responses to the statement "Participating in the PMRT gives me the feeling of being part of a community of like-minded professionals in the field of patient monitoring and digital health" (n=47). Percentages indicate the proportions of answers given per Likert item (eg, "rather applicable"). PMRT: Patient Monitoring Roundtable.



When asked whether attending one or more PMRT events led to new collaborations, 13 out of 47 participants (28%) responded with "yes," while an equal number (28%) stated "no." Additionally, 21 out of 47 respondents (45%) indicated that they had not yet entered a collaboration but intended to do so.

Nine participants gave further details on the kind of collaboration. One innovation manager established connections with PMRT partners and various companies. Three industry representatives and one researcher developed new business contacts, while another industry representative initiated a collaboration within the PMRT network. Further collaborations included one industry representative who connected with a startup and another who started a project with nursing staff. Additionally, one physician engaged in a research collaboration.

Regarding whether attending the PMRT events provided new insights that would not have been gained otherwise (Figure 8), 43 respondents found this to be "very applicable" or "rather applicable." Three participants (6%) remained neutral. One response (2%) was left unanswered. The median response was "rather applicable." The statement "I will apply new insights or knowledge gained through the PMRT in my professional work" was assessed by 46 participants. Out of 47 participants, one respondent (2%) did not answer. One respondent (2%) indicated that the statement was rather inapplicable. Eight participants (17%) were neutral, whereas 24 respondents (51%) considered it rather applicable, and 13 participants (28%) rated it as highly applicable. An analysis by a professional group revealed no significant differences (P=.37). The median response was "rather applicable" (Figure 9).

Figure 8. Distribution of participants' responses to the statement "Attending one or more PMRT events has provided me with new insights that I would not have gained otherwise" (n=46). Percentages indicate the proportions of answers given per Likert item (eg, "rather applicable"). PMRT: Patient Monitoring Roundtable.

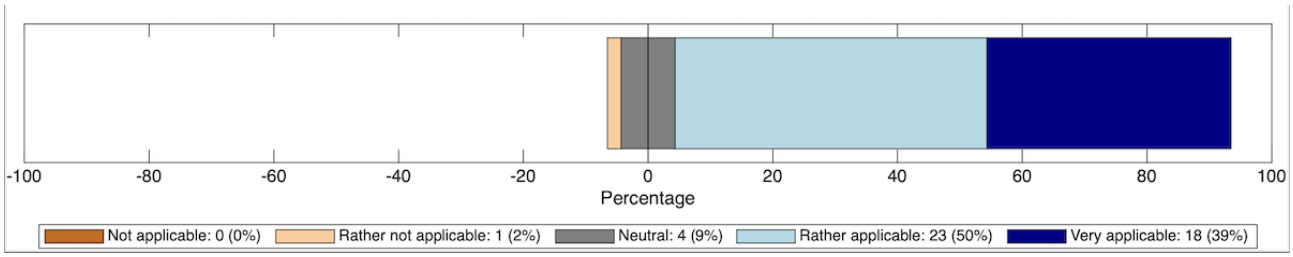
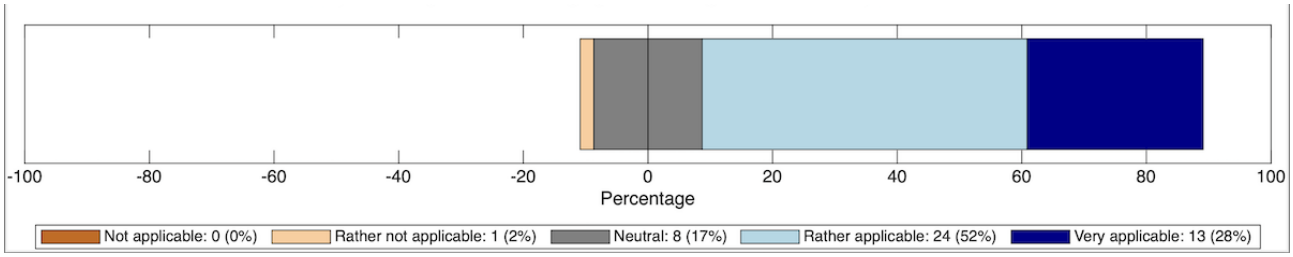


Figure 9. Distribution of participants' responses to the statement "I will apply new insights or knowledge gained through the PMRT in my professional work" (n=46). Percentages indicate the proportions of answers given per Likert item (eg, "rather applicable"). Percentages may not sum to 100 due to rounding. PMRT: Patient Monitoring Roundtable.



Feedback and Suggestions

Participants were asked to rank the most relevant aspects of the PMRT in order of importance. Of the 47 participants, 43 answered the question, while 4 did not provide information. The informal exchange with clinicians and manufacturers was rated as the most relevant aspect, with 25 (57%) of respondents ranking it as their top priority. This was followed by interactive workshops, which were most relevant for 9 (20%) participants and ranked second by 14 (32%). Short keynotes received more mixed responses, with only 8 (18%) ranking them as most relevant, while 12 (27%) placed them in the lowest priority category. The presence of renowned experts was seen as highly relevant by only 2 (5%) respondents, but 14 (32%) ranked it as the least important aspect. Small group discussions were rated as the top priority by 6 (14%) of participants, while the majority (16/47, 36%) ranked them in the middle. A further breakdown of the results by professional group did not reveal significant differences in preferences. The question regarding barriers to participation in PMRT events revealed several challenges faced

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by respondents. The most frequently mentioned obstacle was scheduling conflicts, cited by 30 participants, accounting for 60% of responses. Financial reasons related to travel cost were also a notable barrier, affecting 10 participants (20%).

Discussion

Principal Findings

The PMRT presents a novel, practice-oriented format to foster transdisciplinary exchange and user-centered innovation in the field of patient monitoring and digital health, facilitated through the methodological approach of combining structured event planning with iterative community engagement. The steady increase in event participation, from 20 registrations in 2022 to over 60 per event in 2025, underscores the growing relevance and perceived value of the series. One of the key strengths of the PMRT format lies in its low-threshold accessibility, which has been further enhanced by the integration of hybrid elements since 2025. In methodological terms, the iterative and adaptive character of the PMRT allows for real-time responsiveness to participant feedback and emerging needs. Yet, this flexibility also limits the generalizability of insights beyond the specific context of Berlin and the partner institutions involved.

Based on three years of iterative implementation, several practical insights have emerged that may guide others seeking to establish similar transdisciplinary, practice-oriented formats. These insights reflect the real-world dynamics of engaging diverse stakeholder groups in patient monitoring and digital health.

Key Lessons Learned

The following principles should be considered when designing and implementing the program:

- Ensure relevance: choose topics that closely reflect participants' professional realities to maximize practical value and engagement.
- Maintain continuity: establish a regular event rhythm to build trust, foster relationships, and sustain participation over time.
- Foster true transdisciplinary: involve diverse stakeholder groups so that each gains tangible benefits from the exchange.
- Use engaging formats: combine concise, high-value keynotes with interactive small-group workshops to stimulate discussion and collaboration.
- Implement clear roles: move from ad-hoc responsibilities to clearly defined, specialized roles to improve efficiency and ensure consistent quality.

Understanding Participants' Perspectives

Beyond the quantitative overview, the survey results provide deeper insights into the composition of the PMRT community, their engagement patterns, and perceived outcomes. Nearly half of participants were industry representatives, a proportion that is consistent with observations from the PMRT organization, where this group appeared more inclined to participate than clinical professionals. This likely reflects differences in workload, institutional constraints, and the prioritization of networking opportunities, as well as the more immediate benefits industry stakeholders can derive from qualified feedback. In contrast, the incentives for clinicians may be less tangible. While the roundtable already attracts a diverse audience, future efforts will focus on achieving greater gender balance and increasing participation from health care professionals, and particularly nurses, to better reflect the diversity of perspectives in real-world patient monitoring.

More than half of the respondents had attended four or more events, indicating strong and continued interest. The high likelihood of recommending the PMRT to colleagues further supports the perceived value of the platform. Interestingly, no significant differences in engagement were observed between professional groups.

The event formats were widely regarded as effective in fostering dialogue and participation in PMRT events contributed to a strong sense of professional community, which is a particularly important outcome, as transdisciplinary collaboration is often cited as a critical factor in advancing patient monitoring technologies.

Beyond fostering discussions, the PMRT has effects on professional networking and collaboration. More than a quarter of respondents reported having initiated new collaborations as a direct result of attending PMRT events, including industry partnerships, business contacts, startup engagement, and research projects, while almost half of the participants indicated an intention to collaborate in the future. On one hand, this highlights the PMRT's role not only as a platform for knowledge exchange but also as a catalyst for transdisciplinary cooperation. On the other hand, these collaborations are often one-off and not the kind that supports ongoing innovation.

While the overall reception of the PMRT was highly positive, certain barriers to participation were identified. Scheduling conflicts emerged as the most frequently cited challenge, affecting 30 out of 47 (60%) respondents. This issue will hopefully partly resolve with the introduction of a hybrid solution. Financial constraints were another notable barrier, impacting one-fifth of participants. As of today, the PMRT is free of charge. However, participants without residence in the area need to cover travel expenses. Other obstacles, such as technical difficulties and perceived lack of relevant content, were reported less frequently but still warrant consideration.

The PMRT is intentionally designed as a cross-sector forum that includes medical device manufacturers and is supported by industry sponsors. While this enables direct dialogue and practical feedback loops between clinicians and industry partners, it also introduces a structural risk of positive bias in participant-reported outcomes, particularly given the comparatively high proportion of industry respondents in our sample. Consequently, the results should be interpreted as perceptions of value and usefulness among engaged participants rather than as independent evidence of effectiveness.

Future evaluations should aim for independent replication, proactive recruitment of clinical stakeholders (including nursing professionals), and the inclusion of more objective indicators

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(eg, documented follow-up projects, implementation activities, or longitudinal tracking of collaborations).

Positioning the PMRT in the Context of Innovation Frameworks

To contextualize the PMRT within established innovation models, we draw on the quintuple helix framework [33], which has been widely adopted to analyze innovation processes in knowledge societies, emphasizing the interplay of ecological, social, and cultural dimensions alongside traditional institutional actors [34,35]. Unlike earlier models such as the triple and quadruple helix, which focus primarily on academia, industry, government, and civil society [36,37], the quintuple helix explicitly recognizes the natural environment as a key driver of innovation. The PMRT exemplifies a targeted application of the quintuple helix framework in health technology innovation, emphasizing multiactor collaboration while revealing persistent gaps.

In line with the literature, the PMRT exhibits strong engagement with the academic helix, as it actively addresses all major components, namely teaching and education, research, and initiatives such as innovation, democracy, and civic education [38]. The industry helix benefits from active participation by manufacturers, enabling practical insights into scalable implementation, an approach highlighted in recent studies as critical for bridging the gap between research and market adoption [39,40].

However, the political-regulatory helix remains underrepresented, reflecting broader challenges in embedding governance actors into innovation ecosystems. Although clinical staff across hierarchies and specialties actively represent user interests (aligning with the civil society helix), direct patient involvement remains limited. Ecological impacts are indirect, primarily through optimized technology deployment reducing implementation waste.

Overall, the PMRT aligns with the Quintuple Helix model's emphasis on multiactor collaboration and knowledge integration, yet also exemplifies the persistent underrepresentation of regulatory, civil society, and ecological perspectives that is widely observed in the literature.

Positioning Within the Innovation Landscape

The PMRT builds on the hackathon model described in a previous study [16], which showed that one-time, intensive events can successfully spark user-centered health innovation by bringing together patients, health care professionals, and developers to co-create digital solutions. The hackathon enabled rapid idea generation, multidisciplinary teamwork, and the development of functional prototypes but also revealed challenges in sustaining project momentum and ensuring long-term implementation after the event. In contrast, the PMRT provides a recurring, structured platform that supports ongoing stakeholder engagement and iterative development. By facilitating continuous collaboration and follow-up, the PMRT addresses the key limitation of the hackathon model, namely, the difficulty of maintaining project progress and impact beyond the initial event.

There have also been multiple initiatives with similar goals as the PMRT. One notable example is the Health Informatics Society of Australia Innovating Health Series in Australia, aimed at advancing digital health innovation by fostering new conversations among health care leaders and industry experts [41,42]. Through a series of roundtables and collaborative activities, Health Informatics Society of Australia sought to challenge existing perspectives and stimulate sector-wide change in response to mounting pressures on the health care system and the rapid evolution of digital technologies. Although the series appears to have concluded in 2020, its emphasis on cross-sector dialogue and co-creation closely aligns with the PMRT's ongoing, practice-driven approach to stakeholder engagement and innovation in patient monitoring.

The PMRT also shares foundational similarities with international innovation initiatives such as the European Institute of Innovation and Technology (EIT) Health Think Tank Round Table series [43]. EIT Health convenes pan-European policy forums to identify systemic barriers to health care innovation, focusing on regulatory clarity, resource access, and strategic alignment at a macro level. In contrast, the PMRT is a bottom-up, use-case-driven platform embedded in clinical practice, emphasizing clinical relevance, user-centered design, and interoperability. While EIT Health Round Tables are typically yearly, agenda-setting events, the PMRT operates as a recurring ecosystem, producing tangible outcomes such as structured user feedback that inform product development and implementation research. This positions the PMRT as a distinct and complementary format within the landscape of collaborative health innovation.

Implications for Practice

The PMRT is a well-established initiative that plays a critical role in bridging the gap between clinical practice, research, and innovation development. However, its current format as a local event series inherently limits its broader impact. To enhance its reach and effectiveness, the PMRT concept is being adapted for scalability. This includes transitioning to hybrid event formats and launching an online community platform, thereby facilitating sustained and meaningful exchange beyond the physical roundtable events.

The PMRT model can serve as a foundational element in building communities of clinical innovators, particularly within university hospitals. These innovators, clinicians with intrinsic motivation and interest in digital transformation, are essential for driving organizational change toward a learning health care system [44], as envisioned by the Institute of Medicine. The PMRT provides an effective mechanism for identifying and engaging such individuals and offers a replicable structure that can be adopted by other institutions.

Events like PMRT are more than knowledge exchange platforms; they actively contribute to community building and professional identity formation among digital health pioneers. Organizers and institutions interested in replicating the model are invited to reach out to co-host a local PMRT. The format has proven robust and can be adapted to different clinical environments with minimal effort.

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Further research is needed to assess the transferability of the PMRT concept to other regions or thematic areas within digital health. Future developments should consider ways to formalize the evaluation of impact, for instance, by collecting systematic feedback, tracking follow-up collaborations, or studying the implementation of discussed innovations in clinical practice. Additionally, expanding patient and caregiver participation could further strengthen the roundtable's commitment to inclusive and needs-based digital health development.

Limitations

There are several limitations to these findings. The first limitation lies in the selected methodological approach and the potential for bias due to the dual roles of several researchers, who were also actively involved in organizing and facilitating the PMRT. Regarding the survey, the sample size was limited to 47 participants, which might restrict the generalizability of the results. In addition, recruitment via LinkedIn likely led to an overrepresentation of industry stakeholders, which may not reflect the full spectrum of perspectives in real-world health care settings. Furthermore, a substantial proportion of participants had attended the PMRT four or more times, indicating that regular attendees might have been more willing to participate in the survey and making it plausible that their responses were biased toward positive experiences. Also, the findings are based on participant-reported perceptions and should therefore be interpreted with appropriate caution, as the inclusion of product-focused sessions and the industry-inclusive nature of the PMRT introduce a potential risk of positive bias. Notably, no responses were received from individuals who may have had negative perceptions of the PMRT, introducing the risk of selection bias. The findings must also be viewed in light of the fact that many participants were already well-versed in patient monitoring, which is beneficial for generating in-depth insights in a focus group setting. However, this limits the findings' relevance for understanding the needs of newcomers or for informing strategies to introduce and engage new stakeholders in the field of patient monitoring. Finally, the use of a custom-developed, non-validated questionnaire limits psychometric interpretation and comparability with other instruments. We aim to formally validate the questionnaire in future work, including assessment of reliability and construct validity.

Conclusion

In an era where digital health innovation often struggles to bridge the gap between clinical needs and technological solutions, the PMRT presents a novel, structured low-threshold platform for clinical-centered transdisciplinary dialogue, professional networking, and knowledge exchange. Its strength lies not in broad appeal, but in directly addressing the specific professional realities of its audience, ensuring relevance, trust, and meaningful dialogue. The PMRT's regular, low-threshold meetings create a stable framework for transdisciplinary exchange, enabling clinicians, researchers, and industry partners to engage on equal footing and identify actionable solutions.

Participant reception confirms high acceptance and perceived impact, with many reporting strengthened community ties, new collaborations, and valuing the interactive workshop format. Its participatory, recurring format fosters sustained engagement and has already led to tangible collaborations between clinicians, researchers, and industry partners. While the PMRT primarily attracts individuals who are already experienced in patient monitoring, this focus has strengthened its role as a trusted environment for high-level discussion and co-creation. To further increase its impact, ongoing efforts aim to broaden participation, especially among nurses and emerging innovators, and expand the initiative through a scalable hybrid model and an online community platform.

Acknowledgments

The authors would like to sincerely thank the volunteers and long-time attendees that have helped shape the PMRT events over the years.

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Data Availability

The dataset analyzed during this study is available from the corresponding author on reasonable request.

Authors' Contributions

EH wrote the manuscript, supported by ASP, JW, and MS. ASP, MS, JW, EH, AF, LA-M-S, AC, and MP conducted and supported the conduction of the Patient Monitoring Roundtable. EH, JW, MS, and ASP conducted the survey, and EH analyzed the findings. JW, AF, AC, AP, ASP, and FB critically reviewed the manuscript and provided feedback. All authors approved the final version of the manuscript.

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Conflicts of Interest

ASP reports receiving advisory honoraria from Dräger and Philips. Funding from BMBF, ESICM, and Masimo has been provided directly to Charité. ASP is co-founder and CEO of INCH health GmbH, a company developing digital health innovation platforms. JW, MS, and EH are partners of INCH Health GmbH, a company developing digital health innovation platforms. AF and FB receive research funding from Philips. All other authors declare no conflicts of interest. The sponsors had no influence on the study design, data collection, analysis, or interpretation of the results.

Multimedia Appendix 1
Questionnaire used in the participant survey on the Patient Monitoring Roundtable.
[DOCX File, 17 KB - jopm_v18i1e82786_app1.docx]

Multimedia Appendix 2
List of previous events.
[DOCX File, 19 KB - jopm_v18i1e82786_app2.docx]

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Abbreviations

BIH: Berlin Institute of Health
ECDF: Einstein Center for Digital Future
EIT: European Institute of Innovation and Technology
GDPR: General Data Protection Regulation
INCH: Initiative for Innovation and Collaboration in Healthcare

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PMRT: Patient Monitoring Roundtable

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Experiences and Perceptions Within a Co-Created Drone Transport Initiative With Rural First Nation and Non–First Nation Communities: Semistructured Interview Study

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Abstract

Background: People living in rural areas of British Columbia experience inequities in access to health care that impact health and well-being. Since time immemorial, Indigenous peoples have had a holistic understanding of health and wellness, and knowledge of healthful ways of living. However, in a rural context, Indigenous peoples contend not only with inequitable access to health care, but also with the historical and ongoing impacts of colonization. Virtual health innovations enable access to care closer to home, yet the need for diagnostic tests and essential medicines remains limited by supply chains. In this context, transport of medical supplies by drone offers a promising solution and has the potential to improve access to health care in rural and First Nations communities in British Columbia.

Objective: The Drone Transport Initiative is a co-created health care innovation project between the Stellat'en First Nation, the Village of Fraser Lake, the University of British Columbia, and other health system partners that investigated the feasibility of drones to transport medical supplies in a rural British Columbian context. This analysis aimed to understand the experiences and perceptions of the Project Team, people directly involved in the Initiative.

Methods: Twenty members of the Project Team, including representatives from the Steering Committee and Operational Team having diverse roles within the project, participated in semistructured interviews. Eleven interviews were conducted either individually (n=5), in pairs (n=5), or in a group of 5 (n=1). Interviews were audio-recorded, transcribed verbatim, and anonymized. A reflexive thematic analysis was conducted to understand the Project Team's experiences and perceptions of the project. Initial

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results were shared with coauthors, including project cosponsors and community members, to interpret the findings and formulate discussion topics.

Results: Participants generally expressed positive experiences from being part of the Drone Transport Initiative, despite remarking on various challenges. Major themes derived from the analysis centered upon (1) building respectful and trusting relationships, (2) mutual benefits that enabled effective and engaged partnerships, (3) meaningful community engagement that facilitated community acceptance and ownership of the project, and (4) this project is "the first step of something big." Themes were further divided into subthemes characterized as processes or outcomes.

Conclusions: In this work, we highlight a health innovation project grounded in relational approaches and partnerships, where rural and First Nations communities are champions of advancing their development goals and co-creating solutions that address key social determinants of health. We contribute to the literature by emphasizing the relational foundation that is necessary at the cutting edge of innovation to co-create, implement, and sustain drone projects with rural and First Nations communities.

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KEYWORDS

rural; technology; health care innovation; community engagement; health care access; First Nations; Indigenous

Introduction

Rural areas in Canada comprise 98% of the total land mass and are home to 20% of the population [1]. While definitions of rurality differ, in British Columbia's health care context, rural areas are classified based on proximity to larger health centers and the number of practicing physicians in the area [2]. It is well known that rural populations face inequities in health care: a result of fewer providers, less health infrastructure, and decreased access to specialized services [3]. Rural residents must often travel vast distances to access care, resulting in additional financial costs termed the "rural tax" as well as concomitant social and emotional burdens [4]. These factors highlight geographical location as a key social determinant of health and well-being in a Canadian context.

Indigenous peoples, including First Nations, Inuit, and Métis peoples, across Turtle Island—colonially known as North America—have practiced healthy lifestyles for generations and maintain a holistic understanding of health and wellness [5]. However, historical and persistent colonial forces have intentionally dispossessed and displaced Indigenous peoples from their lands and cultures, and undermined Indigenous worldviews, ways of knowing, and right to self-determination [6]. This historical and ongoing harm has created significant consequences for the health and well-being of Indigenous peoples today. Moreover, Indigenous peoples in rural and remote communities contend with barriers to health at the intersection of colonialism, geographical inequities, and other inequities [5,6]. The need for systemic change is increasingly being recognized within government and nongovernment institutions, academia, and in society at large [7-9]. However, addressing the systemic and structural roots of health inequities is an ongoing task.

Virtual health innovations can supplement in-person health care and address access gaps, especially in rural and remote communities in British Columbia and enable First Nations to access care closer to home [10]. Telehealth services improve access to providers, yet geographical location still impacts access to diagnostic tests and essential medicines. A solution is desperately needed. Drones have been used to deliver health care supplies in multiple contexts globally, to augment the existing supply chain system and enable more timely care [11]. In Canada, drones may complement virtual health services and enable people living in rural areas to access care closer to home. This has the potential to improve overall health and well-being. However, there is currently a lack of research within a North American context focusing on real-world implementation projects that use drones in rural and Indigenous communities, and particularly, the corresponding relational considerations [12].

The Drone Transport Initiative (DTI) is a health care innovation project co-created by the Stellat'en First Nation, the Village of Fraser Lake, the University of British Columbia (UBC), and other health system partners. Phase I of the DTI began during the COVID-19 pandemic when a province-wide state of emergency was declared and transportation was restricted. Many First Nations in British Columbia were locked down, which exacerbated existing inequities in access to health care. At this time, the confluence of political will, regulatory agility, community motivation, and funding opportunities during the COVID-19 pandemic created conditions for rapid innovation. Conceived with the intention to showcase health care applications of drones in resource-constrained settings in British Columbia, the DTI received funding for a 1-year demonstration project. While federal regulations at the time did not permit the transport of patient medications, the project aimed to examine the partnerships necessary to integrate drone technology into communities through the transport of mock medical supplies. In doing so, the project had the potential to provide evidence for regulatory changes, inspire government support, and enable ongoing co-creation with communities. Our team analyzed interview data from people involved in the DTI to identify key facilitators and inhibitors to implementation (K Nouhi, unpublished data). However, analysis of facilitators and inhibitors alone provides only a partial perspective. Gaining a deeper understanding of the broader experiences and perceptions of those involved is also critical for supporting the DTI's sustainability and is the focus of the analysis herein. This particular line of inquiry lent itself to a reflexive thematic analysis of interviews to elicit the unique perspectives of the DTI Project Team.

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Methods

Project Team Structure

The DTI Project Team comprised the Steering Committee (SC) and Operational Team (OT). The SC advised on project direction and included sponsors, the project manager, and representatives from partner organizations with leadership roles. The OT included those who were directly involved in day-to-day operations and oversight. Some were hired by UBC and others were hired by the drone technology provider.

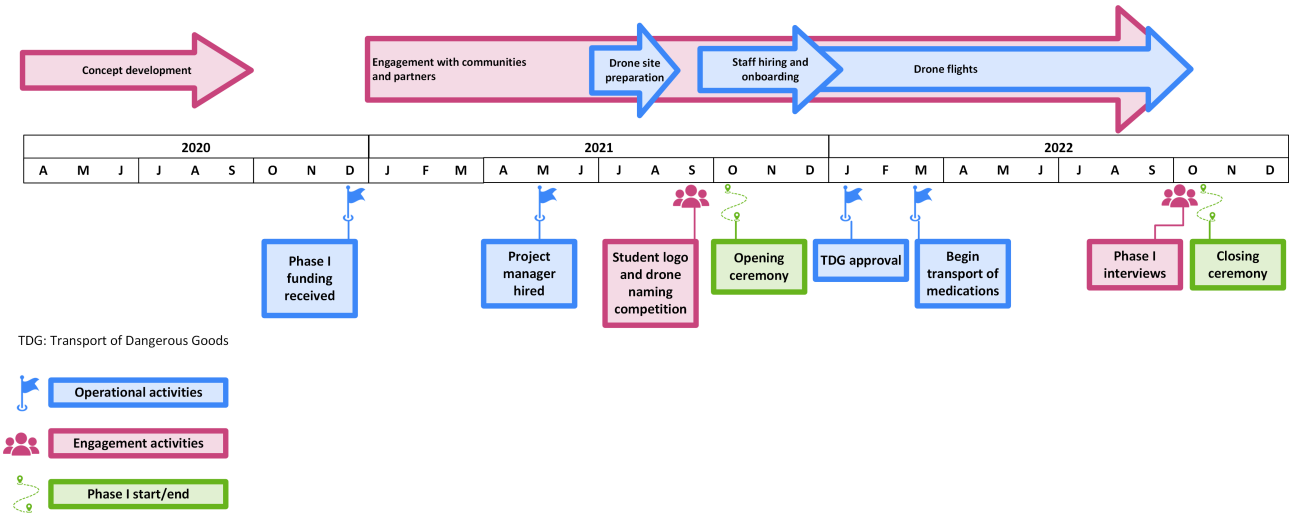
Description of Host Communities

Since time immemorial, Stellat'en (the people of Stella) have lived where the Endako and Stella Koh rivers meet, and the Stellat'en First Nation has a population of about 250 people living on the Reserve [13]. The Village of Fraser Lake, approximately 7 km to the east, has a population of about 1000 people and is located on the traditional, ancestral, and unceded territories of the Stellat'en and the Nadleh Whut'en First Nations. The two communities are approximately 160 km west of Prince George, the largest city in Northern British Columbia.

Sampling and Data Collection

All members of the DTI Project Team were invited via email by SL to participate in semistructured interviews. Of the 22 eligible participants, 20 agreed to be interviewed and 2 declined. Semistructured interviews were conducted in-person or over Zoom (Zoom Communications, Inc) by SL in October 2022 (Figure 1). Eleven total interviews were conducted, individually (n=5), in pairs (n=5), or in a small group of 5 (n=1), and lasted between 20 and 60 minutes. All interviews were audio-recorded, transcribed verbatim, and anonymized with numerical IDs. The anonymized transcripts are securely stored on UBC's OneDrive, and only the lead authors (AW, SL, and FH) have access to the data. All lead authors who interacted with the data have completed training in the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2) and are trained in Ownership, Control, Access, and Possession principles. These data have not been returned to communities; however, trusting partnerships between communities and UBC Project Team members render UBC's OneDrive the preferred location for secure data storage. Data remain accessible to communities should they require access in the future. To enhance the readability of results, AW assigned pseudonyms to participants at random and shortened or revised quotes as necessary. Participants whose quotes are included in the results were contacted for approval of their pseudonyms and for the use of their quotes in the final paper. No participants disagreed.

Figure 1. Timeline of key events and activities in Phase I of the Drone Transport Initiative.



SL had accumulated several years of experience working in public policy for the First Nations Health Authority in British Columbia. Prior to interviews, most participants had completed a short survey based on the Awareness, Desire, Knowledge, Ability, and Reinforcement model of behavior change [14]. The survey context was specific to using drones to transport medical supplies and included questions about partnership development within the project. SL created an interview guide based on survey questions, which was reviewed with community liaisons, project sponsors, the SC, and the receptionist at the Stellat'en First Nation Wellness Center prior to use (Multimedia Appendix 1). The specific survey findings, including group-level responses, are available in Multimedia Appendix 2. We acknowledge that these tools are rooted in Western, Eurocentric approaches to inquiry, yet have aimed to incorporate Indigenous perspectives and approaches to inquiry in this work by seeking input from Stellat'en First Nation members and representatives from First Nations Health Authority (Multimedia Appendix 2).

The DTI took a strength-based approach to the development of interview questions. The interviews aimed to find out from the DTI Project Team "what went well" and "what could have gone better" during Phase I of the project. Members of the Stellat'en First Nation who participated in surveys or interviews were provided with a US $25 gift card to acknowledge their contributions. A temporary, part-time position with opportunities for further training in project evaluation was advertised through the Stellat'en First Nation's administrative office with the objective of hiring an Indigenous evaluator to conduct interviews. However, the team was unable to fill the position, so interviews were conducted by SL, who knew all participants, having been the DTI project manager since May 2021 (Figure

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1). A more fulsome description of the project can be found in Multimedia Appendix 3.

Data Analysis

This analysis is 1 of 2 that will inform future phases of the DTI (K Nouhi, unpublished data). Using a pragmatic perspective, this study considers the truth as relative to individual experiences, and practical outcomes are considered knowledge [15]. A reflexive thematic analysis was conducted with interview data to understand the perceptions and experiences of those involved in Phase I of the DTI. AW managed and coded data using NVivo 14 (Lumivero). An inductive approach following Braun and Clarke's 6-step process facilitated the organic development of a narrative [16]. This involved reading transcripts closely to get familiarized with the data and generate codes while staying as close as possible to the data (ie, avoiding interpretations during the early stages of analysis). Codes were grouped into categories that reflected specific topic areas, such as communication and partner engagement. Themes were generated to encapsulate related categories and summarize an overall message.

Throughout the iterative analysis, SL and FH helped clarify ideas, refine, generate, and review the themes. SL and FH also helped AW create subthemes, which were categorized as either processes or outcomes to produce a preliminary narrative. AW, SL, and FH sought feedback from AJ, JP, and MA, whose feedback further guided the analysis. Data were presented to community coauthors AP, DC, SS, and RM to seek essential feedback and ensure the narrative resonated with communities' experiences. All coauthors were considered "critical friends" and provided essential context and interpretation to preliminary findings based on their direct involvement with the project. The first author (AW) has been transparent in how her positionality shapes the results of this qualitative study (Multimedia Appendix 4). Transparency in reporting was supported by completion of the COREQ (Consolidated Criteria for Reporting Qualitative Research) checklist (Checklist 1).

Ethical Considerations

In accordance with the regulations of the Tri-Council Policy Statement (TCPS 2) governing research ethics in Canada, this study did not undergo a full ethical review as it was not classified as research [17]. In Canada, program evaluation and quality improvement studies do not fall under the auspices of the TCPS or institutional Research Ethics Boards. Participants provided informed consent for the interview and audio recording. Participation in interviews was voluntary, and everyone received a CAD $25 (~US $18) gift card to acknowledge their contributions.

This paper represents entirely original work. Where work and/or words of others have been used, this has been appropriately cited or quoted, and permission has been obtained where necessary.

Results

Overview

We identified 4 themes and 11 subthemes categorized as processes or outcomes (Textbox 1). Processes are steps or activities to achieve an outcome, and outcomes are the results of these processes.

Textbox 1. Themes derived from the thematic analysis.

- Respectful and trusting relationships are key to designing and implementing a community drone project
- Opportunities for mutual benefits lead to effective and engaged partnerships
- Meaningful community engagement helps the drone project become embedded into communities
- The drone represents opportunities and potential for rural and First Nation communities in health care and beyond

Theme 1: Respectful and Trusting Relationships Are Key in Designing and Implementing a Successful Drone Innovation Project

Overview

Natalie (SC) shared, "...the human relationships on the ground were really, really, really valuable." The first theme focuses on the importance of building and strengthening respectful and trusting relationships between project partners. Processes included cultivation of respectful relationships by project champions and flexible and meaningful engagement of involved partners. A perceived outcome was mutual understanding between the involved partners.

Process: Cultivation of Respectful Relationships by Project Champions

Participants recognized that building and strengthening relationships with communities and partner organizations was foundational for progress. Natalie (SC) shared, "how important it is to build those relationships because once you build them, you can just keep moving on."

Participants identified the instrumental role of project champions in advocating for communities and communicating the project's vision, opportunities, and potential. Champions contributed to interest and confidence in the project from communities and partners alike. They also played a crucial role in promoting a culturally safe environment through training that supported effective collaboration. These actions were essential in cultivating relationships between diverse partners and communities.

Sydney (SC) mentioned that in addition to having prior experience working with First Nations on community projects, "support also from UBC to guide us on the right path" was invaluable, and felt that "it was a great joint effort ... [that] made it easy at the end."

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One participant highlighted Dr John's role,

> *I have to give him a lot of credit because he does fight for our communities, and I believe that if we didn't have him to speak for us and say how [the DTI project is] necessary, and how it's needed, it wouldn't have happened.* [Spencer, SC]

Likewise, Chief Robert's invaluable leadership and support of the project were highlighted,

> *I was really impressed with Chief Robert and his commitment and dedication to the project. He just really looked committed to it. He seemed to be communicating with his membership, and he just seemed really engaged which is really great to see.* [Denise, SC]

Denise (SC) also noted the project manager's contributions, "I think the project ran superbly, thanks to you. You're exceptional as to how you managed every detail."

Being endorsed by project champions facilitated the project manager's ability to build trust with communities, effectively delegate resources at an operational level, and act as a conduit between champions and the OT.

Process: Flexible and Meaningful Engagement of Involved Partners

Participants perceived collaboration, commitment, and interdependence of project partners as an important strength of the DTI. There was also a sense of pride in partners and communities coming together to co-create an innovative technological solution to advance the delivery of health services in rural and First Nations communities. Justine (SC) noted, "It was a diverse pocket of people that made this thing work, because it's so novel, right?" One participant shared a similar view,

> *All the different levels, all the different types of personalities, I guess, agencies that are involved to make it come together. I thought that was awesome to have all of that.* [Elise, SC]

SC members were engaged at precommittee meetings, which built an understanding of the different partner roles and the project's vision and goals. Participants indicated that respectful partner engagement is done according to community protocols and requires an understanding of structures and relationship dynamics within organizations and communities.

Initially, meaningful engagement was deduced during analysis from factors that participants highlighted: collaboration, commitment to one another, and respect for individual, cultural, and geographical context. This aligns with definitions of meaningful engagement from other fields, such as spinal cord injury research, where meaningful engagement comprises personal and socially meaningful research, dissemination and/or implementation, and feeling a sense of responsibility to others [18]. Importantly, community coauthors were consulted to develop and approve the following definition of meaningful engagement. In the context of the DTI, meaningful engagement is an approach to planning, implementing, and sharing the project with community members that prioritizes respectful and trusting relationships and centers community values and perspectives.

Some participants experienced personal circumstances, work obligations, or pandemic-related losses that intermittently limited their capacity to engage in the project. Natalie (SC) identified flexible engagement as a way of accommodating partners' capacities. She noted,

> *I appreciated that we could tap out for those reasons. I felt that we were brought in at the beginning and then [the Project Manager] just connected with us when you needed to, when things were moving ahead. I appreciated not being brought along for every stage.* [Natalie, SC]

Within the project, participants saw value in balancing the achievement of project objectives with respect and empathy for the humans who are involved in the work.

Formation of Diverse Relationships Enabled Mutual Understanding

Participants viewed the formation of relationships between diverse partners as a key positive outcome of the project. For example, Denise (SC) shared,

> *The best thing about the project was the relationships that were formed between [the Village of] Fraser Lake, the Stellat'en First Nation, and our project group.* [Denise, SC]

These relationships supported effective partnerships across different sectors, areas of expertise, and lived experiences by enabling partners to better understand each other and "appreciate the challenges that rural and remote communities have to deal with." Understanding that these challenges stem from geographical location, as well as the historical and ongoing impacts of colonization for First Nations peoples, helped to contextualize the critical importance of projects like the DTI.

Theme 2: Opportunities for Mutual Benefits Lead to Effective and Engaged Partnerships

Overview

The second theme explores the mutual benefits that motivated the continued participation of project partners. Contributing processes included (1) creating opportunities for community development and (2) facilitating career development and benefiting partner organizations. Perceived outcomes were strengthened community capacity and the realization of organizational benefits.

Process: Creating Opportunities for Community Development by Hiring Community Staff

Participants identified Dr John's role in conveying the project's opportunities for community development and well-being, both in the Stellat'en First Nation and the Village of Fraser Lake. For example, one participant shared,

> *Dr. John started articulating what it was going to look like, who the players are at the table, what the vision is, what the economic opportunities are going*

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> *to be, what the technology is going to look like.* [Louise, SC]

This helped to affirm the project's potential. Donna (OT) also shared her positive perceptions of local employment opportunities and noted, "I like that you guys hired out of the First Nations community here, that's pretty sweet."

Process: Facilitating Career Development and Benefiting Partner Organizations

Participants mentioned the importance of feeling useful within the project. Some OT members felt that using their existing skillset or developing new skills would allow them to make meaningful contributions and feel more engaged in the DTI project. However, some participants did not feel supported by their organization to get more training. Donna (OT) shared that she wanted to "get more training and be a little more useful" but expressed that her organization did not take her seriously or fully empower her to further develop her skillset.

Kate (OT) suggested that improved communication would have helped her to better understand the project's objectives, feel more engaged, and think innovatively. When referring to the level of engagement she experienced within the project, she shared,

> *It wasn't that bad, because if it was a really big problem and I felt I was completely in the dark, then I would have been like, 'Hey what's the purpose here?' So, it was clear enough that I didn't have to seek out understanding, but it wasn't so clear that I could start doing out of the box thinking in my day-to-day.* [Kate, OT]

For Kate, a directive approach by her organization did not foster engagement or motivation.

While SC members generally perceived that they were engaged appropriately, experiences from OT members were mixed. For OT members, whose roles within the project were not always stimulating, individual-level benefits, such as the opportunity to upskill or grow professionally, may have been leveraged as an additional source of motivation.

Outcome: Strengthened Community Capacity and Achievement of Organizational Benefits

Participants perceived strengthened individual and community capacity as a positive outcome of the project. In addition to tangible outcomes such as deliveries of patient medications, employment opportunities, and exposure to technology, SC members were particularly motivated by the opportunity to support their communities in stimulating economic activity. For example, one participant shared that

> *one of the big priorities was the opportunity to expose some members to new technology and to the employment opportunities. That was real [sic] important.* [Philip, SC]

Louise (SC) also highlighted the positive impact of technology in a rural context, "...to be able to bring this type of technology to a rural area is so beneficial to everybody."

Both SC and OT members recognized the benefits of this project to organizations of which they were a part. For example, one participant shared that the project allowed her organization

> *to take a closer look at drone technology and have a lot of learning. It was good for [our organization] to be a leader in the space, looking to innovate on behalf of the patients of Canada.* [Denise, SC]

Likewise, one participant noted that this project had

> *been successful because the goal was to evaluate if drone transportation was feasible, and to gather metrics to help us build the industry and see how we can scale this going forward.* [Daryl, SC]

Theme 3: Meaningful Community Engagement Helps the Drone Innovation Project Become Embedded Into the Community

Overview

The third theme focuses on the role of meaningful community engagement in facilitating health care innovation projects. A process in this theme was continuous engagement of community members guided by community representatives, and a perceived outcome was community acceptance and ownership of the project.

Process: Continuous Engagement of Community Members Guided by Community Representatives

Participants recognized the importance of continuous community engagement throughout the project. Informal conversations and events, including open houses and visits to the drone site by youth, helped to share the project's aims with community members. Community liaisons provided advice on how to best engage Stellat'en First Nation and Village of Fraser Lake community members and encouraged a focus on youth engagement.

One participant noted that

> *having the schools do site visits helped create more buzz around what we were doing. And it had some kitchen table talk when the kids went home at night which helped promote the project as well.* [Christopher, SC]

The drone's flight path was highly visible to communities, making public acceptance a priority. Louise (SC) noted how communities were informed about the project using posters, Facebook (Meta Platforms, Inc), the community newsletter, and an open house. She noted that the drone would affect community members,

> *…not only Mrs. Smith that lives close is going to be impacted, but Mr. Brown that lives on the other side of town might come down to White Swan Park and walk the dog. And then there's a drone [and he] wants to know what's going on.* [Louise, SC]

However, she remarked,

> *I had zero complaints, zero comments, zero anything on the first day of the drone flying. I was expecting*

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> *the phone to go off the hook, and nothing. So, I think we did a good job of explaining.* [Louise, SC]

Indeed, maintaining positive public perceptions was important. Philip (SC) joked, "so far nobody is taking a shotgun to the drone."

Outcome: Community Acceptance and Ownership of Co-created Health Care Innovation Project

Participants highlighted the role of the community in determining their own priorities and interests. One shared that

> *acceptance by the community itself to allow [the project] to go ahead and not to have too [many] issues with it, that was a good thing.* [Elise, SC]

Louise (SC) mentioned that some community members went to watch the drone fly and perceived this level of interest to be evidence that community engagement was done well.

> *I think we did have a pretty good community engagement because in the first two weeks of operation it was like a drive-in theater down there. There were vehicles parking just to watch this thing go, alright? Which was pretty neat to see.* [Louise, SC]

Theme 4: The Drone Represents Opportunities and Potential for Rural and First Nation Communities in Health Care and Beyond

Overview

The final theme explores participants' visions of what the future of drones might look like. A process involved maintaining the vision during the initial demonstration phase of the project. Perceived outcomes included indicators of progress that were shaped by diverse lived experiences, and envisioning the drone's future potential.

Process: Maintaining the Vision During the Initial Demonstration Phase of a Feasibility Project

Participants described dissonance between what the drone was able to provide, what the community needed most, and what the future could hold. This dissonance was felt by both SC members and the OT. One participant shared,

> *this is the fun stuff that some of us get to do on the side of our desk, right? But the meat and potatoes of it is really not something that's serving our community needs now.* [Justine, SC]

Natalie (SC) shared that staff also found it challenging to see the bigger picture and shared that she

> *would have to constantly remind [them] that we would have no problem receiving [laboratory] specimens from [nearby communities], they're ten minutes away, but it's the bigger picture, [the drone] wasn't just intended to just do this route.* [Natalie, SC]

Some participants recognized this dissonance yet still saw value in the drone project. Even though it was possible to visit the pharmacy, putting the medication on the drone and following the established workflow was fundamental for project partners to get from where they were to where they wanted to be. One participant shared that,

> *rather than just go into the pharmacist, put it on the drone, take it off. Just to protect that process, which I thought was pretty good ingenuity, just to keep that idea of what we're trying to do.* [Elise, SC]

Outcome: Perceptions of Progress That Are Shaped by Diverse Lived Experiences

Participants identified an array of indicators of the project's perceived success. Many remarked on specific positive outcomes of the project, including forming relationships, making progress in the regulatory sphere, and other aspects of community and individual well-being, such as employment opportunities and completing medication deliveries. However, some struggled to see any immediate benefits.

The milestone of transporting real medications instead of surrogate packages was viewed by Thomas (OT) as a significant achievement. He shared,

> *I think the biggest milestone is that we actually did deliver a few medications in the drone. That was the concept, and we actually proved the concept, that it is something which is feasible.* [Thomas, OT]

Sydney (SC) also perceived the delivery of medical supplies as important and noted that it helped staff be more engaged and find purpose in their roles. She noted,

> *when we started to move the medical supplies on Tuesdays and Thursdays, it showed [local staff] there's a real reason why we're doing this, and that helped them get engaged more.* [Sydney, SC]

The diversity of lived experiences within the project contributed to varied perceptions of progress. Although some participants saw the delivery of real supplies as having a positive impact on themselves, staff, and community members, others did not. One participant shared,

> *I understand that it might be beneficial in areas where the roads are not accessible, but I feel like the amount of money that is spent on it, you would be better off driving in a vehicle.* [Rebecca, SC]

She later acknowledged,

> *what you're doing right now, I feel like it is not really valuable to anybody, but I understand that you have to start at that smaller scale.* [Rebecca, SC]

Participants may have had difficulty seeing the drone's positive impact because its service route was between 2 communities connected by road. However, other participants saw it differently: even though the route was short, the drone provided access to those who could not drive. Spencer (SC) shared, "we have clients that have no vehicles that rely on that drone."

An important consideration also emerged when the drone delivery services that community members had begun to depend on stopped with the end of Phase I. Spencer (SC) offered insights on how the end of Phase I impacted community well-being. He shared that delivery of medications by the drone

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> *really helped for people who don't have vehicles within our communities, and some of the Elders, it's delivered right to their door. I wish it would have continued because now I know those clients are going to be expecting the drone to drop it off for them.* [Spencer, SC]

Spencer (SC) also shared a frustration that highlighted discordance between the constraints of project funding models, project implementation, and First Nations cultural values. Spencer (SC) shared, "When you bring stuff to our communities you're supposed to leave it, and you're not supposed to take it back." This frustration is embedded in a long history of government and academic research projects that are constrained to short-term funding timelines and lack continuity and sustainability. These types of projects can cause harm to communities and negatively impact relationships between First Nations and health system partners.

Outcome: Envisioning the Future Potential of Drones

Participants discussed partners' improved understanding of the drone's future potential as an important positive outcome of the project. For example, Elise (SC) said: "the big thing I heard is the possibilities of the drone project." These ranged from further applications in health and wellness including the transport of traditional medicine, blood samples, or "even organs someday." Other ideas included expanding the project to other First Nations communities and diversifying the drone's capacity to assist in climate-change-related disaster relief or economic development opportunities.

One participant noted,

> *the situation especially on the Western side of Canada, regarding disaster recovery because of global warming, it's a pretty significant problem. I think having contingency plans to use some of the drone solutions that we have for disaster support – it's going to be needed for the foreseeable future.* [Christopher, SC]

Participants indicated that the drone's utility could extend beyond medication delivery to facilitate the Stellat'en First Nation in pursuing their distinct priorities (health care, economic development, environmental monitoring, etc). Indeed, participants felt that "idea[s] for the drone [are] endless" and envisioned diverse future possibilities for the project. Although partners expressed innovative ideas for the future, Justine (SC) acknowledged distinctions between Nations and their priorities when considering how this project might be expanded to other First Nations in the future, and shared, "I wouldn't say any one of our communities would look exactly as the other."

Discussion

Principal Findings

Participants generally had positive experiences of being part of the DTI and highlighted the social aspects of this unique health innovation project. While technological challenges and benefits of drone use in health care settings have been widely discussed in the literature [19-21], we contribute an analysis of the social aspects and implications of integrating drone technology in rural and First Nation communities.

Relationship-Building and Community Engagement Are the Foundation

Across all themes, deliberate efforts to cultivate relationships and community engagement were highlighted. Underpinning these efforts were trust and respect, factors which have been found to support efficient development and implementation of virtual health innovations in rural, remote, and Indigenous communities [22]. However, trusting relationships with communities were not built from scratch; rather, they had been cultivated over several decades between communities and Dr John Pawlovich, practicing rural family physician and project cosponsor. A unique characteristic of this project was preestablished, longitudinal relationships which enabled it to be implemented within a short timeframe and during a global pandemic.

Trusting relationships are critical in health projects with Indigenous peoples given the historical and contemporary injustices rooted in colonialism and white supremacy [23-25]. Centering Indigenous values within the project according to relational science models can support sustainable and equitable partnerships with Indigenous communities [26]. Youth engagement amplified support for the project, aligning with findings previously shown in community-led projects [27]. However, the role of youth extends beyond generating excitement; youth are the future of these communities. Exposure to technological innovations via the DTI embeds the project within communities longitudinally and inspires participation and leadership in the project by the next generation, or interest in science, technology, engineering, math, and medicine.

More broadly, public acceptance of drones is important as their use varies from espionage and military to parcel delivery [28]. The public may not typically associate drones with health care, but it has been shown that having knowledge about drones increases their acceptability [12,28]. As described in the literature, building trusting relationships and community engagement activities take time [29,30]. However, with a project manager, time and resources could be dedicated to facilitating continuous opportunities for engagement of the SC, OT, and communities. Moreover, the project manager could "meet people where they're at" and engage them according to a flexible approach that respected individual and community capacity and ensured protocols for engaging with the Stellat'en First Nation were followed.

Achieving Mutual Benefits and Imagining the Future

Participants benefited in various ways from involvement in the DTI at the individual (eg, enhancing medical delivery), communal (eg, strengthening relationships), and organizational (eg, leadership) levels. These findings align with depictions of previous health research partnership projects with Indigenous communities [31], describing benefits on different levels. Achieving mutual benefits relates to the concept of reciprocity: recognized as part of co-created projects in community-based health services, and an important cultural value in an Indigenous context [32].

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Participants valued helping their communities, developing personal capacities, and having the freedom to be innovative. These are also reported as key elements of co-creation [32]. While environments supporting opportunities for creativity, growth, and mutual benefits encourage effective and engaged partnerships, procedures, policies, and organizational culture can impede engagement [33]. This was felt by some participants who did not feel supported by their organizations to build capacity within the DTI project.

Project champions reminded people of the DTI's long-term vision and helped overcome short-term barriers such as perceiving a lack of immediate benefits of the project. This aligns with aspects of transformational leadership theory and the LEADS (Lead self, Engage others, Achieve results, Develop coalitions, and Systems transformation) framework, both Western perspectives that include inspiring, motivating, and empowering teams [25,34]. The LEADS framework is often used in health system contexts to describe strategic approaches to leadership and has been mapped onto Indigenous understandings of leadership [25]. This congruency reflects the true collaboration required within a novel, co-created innovation project.

Drone technology may also address uncertainties faced by rural and remote communities, which include the changing nature of the resource economy and the growing impact of climate change [35]. A drone may offer communities a tool to shape their futures and contribute to their economic well-being, including job creation and opportunities in areas beyond health care such as environmental monitoring, surveying, and natural resource exploration. Moreover, for Indigenous communities, where health is understood holistically, a drone may contribute to community well-being, aligning with the First Nations Perspective on Health and Wellness. In this model, health encompasses not only physical well-being, but also other factors including relationships and economic well-being, caring for the land and natural resources, as well as safety and emergency preparedness [36]. Participants shared how drones could be used according to communities' distinct priorities now and in the future, and co-design of technology will enable the drone to be a fit-for-purpose tool suited to the unique realities of First Nations communities.

Implications and Future Directions

Our findings highlight the importance of relationships within health care innovation projects with rural and First Nation communities that involve drones. Despite the tendency of rural and First Nation communities to be pushed to the edge of health care [22], this study similarly reframes and expands our notion of the edge. Instead of a place of exclusion, the edge in our context refers to the cutting edge—the forefront of innovation—where relational approaches and partnerships position communities to be active champions of projects that align with their development objectives. In a First Nations context, these notions contribute to broader goals of self-determination.

For the DTI Project Team, these learnings are essential to maintain a sustainable project that is accountable to the distinct priorities of the Stellat'en First Nation and informs approaches to forming partnerships with other rural and First Nation communities to expand the project in the future. The next phase of the DTI will involve implementing combined virtual pharmacy services and drone-based medication delivery in rural, remote, and Indigenous communities. The findings from this paper have directly informed our approach moving forward, reinforcing the importance of continuing in partnership using a relational, community-driven process. In collaboration with involved communities, we will co-create the service model, evaluate its impact, and document our findings in detail, from both operational and research perspectives.

The DTI Project Team and other project teams working in a health care innovation context will benefit not only from prioritizing relationship-building, but also from being able to understand and evaluate these partnerships. This may include establishing co-created definitions and indicators of success, partnership strength, effectiveness of leadership strategies, and trust-building that resonate with involved partners. These metrics will be crucial for project sustainability and scaling up the use of drones to other communities. The Partnership Pentagram Plus model previously used in health innovation projects could support future partnership and evaluation efforts for the DTI project, and other health care innovation projects with rural and Indigenous communities [10,37].

The implications of this work for academia more broadly are to exemplify disruption of conventional views of community-academia relationships as transactional and transient; instead supporting the notion that longitudinal partnerships that transcend the research life cycle [29] are not only beneficial, but essential for such work. The DTI's focus on longitudinal relationships and mutual understanding is necessary for co-creating sustainable projects with Indigenous communities.

In a policy context, this work highlights the importance of relationship-building to support collaboration between industry partners, health care, and other sectors, communities, and First Nations rightsholders. However, bold, challenging, and innovative projects such as the DTI also depend on policymakers who can advocate for the value of co-creation, regardless of political leadership.

For health system leaders, this project illustrates how health technology can be integrated into the health care system in rural and Indigenous contexts. The insights described in this paper, together with an additional analysis of influencing factors of the DTI, will guide the development of an integrated drone network within the British Columbia health system (K Nouhi, unpublished data). This work can inform future efforts to expand drone technology to other Indigenous communities within and beyond the province of British Columbia.

Limitations

Phase I was a 1-year proof-of-concept project that explored the feasibility of drone transport from the Village of Fraser Lake to the Stellat'en First Nation. When Phase I began, the drone had not yet been approved to transport medications (Transport of Dangerous Goods), and the Phase I evaluation primarily focused on perceptions and experiences of the Project Team to inform future phases. When approval was received to deliver

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medications, several community members received their medications by drone. As delivery of medication was not initially planned, we did not study the experiences of community members who used the drone's services. Additionally, we did not explore the experiences of youth from communities. Future research is needed to understand how to optimally engage youth in health technology projects and how to evaluate its impact.

Interviews were conducted both individually and in groups, and the interview configuration was not explicitly considered in the analysis process (ie, all transcripts were analyzed in the same way). Group interviews may be influenced by what participants feel comfortable sharing, depending on their relationships with colleagues. Conversely, group settings can also deepen reflection and discussion, thereby enriching the findings.

Initial data analysis was conducted by researchers who were not involved in project planning, implementation, or data collection. This is generally disadvantageous for qualitative research; however, it afforded a "naïve approach" to the analysis that was not influenced by prior relationships or contextual understanding of the project. As AW and FH were not primed to interpret the transcripts in a particular way, the initial analysis enabled coauthors to contribute context and insight from their experiences within the project. Furthermore, the lead authors (AW, SL, and FH) do not have lived experience in a rural community. To mitigate this limitation, coauthors with various backgrounds were involved throughout the analysis and provided their perspectives on the results, and a first author positionality statement has been provided (Multimedia Appendix 4) to share how AW's identity as a researcher and human being has shaped these findings.

Finally, the interview guide for this project was developed for a program evaluation, rather than a research study. For this reason, the questions were pragmatic and closed and were designed to capture pertinent information about the project for communities and funders. However, conversational-style interviews conducted by SL encouraged open and honest responses, in addition to the relationships that had been cultivated between SL and participants throughout the DTI project. This generated rich data suitable for this thematic analysis.

Conclusions

There is promising potential for drones to address health inequities with the transport of medical supplies to rural and First Nations communities in British Columbia and beyond. These findings emphasize the importance of building trusting relationships between involved communities and partners, and the potential for drones to be used by communities for their distinct priorities within and beyond health care. This work highlights the relational foundation that is required for implementing and sustaining drone and other innovation projects in rural First Nations and non–First Nations communities. These outcomes will guide the co-creation of a health model of partnership evaluation specific to drone use in a Canadian context and highlight relational considerations in drone work.

Acknowledgments

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Generative artificial intelligence (AI) and AI-assisted technologies have not been used in this work. All authors have been personally and actively involved in substantive work leading to the manuscript and will hold themselves jointly and individually responsible for its content.

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Data Availability

The datasets generated or analyzed during this study are not publicly available due to ethical considerations, as they may contain identifiable information about participants. Additional data are available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization: FH (lead), SL (supporting)
Data curation: SL
Formal analysis: AW (lead), FH (supporting)
Funding acquisition: SL, JP, TA, MA

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Investigation: SL
Methodology: SL
Project administration: SL (lead), AP (supporting), DC (supporting)
Supervision: SL, FH
Validation: SL, JP, MA, DC, RM, AP, SS
Visualization: AW
Writing – original draft: AW (lead), FH (supporting)
Writing – review and editing: AW (lead), SL (supporting), JP (supporting), TA (supporting), MA (supporting), DC (supporting), AJ (supporting), DK (supporting), KN (supporting), LDL (supporting), RM (supporting), AP (supporting), ER (supporting), AS (supporting), SS (supporting)

Conflicts of Interest

TA is an employee of First Nations Health Authority (FNHA) and University of British Columbia (UBC) and received honoraria from Doctors of BC and Rural Coordination Centre of BC (RCCbc) for work related to Indigenous health in British Columbia. All other authors declare no conflicts of interest.

Multimedia Appendix 1
Interview guide.
[DOCX File, 15 KB - jopm_v18i1e82720_app1.docx]

Multimedia Appendix 2
Survey development and data.
[DOCX File, 23 KB - jopm_v18i1e82720_app2.docx]

Multimedia Appendix 3
Project description.
[DOCX File, 15 KB - jopm_v18i1e82720_app3.docx]

Multimedia Appendix 4
Positionality statement.
[DOCX File, 14 KB - jopm_v18i1e82720_app4.docx]

Checklist 1
COREQ checklist.
[PDF File, 360 KB - jopm_v18i1e82720_app5.pdf]

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Abbreviations

COREQ: Consolidated Criteria for Reporting Qualitative Research
DTI: Drone Transport Initiative
LEADS: Lead self, Engage others, Achieve results, Develop coalitions, and Systems transformation
OT: Operational Team
SC: Steering Committee
TCPS 2: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans
UBC: University of British Columbia

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Developing a Culturally Tailored Narrative Video for Skin Cancer Prevention Among Spanish-Speaking Hispanic Outdoor Workers: Co-Design Study

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Abstract

Background: Hispanic individuals face a higher risk of skin cancer due to disproportionate occupational sun exposure; yet, culturally tailored resources for this demographic are scarce.

Objective: The aim of this study was to codevelop a culturally tailored narrative video to enhance skin cancer prevention among Spanish-speaking Hispanic outdoor workers

Methods: We partnered with the National Conservatory of Dramatic Arts, medical specialists, national skin cancer prevention organizations, occupational health experts, and Hispanic outdoor workers to create an educational video that promotes sun protection and skin cancer awareness and prevention among Hispanic outdoor workers and their families. Development was based on extensive formative research, health behavior models, and interactive script review by multistakeholder and community advisory boards.

Results: The final result is a 27-minute video that follows Miguel, who is taking ownership of his father's landscaping business as he is diagnosed with basal cell carcinoma. Throughout the video, Miguel and his wife, Sofía, learn about skin cancers, their warning signs, and steps for prevention, ultimately using this knowledge to protect and empower his employees and family. Key engagement strategies include cultural tailoring, story-driven learning, and visual modeling.

Conclusions: This culturally and theoretically informed video represents a tool to increase knowledge and self-efficacy among Spanish-speaking Hispanic outdoor workers and their families, potentially reducing their skin cancer risk. Future research should evaluate the video's acceptability and impact on enhancing awareness, knowledge, and sun-protective behaviors.

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KEYWORDS

skin cancer prevention; Hispanic outdoor workers; cultural intervention; health communication; ultraviolet radiation; melanoma; community engagement; early detection

Introduction

Skin cancer remains the most commonly diagnosed cancer in the United States [1]. In 2025, projections indicated that approximately 104,960 cases of melanoma and 5.4 million cases of nonmelanoma skin cancer—basal cell carcinoma (BCC) and squamous cell carcinoma (SCC)—would be diagnosed in the United States alone [2]. Exposure to solar UV radiation is the most common modifiable risk factor for skin cancer, making it largely preventable [3-7]. Outdoor workers have an increased risk of developing skin cancer as they are exposed to 8 times more UV radiation and are 60% more likely to develop skin cancer than indoor workers [8]. Hispanic individuals in the United States are overrepresented in outdoor jobs, including construction (53.9%) and landscaping or groundskeeping (48.1%), with men comprising the majority of this workforce [9-11]. Nationally, only 3.5% of construction laborers and 6.2% of groundskeeping workers identify as women. The incidence of both nonmelanoma and melanoma skin cancers has risen in Hispanic individuals over the past decades [12-15]. While non-Hispanic White individuals have a higher incidence of skin cancer, Hispanic patients of all races have worse health outcomes (eg, larger invasive tumors diagnosed at later stages) and higher mortality than non-Hispanic White patients [16-21]. Despite these disparities, most interventions and public health campaigns have been developed for and implemented among non-Hispanic White populations [22-24].

Sun protection behaviors are key to skin cancer prevention [25-28]. However, compared with non-Hispanic White individuals, Hispanic individuals are less likely to use sunscreen and wear protective clothing, sunglasses, and hats [28]. Even among Hispanic outdoor workers, who experience disproportionately high UV exposure, sun protection behaviors are suboptimal. In a population-based sample of Hispanic outdoor workers, 69% reported never or rarely wearing sunscreen while working outdoors [29]. Likewise, a study of Hispanic farmworkers found that only 9.2% used sunscreen and 11% used sunglasses [30]. Additionally, Hispanic individuals are less likely to perform skin self-examination (SSE), to be taught how to perform SSE, or to have a total skin examination conducted by a provider than non-Hispanic White individuals [28,31]. There is a critical need for culturally relevant materials among Hispanic populations, especially outdoor workers at high risk of sun exposure–related adverse health outcomes [25-29,32,33].

Hispanic individuals face multiple barriers to engaging in skin cancer prevention, including occupational (eg, workforce constraints), health care (eg, lack of access and socioeconomic factors), and psychosocial barriers (eg, knowledge, attitudes, and cultural factors). Studies have consistently shown very low awareness and knowledge about skin cancer and protective behaviors among this population, including outdoor workers [29,30,34,35]. In a study that had representation of different ethnic and racial groups, Hispanic individuals had the lowest skin cancer knowledge compared with other ethnic and racial groups but the highest level of interest to learn more about skin cancer, highlighting both an important gap and a key opportunity [26]. In addition, Hispanic individuals are more likely to have skin cancer misconceptions than non-Hispanic White individuals [28,32]. Common misconceptions and knowledge gaps include the beliefs that people with tanned to dark skin cannot develop skin cancer, that skin cancer would cause pain before diagnosis, that one cannot lower the risk of skin cancer, and that it is difficult to know which skin cancer prevention recommendations to follow [27,28,32,36]. There are also important knowledge gaps about sunscreen (eg, the meaning of sun protection factor) and how to use sunscreen properly. For example, a focus group study found that Hispanic men used sunscreen to cover up after sunburn to avoid pain [27].

Among Latino day laborers, sun-protective behaviors were more common when workers observed their supervisors practicing such behaviors [35]. Intention to engage in sun-protective behaviors has also been associated with normative beliefs such as how much peers engaged in sun-protective behaviors [37]. Some studies have shown that Hispanic individuals have negative attitudes about using sunscreen because they find it uncomfortable (eg, sticky and white cast) or believe that its use makes them feminine as a result of cultural beliefs such as *machismo*, which emphasizes strength and discourages behaviors perceived as vain [34]. On the other hand, *familismo*, a cultural value emphasizing the importance of and the need to take care of family, has been reported as a facilitator for Hispanic individuals to engage in sun-protective behavior [34]. Other social determinants of health, such as low education and low health literacy, have also been associated with lower engagement in sun-protective behaviors, lower perceived skin cancer risk, reluctance to perform SSEs out of fear of discovering skin cancer, and a greater number of sunburns [29,32,34,35].

Substantial evidence documents Hispanic individuals' preference for interventions and education materials in Spanish that include plain language, visual aids, and a narrative format [13,18,37-39]. Narrative health education materials embed health information in the context of a character-driven story as opposed to traditional didactic materials, which rely primarily on facts and statistics [40,41]. Evidence suggests that narratives can be an effective strategy for cancer communication in Hispanic populations [38,41-43]. Video interventions have been shown to be more effective than written materials for sun protection and skin cancer education [44]. Studies have also documented Hispanic individuals' preference for skin cancer video interventions over other types of interventions (eg, brochures) [26,36,45].

Additionally, Hispanic individuals are among the quickest-growing demographic in the United States, accounting for nearly 71% of the country's growth between 2022 and 2023, and now comprising approximately 20% of the total population [46]. Despite national data showing that about 38% of US

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Hispanic adults primarily speak Spanish, prior research has repeatedly found limited availability of Spanish language dermatologic educational resources [45,47,48]. In response to this gap and the others previously identified, the goal of this study was to develop a culturally tailored narrative video intervention to promote skin cancer prevention among Spanish-speaking Hispanic men and women working in outdoor occupations. To date, and to our knowledge, this will be among the first video interventions specifically tailored to Spanish-speaking Hispanic outdoor workers. In this paper, we (1) describe how we used theoretical conceptual models and formative research to develop the script, (2) outline the script of the video, and (3) discuss the partnership and lessons learned among the research team, our advisory boards, and the National Conservatory of Dramatic Arts (NCDA) during script development.

Methods

Ethical Considerations

This study was reviewed by the Georgetown University Institutional Review Board and granted an exemption (Institutional Review Board ID: STUDY00007990) on August 23, 2024. In lieu of a traditional informed consent process, all community advisory board (CAB) and multistakeholder advisory board (MAB) members were required to sign a formal agreement form prior to participation, which outlined the roles and responsibilities of both the research team and the board members. The agreement detailed the research team's commitments, including ensuring fair participation opportunities, providing feedback on member engagement, and offering compensation. This form also detailed members' responsibilities, which included attending all 3 remote advisory board meetings via Zoom between January and March 2025, actively participating with cameras on and from distraction-free environments, and promptly notifying the research team of any scheduling conflicts or changes in contact information. Agreement forms were made available in both English and Spanish, according to each member's preference, to ensure accessibility and comprehension across membership. To protect member confidentiality, all members agreed, as part of their signed agreement form, to refrain from sharing names, addresses, phone numbers, or other identifying information about fellow members outside the group or on social media. All member contact information was stored securely in Box, a password-protected platform accessible only to members of the research team. Regarding compensation, advisory board members were offered US $150 per meeting attended, for a maximum total of US $450 per member across 3 meetings. MAB members were compensated via honorarium payments; prior to payment, members independently completed Georgetown University's online supplier registration process through the GU Supplier Registration portal, after which payment was directly deposited upon completion of their 3-meeting commitment. Notably, a few of the MAB members preferred to waive compensation and provided their expertise voluntarily to support the study's goals. CAB members were compensated via their choice of mailed check or direct deposit, also issued upon completion of their 3-meeting commitment. These payment methods were intentionally selected to prioritize convenience and accessibility for each respective group. Specifically, streamlined direct payment options requiring minimal paperwork were chosen for community board members specifically to reduce potential barriers associated with sharing sensitive personal or financial information.

Theoretical Frameworks

The script was developed using an integrated approach grounded in 3 established behavioral theories: the Health Belief Model (HBM), the Theory of Planned Behavior (TPB), and Social Cognitive Theory (SCT). HBM explains health behaviors as a function of individuals' perceptions of risk and the benefits of taking action [49]. HBM constructs addressed in the script include perceived susceptibility, perceived severity, perceived benefits, perceived barriers, and cues to action. TPB posits that behavior is shaped by intention, which in turn is influenced by attitudes, perceived subjective norms, and perceived behavioral control [50]. Tenants of TPB used in the script include attitudes toward behaviors, subjective norms, and perceived behavioral control. SCT emphasizes learning through observation and the role of self-efficacy and social support in behavior change [51]. SCT constructs integrated into the script include modeling, self-efficacy, social support, and outcome expectations.

We also included anticipatory emotions, as previous work, including our own, demonstrates that the inclusion of anticipatory emotions enhances the predictive capacity of behavioral health models [52-55]. Anticipatory emotions are emotions experienced in the present when thinking about future events (eg, feeling fear now when thinking about the possibility of a skin cancer diagnosis). Emotional appeals in health-related messages are effective in motivating behavior [52-55]. For instance, fear appeals can prime individuals to avoid harm by engaging in protective behaviors. However, they can also generate defensiveness when the message leads to higher perceived threat than self-efficacy [52-56]. Fear appeals should thus be accompanied with messages that increase self-efficacy and treatment effectiveness [52-55]. Cancer prevention and control interventions have mostly targeted negative emotions [52-55]. Nevertheless, mixed messages that sequentially introduce both negative and positive emotions toward a health behavior (vs only negative) generate lower defensiveness, increase response efficacy, and strengthen intentions to follow the health recommendation [52-55].

To complement these behavioral frameworks, the Narrative Immersion Model (NIM) was integrated to guide the story structure and improve message engagement [57]. The NIM builds on broader theories of narrative persuasion (eg, entertainment-education), which explain the mechanisms by which narratives engage audiences more effectively than purely informational messages [57]. Following the NIM, we incorporated structural elements shown to enhance the processes of immersion, including temporal structure, realism, perceived similarity, humor, and surprise, through an outcome narrative focused on the consequences of unprotected sun exposure [57].

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Formative Focus Group Data to Inform the Video Script

We leveraged our ongoing partnerships with community-based organizations (ie, Spanish Catholic Charities) to connect with and interview 25 outdoor workers across 3 focus groups [58]. Participants were predominantly male (22/25, 88%), 48% (12/25) had a middle school education or less, 52% (13/25) reported incomes ≤US $39,999, and 60% (15/25) were uninsured [58]. Results from these discussions gave the research team insight regarding existing skin cancer awareness, risk perception, risk reduction strategies, and barriers and facilitators for skin cancer prevention among Hispanic outdoor workers [58]. Findings from this study have been reported elsewhere [58]. The script also drew on existing literature and recommendations from organizations dedicated to skin cancer prevention [8,29,32,34,35,59,60].

Methods to Develop and Obtain Feedback on Video Script

Following the analysis of our data, the research team assembled both a MAB and a CAB. The MAB consisted of members representing dermatologists, oncologists, family medicine clinicians, occupational health experts, national skin cancer prevention organizations, patient navigators, and Hispanic melanoma survivors. The CAB included Spanish-speaking outdoor workers from various outdoor sectors including agriculture, construction, and landscaping. Table 1 provides a description of the specific organizations and individuals on each board.

Table . Member characteristics.

Profession/expertise	Quantity
Multistakeholder advisory board	
Dermatologists	2
Oncologist	1
Family medicine clinician	1
IMPACT Melanoma and National Council on Skin Cancer Prevention	1
Latinas in Construction	1
Patient navigator	1
Hispanic melanoma survivor	1
Farmworker Justice	1
Professor of occupational and environmental medicine	1
Community advisory board	
Agricultural, construction, and landscaping representatives	3

We met with each advisory board separately for 2 hours across 2 sessions to review and gather suggestions for the script. The research team chose to establish 2 separate boards in order to create a space where CAB members could speak in Spanish and express their perspectives openly. For both cycles of input on the formative findings and script review, the CAB meeting was always held ahead of the MAB meeting. Recommendations from the CAB were then presented at each MAB meeting for consideration. The research team collaborated with the NCDA in Washington, DC, to develop the script and produce the video. NCDA members were present at every MAB meeting to engage with the board and ensure that suggestions were clearly understood before incorporating them in the script.

In the first meeting with our CAB, we presented the findings from our focus groups and asked about their thoughts regarding the results and content for the script. We subsequently met with our MAB and similarly discussed the focus group findings, the suggestions from our first CAB meeting, and gathered their recommendations. A first draft of the script was then developed by the NCDA. Upon obtaining the first draft of the script, the research team distributed the script to all board members for review.

Following a multiweek review period, we held a second meeting with our CAB to hear their thoughts on the script and gather their recommendations for refinement. We then met with our MAB to present the CAB's suggestions and obtain the MAB's recommendations. The research team subsequently consolidated and triangulated all suggestions before sending the script to the NCDA for final development.

After receiving the final version of the script, the research team translated the script into Spanish and consulted with a Spanish-speaking dermatologist on our MAB to ensure the medical terminology was accurate and consistent with dermatologic terms in Spanish.

Results

Findings From the Focus Group Formative Work

Previously unreported recommendations from participants addressed video content and dissemination, including presenting clear information about skin cancer and sun protection, featuring relatable characters, and sharing the video through workplaces, community networks, and social media (Table 2).

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Table . Video suggestions from focus groups.

Themes	Responses
Video information	• Clear, simple, and straightforward information. • Use humor or entertaining elements to maintain engagement. • Address what skin cancer is, its causes (sun, genetics, and environment), and symptoms. • Explain treatment options and recovery. • Provide guidance on sunscreen (SPF[a] and recommended products), protective clothing, and hydration. • Should be short or longer if engaging.
Characters	• Include strong, relatable characters (eg, athletes who use sunscreen). • Include families and children. • Represent workers in relatable environments.
Visuals	• Show real images of skin cancer. • Show protective clothing (eg, color and material). • Depict long-term consequences (childhood to adulthood).
Dissemination	• Use social media, advertisements, and television. • Distribute at worksites, in safety talks, and through flyers. • Engage communities (eg, churches and Facebook groups). • Share in schools, companies, and community centers. • Encourage peer-to-peer awareness (eg, among coworkers).

[a]SPF: sun protection factor.

Feedback From the CAB and the MAB

CAB recommendations focused on explaining the causes of skin cancer, signs to look for, and how to protect oneself. MAB feedback emphasized clear clinical details, dialogue about the most common skin cancer diagnoses, and concise and relevant information on melanoma and nonmelanoma skin cancer types. Both boards suggested incorporating family-centered activities, including culturally relevant foods and sports, and providing national and local resources. Table 3 shows a detailed breakdown of the specific recommendations from each advisory board and the resulting adaptations to the video script.

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Table . Script recommendations from advisory boards (community advisory board and multistakeholder advisory board).

Category	CAB[a] feedback	MAB[b] feedback	Script adaptations
Skin cancer awareness	• Extend conversation with the doctor to address questions, such as "What does this diagnosis mean?" and "What are the next steps?" • Introduce the different types of skin cancers that exist for educational purposes[c]. • Include images of how different types of skin cancer look[c].	• Have Miguel go to the doctor for a sore that was not healing, and display how the doctor performed a full skin examination. • Clinical information should come from the physician scene in the video. • Miguel's diagnosis should be either basal or squamous cell carcinoma, as those are most common in outdoor workers. • Introduce the different types of skin cancer that exist and briefly discuss melanoma[c]. • Include images, information on warning signs, or ABCDEs of melanoma[c,d]. • Include information about acral melanoma. Although it is not associated with UV radiation, it has a higher prevalence among Hispanic individuals.	• Expanded the conversation between the physician and Miguel to include more information about his diagnosis, treatment, and timeline for recovery. In this scene, the physician also briefly explains the different types of skin cancers that exist and shows images and ABCDEs. • Miguel is diagnosed with basal cell carcinoma.
Skin cancer risk perception	• Include a scene toward the end where Miguel is talking to his staff about their risk of UV exposure and his experience with a skin cancer diagnosis.	• Describe federal regulations regarding occupational skin cancer risk.	• Included a scene toward the end where Miguel calls for a company meeting. During the scene, Miguel shares his diagnosis, addresses common misconceptions about skin cancer risk, and discusses the steps he plans to take to protect his workers.
Skin cancer risk reduction strategies	• Display how to conduct self-checks and encourage the audience to check with their physician for concerning moles and other skin irregularities suspected to be skin cancer[c].	• Emphasize the importance of regular screenings and early detection, not just when the disease is already advanced. • Emphasize prevention throughout the video. • Display how to conduct self-checks[c]. • Discuss and emphasize the different types of sunscreen (cream, spray, roll-on, etc). • Introduce risk reduction that can be implemented across all sectors (construction, landscaping, and agriculture). • Do not mention SunGuard (Rit) as it has not been recommended by the American Academy of Dermatology.	• Emphasized the importance of conducting self-checks as a risk reduction strategy. • Embedded message focusing on early detection and prevention throughout the scenes. • Explored different forms of sunscreen based on preference.

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Category	CAB[a] feedback	MAB[b] feedback	Script adaptations
Barriers and facilitators for risk reduction behaviors	• Include or introduce cultural role models practicing sun-safe behaviors, such as sports athletes, to motivate male outdoor workers. • Show the steps Miguel takes as a company owner to protect his workers (eg, providing them sunscreen) from UV exposure. • Ensure that the physician reassures Miguel after the diagnosis so that he feels uplifted and empowered to know that he can fully recover after treatment[c].	• Include a patient navigator to reiterate the information discussed in the video. • Have one of Miguel's workers ask whether skin cancer hurts, and address this in the video. • Explain how to use clothing as a form of protection and highlight differences between clothing that protects from heat vs UV radiation. • Introduce UPF[e] clothing and the impact of different clothing colors on sun absorption. • Include a list of national and local resources at the end of the video. • Include a scene or image at the end summarizing the key points or messages of the video. • Emphasize that sun protection is easy and affordable[c].	• Included a scene toward the end where Miguel calls for a company meeting. During the scene, Miguel shares his diagnosis, addresses common misconceptions about skin cancer risk, and discusses the steps he plans to take to protect his workers. • Embedded positive and uplifting messaging throughout the video, including Miguel's actions to protect himself, his workers, and his family from UV radiation. • Included extended discussion in the work meeting scene about UPF clothing, color of clothing, and other appropriate protection strategies. • Included a list of local and national resources in the end credits.
Cultural aspects	• Change food and drinks from the initial script to traditional foods. • Change the way Miguel receives the biopsy results to a phone call. Hispanic individuals do not usually check email or patient portal[c]. • Emphasize the importance of protecting one's family[c]. • Change baseball game to soccer[c].	• Include a family or friend soccer game at the end to include teaching point in action. • Do not include expressions conveying "machismo" in the video as it may distract from the main messages. • Extend scenes with family gatherings[c]. • Change the way Miguel receives the biopsy results to a phone call. Hispanic individuals do not usually check email or patient portal[c].	• Removed pizza from script and replaced it with traditional foods such as pupusas and carne asada. • Adapted the news of biopsy results to a phone call instead of email. • Emphasized the message of family unity and support throughout the script. • Added a scene at the end where Miguel and his family are having a picnic and children are playing soccer. This scene serves to summarize the main points discussed throughout the video.

[a]CAB: community advisory board.

[b]MAB: multistakeholder advisory board.

[c]Feedback that was provided by both the CAB and MAB.

[d]ABCDE: Asymmetry, Border, Color, Diameter, Evolution.

[e]UPF: ultraviolet protection factor.

Video Description

The 27-minute video consists of 8 scenes, each designed to address specific behavioral constructs. The video narrates the story of Miguel, a landscape worker who is transitioning to lead his father's landscaping company when he is diagnosed with BCC. The cancer is detected early and he undergoes a minor surgery, but the diagnosis raises concerns about the potential skin cancer risks for his family and employees. In his visits with the doctor, Miguel and his wife, Sofía, learn about different types of skin cancers (BCC, SCC, and melanoma), skin cancer signs, the importance of early detection, and key sun-protective behaviors. Following these visits, Miguel and Sofía share the information with their relatives and implement new sun safety practices at their workplace. Throughout the video, we target key Integrated Behavioral Model theoretical constructs as well as the barriers and facilitators we found in our formative work [58]. For instance, the video dispels common misconceptions (eg, skin cancer cannot occur in people with darker skin) and addresses knowledge gaps (eg, most efficient protective clothing). The video also models behaviors (eg, how to properly apply sunscreen) to increase self-efficacy and illustrates how subjective norms change throughout the narrative, from many coworkers being reticent about sunscreen use to then valuing and using sunscreen by the end. Finally, we included superficial cultural tailoring, such as having Hispanic actors, filming the video in Spanish, and including traditional Hispanic foods and popular sports such as soccer. Deep structure tailoring, addressing key core values and beliefs, included appealing to

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familismo as a core motivation to engage in sun-protective behavior and in portraying family support. Table 4 provides a detailed description of the video by scene, outlining the content and the theoretical constructs addressed in each segment.

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Table . Description of video by scene.

Scenes: Description/messages	Conceptual model constructs addressed
 *Scene 1. Work*: The film begins at a landscape work site where Miguel is working with his brother and coworkers.	Health belief model: • *Perceived susceptibility*: Presents common misconceptions (eg, Hispanics do not need sun protection).
 *Scene 2. Diagnosis*: While preparing for a family dinner, Miguel receives a phone call from the doctor confirming positive biopsy results for skin cancer. His wife notices his concern and asks him about it.	Health belief model: • *Perceived severity*: Miguel recognizes the seriousness of his diagnosis, feeling emotional concern not only for himself but also for the impact it may have on his family. Social cognitive theory: • *Self-efficacy*: After informing Sofía and engaging her support, Miguel gains confidence in his ability to navigate the treatment process and face the challenges ahead. *Emotional appeal:* The cancer diagnosis causes fear, but telling Sofía results in reassurance, balancing the negative emotion with support.
 *Scene 3. Doctor consultation*: Miguel and Sofía discuss his diagnosis of BCC with the doctor and next steps for treatment.	Health belief model: • *Perceived susceptibility*: The doctor explains that skin cancer can develop across decades. • *Perceived severity*: The doctor explains prognoses and treatment of detected vs undetected melanocytic and nonmelanocytic skin cancer. • *Perceived barriers*: *machismo* and denial. • *Perceived benefits*: Early detection leads to simpler treatment. • *Cues to action*: The doctor reinforces skin checks, warning signs (eg, ABCDEs[a] of melanoma), and follow-up care. Theory of planned behavior: • *Attitudes toward behavior*: Miguel and Sofía develop a positive outlook toward treatment and prevention. Social cognitive theory: • *Outcome expectations*: Clear explanation of treatment outcomes and benefits of early action. • *Social support*: Sofía's presence and encouragement highlight the importance of family support in health decisions. *Emotional appeal:* Revisits fear by emphasizing the seriousness of cancer but also introduces self-efficacy and reduces defensiveness as the doctor explains treatment options.
 *Scene 4. Daydream*: Miguel daydreams of the moment he told his son he did not need to wear sunscreen while working in the garden. Miguel remembers how his father would tell him that there was no need for protection. Miguel decides to be proactive and teach his employees and children about sun protection.	Health belief model: • *Perceived susceptibility*: Miguel imagines his son facing the same diagnosis, personalizing the risk and recognizing intergenerational vulnerability. • *Perceived benefits*: Miguel sees value in prevention for his family and workers. • *Perceived barriers*: Miguel acknowledges misinformation he once believed and passed on as barriers. • *Cues to action*: Dream functions as a cue and prompts Miguel to reconsider past behaviors. Theory of planned behavior: • *Attitude toward behavior*: Previously viewed sunscreen as unnecessary; dream reflects a shift in attitude. • *Perceived behavioral control*: Miguel believes that he can implement changes with Sofía's help and support from the doctor. Social cognitive theory: • *Modeling*: Dream reveals how Miguel internalized negative attitudes about sun-protective behaviors from his father, subsequently teaching them to his children. • *Outcome expectations*: Miguel understands that behavior changes can protect his son and workers in the future. *Emotional appeal*: Regret and fear about past inaction are offset by Miguel's drive to educate his employees and family.

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Scenes: Description/messages	Conceptual model constructs addressed
 *Scene 5. Family dinner*: Miguel shares his diagnosis with his family.	Health belief model: • *Perceived severity*: Skin cancer diagnosis presents emotional concern in family. Theory of planned behavior: • *Subjective norms*: Expectation of family involvement. Social cognitive theory: • *Outcome expectations*: Family expects that a united approach will lead to better outcomes. • *Self-efficacy:* Miguel gains confidence through family support. *Emotional appeal*: Despite the worry about his diagnosis, there is a shift toward hope as they prepare to face his cancer together.
 *Scene 6. Doctors' office*: Miguel asks the doctor about strategies to protect his team and his family.	Health belief model: • *Perceived susceptibility*: Miguel now acknowledges risk, not just for himself but for his workers and family members. • *Perceived severity*: The experience of treatment reinforces that skin cancer is serious but manageable if addressed early. Theory of planned behavior: • *Attitudes toward behavior*: Now associate prevention and follow-up with empowerment and responsibility, rather than fear. Social cognitive theory: • *Modeling*: Miguel becomes a model of transformation. • *Outcome expectations*: Early action and education can prevent future harm to others. • *Social support*: The doctor provides emotional and informational support to sustain Miguel's motivation. • *Response efficacy*: The doctor explains the effectiveness of the recommended response. *Emotional appeal*: Miguel turns uncertainty into empowerment.
 *Scene 7. Work place*: Miguel and Sofía share his diagnosis with his employees along with recommendations for sun-protective behaviors while dispelling common myths.	Health belief model: • *Perceived susceptibility*: Miguel explains that outdoor workers are at higher risk for skin cancer due to daily UV exposure, even in cold or cloudy weather. • *Perceived severity*: Miguel discloses his skin cancer diagnosis and underscores the potential seriousness of ignoring symptoms or misconceptions. • *Perceived benefits*: The team learns how sun protection (eg, UPF[b] clothing, sunscreen, etc) can reduce long-term risk. • *Perceived barriers*: Workers express common concerns (eg, sunscreen discomfort, environmental barriers, disbelief regarding the need for sun protection, etc), but Miguel and Sofía address each with practical solutions. • *Cues to action*: Miguel's testimony and new workplace protocols (gear, sunscreen access, and flyers) act as strong motivators. Theory of planned behavior: • *Attitudes toward behavior*: Initially negative or dismissive attitudes are challenged and reframed through lived experience and evidence. • *Perceived behavioral control*: Workers are provided with tools (sunscreen, hats, and educational materials) to make protective behaviors more feasible. • *Subjective norms*: Although workers voice negative attitudes initially, attitudes change and sun-protective behaviors are valued at the end. Social cognitive theory: • *Modeling*: Miguel teaches his employees how they can protect themselves; Sofía also provides flyers for family engagement. • *Outcome expectations*: Preventive behaviors are linked to staying healthy and being present for loved ones. • *Self-efficacy*: Miguel and Sofía empower workers with concrete steps and tools. *Emotional appeal*: Balances concern about UV risks among employees and their families with collective self-efficacy.

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Scenes: Description/messages	Conceptual model constructs addressed
 *Scene 8. Family/friends gathering*: Miguel and Sofía share the importance of sun protection with friends working in other industries and reinforce the importance of sun-protective behaviors with their kids who are playing soccer.	Health belief model: • *Perceived susceptibility*: Miguel's story motivates Arturo (a construction worker) to check a mole; the risk is now seen as real and personally relevant by peers. • *Perceived severity*: Recognition that long-term sun exposure without protection has serious consequences, even if symptoms seem minor. • *Perceived benefits*: Articulated through praise from Teresa and another outdoor worker. • *Perceived barriers*: Addressed with practical tools (eg, visors, neck flaps, multiple sunscreen formulations, etc) and culturally relevant role models (eg, renowned soccer athletes) to normalize sun protection and reduce stigma. • *Self-efficacy*: Everyone now has the knowledge, tools, and social support to feel confident in protecting themselves and their families. Theory of planned behavior: • *Attitudes toward behavior*: Positive reinforcement of sun safety behaviors as part of being a good parent, worker, and friend. Social cognitive theory: • Multiple generations model protective behavior in a communal setting. • *Outcome expectations*: Reinforced via testimonials (eg, Arturo's early detection, new workplace changes, etc). *Emotional appeal*: Joy and pride from seeing family and peers engage in sun protection. Fear has been overcome.

[a]ABCDEs: Asymmetry, Border, Color, Diameter, Evolution.

[b]UPF: ultraviolet protection factor.

Discussion

Principal Findings

The development of our educational video aimed at promoting sun protection among Hispanic outdoor workers and their families incorporated lessons learned from prior community outreach materials as well as guidance from workers, community leaders, and other stakeholders. In contrast to past approaches, our video uses entertainment-education, using a culturally contextualized narrative and visual demonstrations to impact knowledge, risk perception, and self-efficacy. Entertainment-education is unique among other approaches in that it delivers health messages through engaging stories that increase identification and reduce resistance to achieve lasting changes in attitudes and behaviors, demonstrating effectiveness in diverse contexts with empirical evidence and practical experiences [61,62].

Collaboration with national organizations, medical specialists, occupational health professionals, and community advisory members was crucial to the development of the video. Advisory boards built from personal experiences along with professional knowledge helped make the content practical and culturally sensitive. As reported by Cargo and Mercer [63], keeping community voices at the forefront of decision-making minimized technical or distant messaging, ensuring that behavior change strategies mirror real-life situations. Iterative review between the research and production teams was vital to preserving scientific accuracy while supporting the development of scenes that would resonate with our target audience. For instance, feedback from the CAB led to more scenes illustrating family members practicing sun safety and a soccer game to showcase healthy habits in culturally meaningful settings. These suggestions were consistent with findings from Perez et al [58], which highlight the value of a family-centric approach as well as appealing to the use of sunscreen by cultural role models (eg, soccer players). Feedback from the MAB, which was always informed by CAB suggestions, similarly resulted in expanding the doctor-patient conversation to clarify the differences in risks between BCC, SCC, and melanoma, as well as their prognosis and treatment timelines. It also prompted the inclusion of brief information regarding acral lentiginous melanoma because of its higher incidence among Hispanic White individuals than among non-Hispanic White individuals, despite being unrelated to occupational UV exposure [64,65]. Each scene thus reflects the integration of advisory board recommendations with theoretical concepts, behavioral goals, and cultural adaptations. This ensured that the video remained connected to both research and community priorities in concise, clear, and meaningful ways. Several challenges emerged from this development process, revealing key lessons about creating a culturally tailored, theory-driven video for health behavior change.

Embedding Health Messages Within Storylines

Producing an engaging video required balancing essential health information about skin cancer prevention with a culturally meaningful storyline, while keeping the length short enough for dissemination across various platforms. This meant trimming scenes, limiting transitions, and reducing extraneous lines, all of which required iterative reviews of the script, as well as weighing which elements were essential for educational impact versus narrative appeal. This demonstrated the value of not only developing the scenes based on specific health messaging but also discussing potential time distributions for each scene with the production team at the onset of script development.

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Ensuring Gender Relevance

Creating a gender-inclusive video required balancing culturally tailored content for a Hispanic outdoor workforce, which is predominantly men, while carefully integrating the representation of female workers [66]. To achieve this, Sofía acts as a primary educator in the video. She specifically educates female outdoor workers in scene 7 and addresses their specific concerns about workplace challenges to sun protection. Outside the workplace, Sofía demonstrates family-focused sun protection by showing how protective habits can fit into everyday life. In addition to discussing practical strategies for outdoor workers and their families, she models them in many ways (eg, sharing a basket of sunscreen with the children playing soccer in scene 8). Through these interactions, Sofía emphasizes the key role women have in promoting sun-safe behaviors both at work and home. Importantly, these strategies were shaped by female viewpoints. This included insights from 2 female members of the CAB and collaborations with female-led groups, such as Latinas in Construction, ensuring that women's voices were consistently included throughout the process.

Balancing Technical Language With Acting Techniques

As reported by Hurtado-de-Mendoza et al [67], scenes discussing medical information require strict adherence to the script. When making this video, we had to ensure that the actors delivered their lines exactly as written, as even minor paraphrasing, which is common in filmmaking, could misrepresent important health information. For example, describing a new skin change as a "pimple," which suggests something temporary and harmless, instead of as a "bump," which can indicate a concerning change, is critical. Translating these terms into Spanish with precision in ways that are understandable added a layer of complexity, but it was facilitated by our MAB, which included a Spanish-speaking dermatologist. This process highlighted the additional time and effort it may take to film content that is both medically accurate and engaging, especially when there are time and budget constraints.

Coordinating Multiple Advisory Boards

Managing input from 2 advisory boards required careful planning and execution. Scheduling across time zones and differing availability among clinicians, researchers, organizations, and community members often resulted in longer timelines. However, creating a distinct space in which community members could use their native language allowed us to build rapport and elicit conversations that yielded genuine and thorough suggestions. This approach underscored the importance of structuring engagement in a way that welcomes differing perspectives without diminishing the contributions of any group.

Addressing Behavioral Complexity in Prevention Interventions

Prevention-based messaging for modifiable behavioral risks such as UV exposure, which are shaped by a range of daily behaviors, contexts, and environments, must anticipate multiple pathways of action and resistance. This includes but is not limited to addressing various considerations such as why outdoor workers may avoid sunscreen, the range of protective methods available, and the questions participants may have about each option. Messaging must not only provide guidance across multiple scenarios, but it must also recognize and support the agency associated with behavioral risks to encourage choices that directly influence risk.

Keeping the Video as Neutral and Timeless as Possible

Throughout our board discussions, we remained intentional about creating a video that would be clear for diverse audiences and remain accurate and relevant over time. A topic we extensively discussed, for example, was whether to show images of skin cancers. While we illustrated the ABCDEs (Asymmetry, Border, Color, Diameter, Evolution) of melanoma and described how skin cancers may look through dialogue, we ultimately chose not to include specific images as we recognized that Hispanic individuals have a wide range of skin tones. Thus, a particular image of how skin cancer looks in one person may not reflect how cancer appears on someone else. Showing such images could mislead viewers, leading them to think that a skin change that looks different from the example shown is harmless. Additional information and resources can be included as complementary materials to the video in future interventions. Furthermore, although questions about the role of government in preventing occupational skin cancer were raised by various collaborators, the prospects for action were unclear, and the decision was made to focus on empowering outdoor workers directly, as we recognize that not all employers provide resources regarding skin cancer awareness and prevention [68,69]. Therefore, all information in the video was limited to factual content, avoiding anything that could be misunderstood or become outdated. This logic was helpful as we considered other recommendations, and it also supported our aim of creating a video focused primarily on prevention among outdoor employees.

Strengths and Limitations

This project was strengthened by its theory-based and community-involved process. Most psychoeducation interventions follow a traditional didactic approach. Our video is innovative because it uses a narrative communication approach to convey health information through a story developed in collaboration with our advisory boards to ensure that the narrative resonates with the target population. The use of constructs from the HBM, TPB, and SCT ensured that the script addressed multiple determinants of behavior change, while input obtained through separate advisory boards allowed for open dialogue within each board and minimized the influence of professional hierarchies. Additional strength was provided by our partnership with a range of stakeholders, including dermatologists, occupational health experts, and representatives from various national organizations involved in skin cancer prevention. Outdoor workers consulted on the project also represented diverse geographic areas, including the District of Columbia, Maryland, Virginia, and Florida, increasing the cultural and contextual applicability of the script. The video format also provides practical benefits for sharing and scalability. Its visual and narrative style can overcome literacy barriers, demonstrate protective behaviors, and stress socially

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supported practices in ways that traditional print or educational materials cannot. Recognizing that the video was produced in Spanish and not all Hispanic outdoor workers may speak Spanish, however, we also created a version with English subtitles. In addition to helping it remain accessible in a lens that still resonates with non-Spanish speakers, given the overarching cultural values and experiences it is grounded in, the video can be broadly shared via various channels, including workplace training, community health clinics, and online platforms. Despite these strengths, the script was developed for a particular demographic and may require modification for use in alternate populations or settings beyond landscaping and construction. Additionally, although the CAB included representatives who were small business owners, we recognize that this level of representation was not sufficient to ensure comprehensive incorporation of employer-level perspectives. As a result, important organizational perspectives relevant to workplace implementation may not have been fully captured. Furthermore, while the development process was informed by theory and stakeholder feedback, the impact of the intervention on behavior change has yet to be evaluated and should be the focus of future research.

Future Research Recommendations

Additional research needs to be conducted to assess the acceptability and efficacy of our video on sun protection behaviors, psychosocial (eg, knowledge and self-efficacy) outcomes, and process evaluation outcomes. In addition to obtaining preliminary feedback from outdoor workers, future approaches could include a randomized controlled trial in which the video is compared with a control arm (eg, traditional didactic video or fact sheet) with longitudinal follow-up. This may also include the development and piloting of complementary tools or resources on sun protection, followed by studies comparing their efficacy to the video. Subsequent studies could also explore knowledge and behavioral changes not only among workers but also among their families to provide insight into the broader effects of the video, recognizing that its plot and call to action were guided by the principle of *familismo*. Pending these findings, future work should also consider adapting the video into English for non–Spanish-speaking outdoor workers and engaging a broader range of employers to ensure that workplace perspectives and implementation insights are fully incorporated. This could include a multilevel intervention addressing individual behaviors and organizational supports for sun protection, including workplace facilitators and barriers, integrating the video into workplace wellness and safety programs, input on acceptability, and alignment with existing training.

Conclusions

By combining formative research with input from both CAB and MAB, we developed a theory-driven, contextually relevant intervention that is responsive to the gaps reported in the work of others as well as our own. The resulting video is both a reflection of and response to the occupational realities faced by Hispanic outdoor workers, demonstrating how codeveloped interventions can bridge the gap between evidence and experience. Rather than imposing predefined messages, our approach relied on active listening and iterative content-tailoring, representing a departure from passive information transfer. We present this as an innovative approach in an effort to increase engagement, comprehension, and sun-protective behaviors among this population relative to traditional didactic methods. Based on the active participation from the workers who were involved in the video's development, the video appears to have strong potential for effective implementation in real-world settings. More broadly, this project illustrates how integrating community participation with theory-based frameworks can enhance translation from research to practice, foster engagement among underserved populations, and promote health equity through culturally resonant prevention strategies.

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Conflicts of Interest

LCS is a consultant for Accutec and Enspectra Health, a consultant and researcher for Novartis Pharmaceutical, and a researcher for Regeneron, Pfizer, and Sanofi. She also serves on the Advisory Board for the Jacinto Convit World Organization and the Dermatology Advisory for Melanoma Research Foundation. GTG has served as a consultant for Bristol-Myers Squibb, Immunocore, Incyte, Iovance, Lyell Immunopharma, Merck, Novartis, Pfizer, and Replimune, and participated on an advisory board for Huyabio and a speaker bureau for Immunocore. He also has received institutional research support from Exelixis. RY works at Farmworker

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Abbreviations

ABCDEs: Asymmetry, Border, Color, Diameter, Evolution
BCC: basal cell carcinoma
CAB: community advisory board
HBM: Health Belief Model
MAB: multistakeholder advisory board
NCDA: National Conservatory of Dramatic Arts
NIM: Narrative Immersion Model
SCC: squamous cell carcinoma
SCT: Social Cognitive Theory
SPF: sun protective factor

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SSE: skin self-examination
TPB: Theory of Planned Behavior
UV: ultraviolet

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Joint Adaptation of a Digital Mental Health Intervention for University Students: Inductive Qualitative Analysis

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Abstract

Background: Digital mental health interventions (DMHIs) can be particularly effective for young people, who live more of their lives online than older generations. Co-designing mental health support with young people can combat the challenges of a lack of engagement and sustained use. While this is increasingly common, there are often budget and timeline restraints in research settings that limit true co-design. As part of the Nurture-U project exploring a whole-university approach to student mental health, we coadapted an existing digital platform, i-Spero (P1Vital), with university students. This paper is a reflection on the impact that our student advisors had on the end product, and where the guidance of the young people was implemented, and not implemented, within the existing research parameters.

Objective: This study aims to present an inductive analysis of meeting notes and recordings of the co-design process, in order to highlight what aspects of DMHIs our advisors valued and what, as a research team, we were able to implement. The hope is that this will inform future mental health interventions in this age group.

Methods: The i-Spero digital well-being platform was developed over an iterative process with multiple rounds of feedback from student advisors in 2022-2024. An inductive qualitative analysis approach was implemented by 2 authors (NA and JD) on the detailed feedback reports and meeting summaries of this process to generate categories and themes from the student advisors' feedback.

Results: Three themes were created: "Relevance and Usefulness," highlighting the importance of comprehensive features linking in with all aspects university life, while treating young people as adults; "Simplicity and Clarity," with student advisors suggesting edits that removed burden from the user and eased access to support; and "Acceptability and Inclusiveness," ensuring awareness of the needs of students from different backgrounds, and what young people with mental health difficulties may be able to access in times of need.

Conclusions: There are some challenges in ensuring that DMHIs are both comprehensive and simple. These can be met by ensuring the aesthetic design and platform structure are consistent and clear. Co-design and development are crucial due to the difficulty in ensuring that online interventions are relevant to specific audiences in the constantly evolving digital landscape. The structures surrounding our joint adaptation of an existing intervention meant that not all the changes suggested could be implemented. Future work should explore the impact of different participation frameworks when coproducing interventions with young people.

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KEYWORDS

youth mental health; co-design; co-development; university students; digital platforms

Introduction

There are estimated to be more than 2 million mental health apps worldwide, with a market value of more than US $8 billion in 2025 [1,2]. While the popularity and growth of these are due in part to ongoing digital wellness trends [3], there is also an increase in need. Worldwide, there is a mental health care crisis with services unable to cater to those who require access [4]. This is especially the case for young people, who have had an exponential increase in mental health challenges in recent years and have been particularly affected by the COVID-19 pandemic [5]. As evidence of this, 7.5% of UK university students declared a mental health diagnosis in 2023, compared to 0.7% in 2011 [6]. Recent research indicates 57% of university students have a mental health condition [7].

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In addition to the increase in need for digital mental health interventions (DMHIs), there is also a strong argument for their use for young people. Young people aged 18 - 25 years have grown up in a digital landscape. Overall, 79% of youth globally are online, compared to 65% of adults [8]. Additionally, young people have increased barriers to using mental health services due to a lack of mental health literacy, that is, understanding and knowledge of mental health conditions, how to get help, and how to prevent worsening of symptoms [9]. Hence, the accessibility of mental health support that can be accessed through a mobile phone or laptop could improve the well-being of young people [10].

However, there is a huge variety of apps that are designed to improve young people's mental health, with inconclusive research evidence on their effectiveness [1]. Only apps that are based on cognitive behavioral therapy, supplemented with therapist contact, have been shown to be effective [11]. There are many contextual factors as to whether people engage with DMHIs, including the relevance of the content, the length of the activities, and ease of integration into daily life [12]. Use of digital mental health apps is rarely sustained over time [13].

A solution to this is to include young people in the development and evaluation of DMHIs [1]. This has been argued to be particularly important in increasing the use of mental health support for marginalized and underserved groups, enabling product developers to identify aspects of interventions that cause users to engage or disengage [9]. There has been a recent growth in studies reporting on the codevelopment of interventions in a research setting. However, this has occurred alongside increasing concerns about the quality of the co-design process, with arguments that the amount that young people can truly impact an end product is always limited by time and budget constraints [14,15].

This paper describes the advice given by young people, namely university students, in the process of adapting a preexisting web-based digital tool (i-Spero) for use in the university setting in the United Kingdom. This was conducted as part of the UK Research and Innovation–funded Nurture-U project that explored the whole-university approach to student well-being [15,16]. The i-Spero is a mental health symptom monitoring and care planning tool which, prior to its use in Nurture-U, had been implemented in UK National Health Service (NHS) settings and shown to be effective in supporting students in a Canadian university setting [17]. The Nurture-U research team worked collaboratively with the project's student advisory group (SAG) to maximize the appeal, relevance, and usability for university students in the United Kingdom as part of a 3-year feasibility project. This study aims to present an inductive analysis of meeting notes and recordings of the joint adaptation process, aiming to highlight what aspects of DMHIs our advisors valued, alongside details on what changes were and were not implemented as a result. We will then reflect on this process in the discussion, highlighting the challenges in codeveloping DMHIs with young people. The hope is that this will inform future mental health interventions in this age group.

Methods

Existing Product for Development

i-Spero a web-based platform developed by P1Vital as a digital tool for mental health, contains mental health and well-being measures and allows users to complete these and monitor symptoms over time [16]. It was developed to help individuals work with clinicians, for example, general practitioners (GPs), to identify the effect of antidepressants and predict response levels as early as possible. Figure 1 shows the key areas of the platform, in the format used in the Nurture-U project. Figure 1A shows the user dashboard with graphs tracking well-being over time, using responses to questionnaires chosen by the user. The platform links users' answers on well-being questionnaires with in-built "well-being plans" (Figure 1B), which are categorized according to different types of support. Users can either choose their own well-being plans or i-Spero will suggest well-being plans based on their answers to the questionnaires (see "Notifications" in Figure 1B). The well-being plans also allow users to create "goals" and "actions" to improve their well-being (Figure 1C). Users can choose what to track and how often (Figure 1D). For example, if a user's answer on a mood questionnaire indicates low mood, the platform will show a message recommending well-being plans to alleviate mood, such as making social connections, exercising, or mindfulness exercises. Additionally, users can share their information through dashboards with health care professionals or friends and families.

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Figure 1. Overview of the i-Spero platform.

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Initial Joint Adaptation Process With the Nurture-U SAG

The Nurture-U SAG played a crucial role from the start of the project and fed into all aspects, from branding, content development, data collection, marketing, analysis, and dissemination. Students were recruited through university newsletters and groups from the 6 partner universities in the United Kingdom. There was no selection process for joining the SAG. Instead, on consenting to participation, students joined a mailing list where opportunities to input into different parts of the project were advertised. If the student advisor had capacity and an interest in that activity, they would email the group lead, who would add them to a working group for that project. Student advisors were paid £16 (US $21.48) an hour for attendance at meetings and work done outside of meetings. More details on the set-up and impact of the Nurture-U advisory group have been described elsewhere [18].

The opportunity to support the adaptation of i-Spero to Nurture-U was advertised to the SAG in December 2021 with an initial introduction to the tool from P1Vital. Four 2-hour meetings were held weekly in February 2022 on the following areas: in-built questionnaire design, well-being plans, notifications and messaging, flow, and evaluation. An average of 26 (SD 2.6) students attended per group. Following these intensive meetings, the research team adapted the design specifications using student feedback, and P1Vital implemented the Nurture-U adaptations to the i-Spero package for initial user testing.

Using Shier's participation model [19], as implemented in the scoping review by Larsson et al [15] in this area, this was a Level 4 participation framework. Shier's model has 5 levels, ranging from 1=listening to 5=sharing power. In our study, student advisors provided pointers and suggestions for edits to i-Spero, an existing product, and these were taken away by the research and software development team, who made the final decision on implementation according to practicality and relevance.

Development of University-Specific Content With the SAG

The development of i-Spero for the university setting was motivated by evidence that one of the key barriers to support for students is accessibility, with students reporting complex websites and disparate services [20]. To this end, a crucial part of the integration of i-Spero within universities was that it allowed personalized recommendations for university campus–specific support for students. This entailed 6 different iterations of i-Spero for the partner universities within Nurture-U. The project leads in each institution led on the compilation of this information and extensive testing to ensure links and contact details were up to date.

Additionally, the tool was developed with a research aim of collecting prospective mental health data from university students through the tool's mental health tracking feature, as a companion to a large-scale student mental health survey [21]. Alongside the development for university settings in the United Kingdom as part of the Nurture-U project, there was development for college students in Canada through the U-Flourish project [17].

User Testing and Feedback

The first prototype of i-Spero for Nurture-U was ready for testing by students and the research team in June 2022. This did not include all the questionnaires and well-being plans but allowed the students and researchers to experience the tool and provide feedback. Student advisors provided notes and comments in self-created Microsoft Word documents or Excel spreadsheets to the SAG facilitator (JD). JD synthesized these comments with the researcher team's comments and sent them to P1Vital to complete their adaptations.

The development was complete in November 2022. Plans for branding and marketing were built with the SAG, and it was rebranded as "the Nurture-U Wellbeing Toolkit." This was launched across the 6 Nurture-U partner universities in January 2023. The Toolkit was marketed through stalls on campus, newsletter bulletins, social media posts and advertisements, and emails to students.

As well as the broad marketing to all students, SAG members were specifically invited to test the Toolkit and provide qualitative feedback through an online focus group with Nurture-U researchers and the P1Vital team in July 2023.

This feedback led to the next iteration of the toolkit, which was available and promoted through the same avenues in January 2024. Again, SAG members were invited to test the toolkit and provide qualitative feedback in April 2024. P1Vital implemented the suggested changes, and the final iteration to be tested in the Nurture-U study was launched in September 2024. As stated previously, evaluation and analysis of the user data to establish the acceptability of the software is currently ongoing, with the latest information from this process available on the Nurture-U website [22].

Qualitative Analysis

The contents of 12 documents were analyzed. In total, 4 of the documents contained meeting notes from the initial development stage, with a range of 6 - 9 pages of text, and the remaining documents ranged from 1 - 9 pages of user feedback. A general inductive approach was implemented [23]. This is a method that aims to condense raw data into a concise summary for evaluation purposes. It is purely data-driven, with a bottom-up approach creating categories from participant quotes, using these to derive themes relating to the research question. This inductive process aimed to allow an overarching description of the student feedback across the different data sources.

Initial codes and categories stuck closely to the wording from the documents, for example, "if given too many options then too hard to engage" or "don't want it to feel like extra work." The initial inductive coding was completed independently using NVivo (version 14; Lumivero) by researcher JD and Nurture-U student advisor NA. JD and NA then compared initial codes, and then these were synthesized by JD into broader themes and checked by NA. This method of independent parallel coding is commonly reported in qualitative analysis as a method of ensuring rigor and trustworthiness [24]. As the author, JD had

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a research team perspective and NA had a student advisor perspective. This allowed for reflexive discussions about positionality and an exploration of the impact that had on the coding.

Ethical Considerations

Ethical approval for the collection and publication of data related to the SAG was granted by the University of Exeter Centre for Life and Environmental Sciences Ethics Board (application ID 493946). All participants provided informed consent prior to taking part in the study. They were given clear information about the purpose of the research, what participation involved, and their right to withdraw at any time without penalty. All data were collected and processed in accordance with the General Data Protection Regulation and University of Exeter data protection policies and were only accessible to the research team. Personal identifiers were removed at the point of collection, and anonymized documents were used for analysis. Results are reported in aggregate form to ensure that individual participants cannot be identified. Participants were informed of their rights under the General Data Protection Regulation, including the right to access, rectify, or request deletion of their data.

Results

Overview

The Nurture-U student advisors provided input and feedback on the development of i-Spero in 4 different stages of its development over 2 years. A summary of changes that were and were not able to be implemented can be found in Textbox 1.

Textbox 1. Implemented and nonimplemented student feedback.

Student-led changes implemented into the final product

- All language suggestions for messages and notifications.
- Addition of student-designed questionnaires relevant to student issues.
- Changes to the color and layout of the interface.
- Addition and restructuring of well-being plans to enhance user experience.
- Addition of emojis and motivating messages.
- Inclusion and emphasis on methods of self-help.

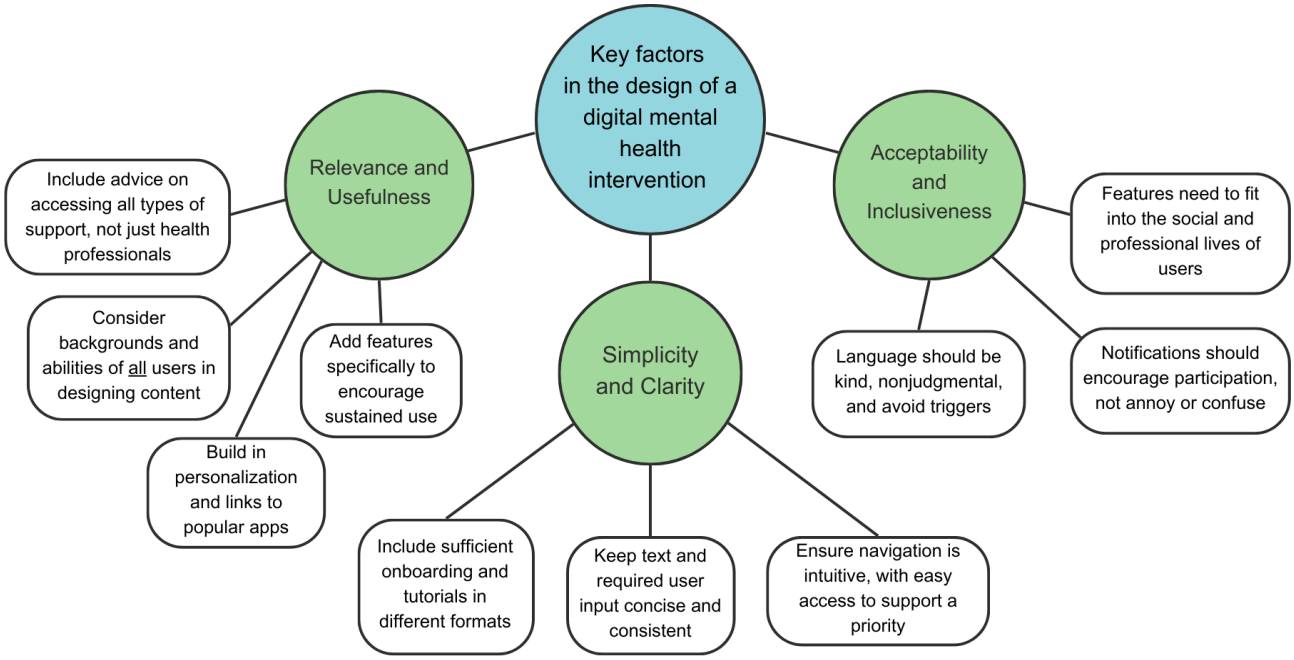
Student suggestions not implemented by the research or software team

- Language suggestions for standardized research questionnaires.
- Removal or shortening of standardized research questionnaires.
- Addition of an area within the platform where users can connect with other users.
- Restructuring of software so that support can be accessed without well-being plans.
- Addition of motivational tools, such as a growing tree, or linking with other apps.
- Removal of signposting to medical and university settings.

Analysis of development notes and documents identified 4 key areas where students consistently highlighted the need for improvement: “Relevance and Usefulness,” “Simplicity and Clarity,” and “Accessibility and Inclusiveness.” These are summarized in Figure 2.

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Figure 2. Core themes in i-Spero codevelopment.



Relevance and Usefulness

This theme encapsulates feedback from the student advisors that highlighted that the platform essentially had to be something that students actually want to use. The feedback was mostly positive; advisors highlighted the ease of navigation and appealing design, noting that the platform is accessible across different devices. Student advisors gave specific feedback from the perspective of young people on what aspects of the content were useful and what was not. For example, while they understood that repeated signposting to medical or university services in different areas of the platform may be necessary to ensure people get the care they need, they argued that this was not useful, as students already know this is where they can go for help.

> *It would be good to have specific apps and resources and not just to signpost people to Wellbeing Services and GP.*

They argued that students will be attracted to the platform because they are struggling to find where to get help or have a reason to want to avoid traditional support options. Hence, student advisors argued that:

> *The hierarchy should change for suggestions for contact. So start with (1) friends and family, (2) wellbeing services, and then (3) GP.*

Additionally, advisors fed back that vague language or advice was not helpful and could be found anywhere. They repeatedly highlighted where unnecessary words could be deleted. They also helped tailor advice so it was relevant to student contexts, for example, academic study. They also advocated for considering students from all backgrounds, for example, making alcohol-related content optional and creating specific content for underrepresented students, for example, those who are neurodiverse, or for parents or carers. Students advising on the initial iteration argued, for example, for the inclusion of a personality questionnaire, as something that would appeal to students at an age when they are learning who they are in the world.

The structure of the platform, tracking and setting goals, had mixed responses according to their relevance in the student context. Some advisors reflected that its usefulness lay in providing a bigger picture of emotions and mental health symptoms over time. However, the weekly "repetitive" questionnaires, some advisors argued, "felt like research" rather than something of use to them. They described the ability to set goals and tick them off as encouraging but reported little in the platform that encouraged sustained use and "ongoing management" of these goals when they were in place.

> *I don't find much reason to look back at the wellbeing plans I set myself.*

Some advisors suggested direct feedback, which congratulated users on sustained use.

> *Could there be some sort of visual feedback so that people have a sense of accomplishment when they complete a questionnaire? Because at the moment there is no positive feedback until you have filled it out over time. For example, there could be a tree or sapling that grows into a forest?*

An often-repeated aspect of feedback was to provide more areas for personalization, so users could individualize the content according to their preferences and experiences. Many advisors advocated for space in the platform for journaling and writing notes, creating a record of why they felt a certain way at different points over the academic year. Additionally, the ability to set their own reminders, notifications, and well-being plans so that they were experiencing the functioning in their own language and contexts was requested. They also repeatedly asked for the ability to link to apps they already use (eg, Spotify or exercise apps), or to include a social aspect such as a forum or the option to connect with other users and motivate each other to use the platform.

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> *Could this Tool connect people together to talk about their mental health?*

Another factor that student advisors identified as important in young people finding the platform useful was that it should be motivating and positive. The danger that student advisors highlighted was that in tracking mental health over time and signposting to support, there was a risk that the platform would be repeatedly telling people they feel depressed or anxious, and that could be "disheartening." The largest impact that the student advisors made in adapting the platform was in rewriting all the notifications, messaging, and well-being plans to provide encouragement to users regardless of their outcomes on the questionnaires. Advisors described a nuance to this where positive messaging could be "slightly patronizing" and hence more practical messaging and advice would be most relevant to their context.

> *Motivational messaging might be condescending. We could have testimonies or real-life stories of people who use the Tool – this is more likely to make a user feel better rather than something overly positive.*

They emphasized how students were mostly young people who appreciated being "treated like an adult" as they began to build their lives away from home, and that the platform content needed to reflect this.

Simplicity and Clarity

The second ongoing aspect of student advisor feedback on the intervention was to increase its simplicity of use and clarity of the information provided. Student advisors stated that anything that felt like "extra work" would not appeal to students, who already have enough to juggle with academic work and navigating new social situations. Initial feedback highlighted a lack of clarity in how to use the tool.

> *It's very fiddly and complicated to use. The wellness plans still confuse me, and it doesn't seem easy to identify or access resources.*

While guidance was provided in later iterations in the form of video onboarding on sign-in and links to external, more detailed video tutorials, this feedback continued. Advisors argued that navigation around the platform should be intuitive. They highlighted the need for improvements in how the information was organized, such as increasing the directions on the home page, moving from having "history" and "upcoming" areas to view activity on the platform to having an ongoing timeline, and being able to mark all notifications as read in one click. These were all implemented by the software team.

Consistency was a key area that students highlighted as important to usability, for example, scales on graphs all going the same direction. Another example given was that postquestionnaire messaging could be contradictory, so if you answer indicating, for example, low mood on one questionnaire but good sleep on another, you may receive contradictory positive and negative messages about your well-being.

> *Is there a way they can "trump"' the other messages so they don't contradict each other?*

This solution, also implemented by the software team, was to have a hierarchy of messaging, where messages in response to mental health questionnaires (ie, mood or anxiety) would take precedence over lifestyle factors (eg, sleep or social connections).

In relation to the tracking element of the platform, an emphasis was made on avoiding burden for student users.

> *Won't long questionnaires mean the students will get bored?*

This led to the development of tracking questionnaires designed by student advisors, which involved branching elements where further questions were only asked in response to certain responses to initial brief questions.

> *This could start with a general question (e.g. "I've been feeling stressed a lot lately" rated from strongly disagree to strongly agree). You could then have follow up questions depending on your answer to the first general question, so if you indicate you are stressed you could have a list of things that might be causing you stress (for e.g. "what causes you to feel stressed?" with various categories (finance, relationships, academic work, cu), about frequency "how many days this week have you felt stressed?", or "what do you to deal with stress?". This could help find out the cause of stress and come up with coping strategies.*

Additionally, students designed the user satisfaction questionnaire so that it was as concise as possible. However, the fact that the platform was embedded in a research project meant that certain standardized mental health questionnaires needed to be retained, for example, the Patient Health Questionnaire-9 (PHQ-9) and Generalized Anxiety Disorder 7 (GAD-7), and the wording of these questions could not be changed. The inclusion of these, alongside the additional questions designed by student advisors, led to a total of 33 questionnaires that student users could engage with. The student advisors who led the initial development of the questionnaires argued that all should be clearly labeled as to what they measure, including citations and links to sources, to enable students to engage with the ones that work best for them. Those that were designed by student advisors were named "student co-created." However, student advisors who tested the later iterations of the platform expressed some confusion about the number of questionnaires and how they were labeled.

The well-being plan function, where users could choose certain areas to work on (eg, managing their mood and academic stress) and then access specific information and set goals, was seen as too complicated for many:

> *I feel like the well-being plans are just extra work, so I did not want to do it.*

Advisors argued for a separate page where resources and signposting could be read outside of the well-being plan format for ease of access. This was implemented by the software team. The type and level of support wanted from the intervention was a subject of debate, with some advisors wanting "comprehensive" and detailed psychoeducation, as that is what

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they saw as the function of the platform, while others wanted less information and text and instead practical and accurate signposting for different areas of need. Advisors argued that text should be broken into paragraphs and boxes to reduce "overwhelm." This was implemented by the research team.

Acceptability and Inclusiveness

Finally, student advisors were central to ensuring the design was acceptable to the student population, the majority of whom were under 25 years of age. A key factor in this was the aesthetic design and "feel," with initial feedback on the version that had been used in the NHS declaring it "outdated," "medical" and "bland." The Nurture-U brand colors [22] were decided upon as a potentially recognized design that was distinct from the participating universities and the NHS. Given the many iterations of the platform, with different versions for different campuses entailing many different stakeholders providing input, there were initial areas of inconsistency or errors in the language used, which student advisors highlighted as off-putting in an intervention targeting well-being. Hence, while student advisor input was built in for the purpose of ensuring relevance to students, they also provided basic error checks, which were extremely valuable.

A big part of the feedback on the acceptability of the tool for young people was the role of the notifications for engaging in the questionnaires and the well-being plans. Advisors provided the wider context of the use of the platform: students live busy social lives where their phones and laptops are often on display, and hence the subject line of reminder emails and texts needed to be neutral or "vague" to protect people's privacy. Notifications needed to be unintrusive but also engaging to encourage students to prioritize the platform over their other tasks.

> *We could make [the reminder message] more positive: "We've missed you! Click here to do your wellbeing questionnaire now"*

Notifications containing a list of "long, formal questionnaire names" were anxiety-provoking and would be identified as another burden in a busy period of academic work. These contextual descriptions of the target user allowed for changes, which it was hoped would encourage higher levels of engagement from students.

However, student advisors also highlighted that it was not only young people as a broad audience who would be using the platform, but young people who were likely to be experiencing challenges with their mental health.

> *Make it more organised and aesthetic - If a person is struggling, they don't want red bold text or long paragraphs. It should feel like a safe space.*

There were concerns from some of the advisors with lived experience of depression and anxiety that when they were experiencing more severe symptoms, they would not have had the energy and motivation to engage with tracking and goal setting. While some aspects to deal with this challenge also arose in the previous theme surrounding ease of access to resources, advisors also specifically discussed the "tone" of the information given. They asked for the removal of moral descriptions of behaviors as good or bad, advising that language should be neutral and warm:

> *We don't want the questions to be judgemental or triggering. For example, people may have different perceptions of what constitutes "good" sleep or diet depending on their lifestyles, experiences of eating disorders, cultural backgrounds. This is why more generic questions that people can tailor to their own personal experiences might work best. The language should be kind and inviting.*

Language should also be neutral and warm in describing lifestyle factors such as sleep or diet, which are individual and may vary according to background and experiences. They also highlighted instances of tonal mismatch, where messages starting with "hello" were too informal for serious notifications about mental health.

Student advisors argued that users would be logging on to the platform specifically for support, and, hence, ease of access to this support is of high importance. As discussed in the theme relating to simplicity, students argued that the well-being plan interface was a barrier and that students should not have to "commit to a plan" to get support. Similarly, in order to engage those who are having difficulties with their well-being and mental health, advice should be "reassuring": not telling students what to do but "talking to them on a level." Student advisors highlighted specific language changes that could achieve this, for example, normalizing experiences and pitching advice as "beneficial to lots of people," and not promising an unachievable cure but highlighting "useful steps" toward an improvement in symptoms. Finally, student advisors highlighted several reasons why users may have difficulty understanding certain terminology in the advice sections, whether it was a lack of mental health literacy, cognitive challenges due to poor mental health, or not having grown up in the United Kingdom. Hence, there were many aspects of the content where they suggested simplifications or the need for additional definitions to enhance accessibility. These were all implemented by the research team.

Discussion

Principal Findings

In the joint adaptation of the i-Spero platform for university student users, 3 key concepts were identified as crucial to designing DMHIs for young people. These core ideas of relevance and usefulness, simplicity and clarity, and acceptability and inclusiveness should be central to all elements of interventions, from the interface to the content to the notifications. While we were unable to implement all suggested changes within the Nurture-U project, this study aimed to specify what young people want from digital mental health support to inform future design.

Where the Nurture-U student advisors made the most impact in adapting i-Spero was in highlighting where information and support needed to be added for underrepresented groups and where edits needed to be made to remove burden from student users. These 2 areas of feedback, however, became contradictory over the development process: including questionnaires and

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well-being plans that covered the needs of all students necessitated more text and information, which in turn created more content that student advisors identified as overwhelming. This is the key challenge in developing online mental health support: trying to appeal to all when everyone's needs are different [25-28]. There is a difficult balance, identified both by our advisors and in the wider literature, in making information comprehensive but also digestible [27]. What the advisors highlighted as key to engagement is not so much the amount of information contained in an intervention, but how it is presented and how easy it is for users to find what they need. A recent interview study with teenagers found that while a clinical approach to presenting information, such as that on NHS websites, promotes trustworthiness, it can be intimidating and difficult to read [27].

Student advisors overhauled the language used in the intervention. We were not surprised that they would highlight the need for clarity; clear and nonjudgmental language is well-known to reduce mental health stigma and promote support [29]. What perhaps was novel to the research team was the advisors' requirements for motivational language, positivity, and interaction to increase engagement. In a competitive online landscape, it is the "gamification" of apps and content, defined by creative thinking and activation, which encourages use [30]. To adapt to these suggested changes in mood and aesthetic of the intervention, we implemented all edits to language and messaging, including brighter colors, and minimized the use of buttons and extensive scrolling to achieve tasks. However, there were features in the original platform design, such as the format of the well-being plans and the research design, such as the language in the standardized questionnaires, which we were not able to adapt as the student advisors may have wished. We will see the impact of keeping these functions as we analyze the user data [22].

Another aspect of engagement that we had not anticipated was how much student advisors asked for personalization of the intervention. Research has shown that personalization of the mode of delivery of online health information can increase website satisfaction and information recall of participants, and that this effect was particularly strong with younger people [31]. However, research into how to personalize digital health interventions is relatively recent; where personalization is built in, it is usually for content over format, and there is not yet evidence on the effect of different levels of personalization on outcomes [29]. As personalization through algorithms is becoming more ubiquitous on social media, in search engines, and music and video streaming sites, this is something that is likely to become increasingly necessary to ensure engagement in DMHIs.

Another aspect that the research team was unable to change, despite the student advisor's recommendation, was to step back from signposting users to professional services for mental health. Highlighting the need to access GP or university well-being services was crucial for managing the associated risks of mental health difficulties, especially as the target user would be young people who are likely to be away from home for the first time. Research shows that many young people are not aware of where to get professional help for mental health difficulties [32]. However, advisors argued that student users would not only be aware of these options but actually may be accessing the platform specifically looking for other ideas to support their mental health. This mirrors Biddle et al [33] review of young people accessing support for suicidal thoughts online, where being referred back to a doctor was not only frustrating but also damaging to those in crisis: seeing this as the only option when it has not worked previously makes people think they cannot be helped. Those who develop mental health interventions must not see the user as accessing the intervention in isolation and be aware of the real-world contextual influences and experiences on the target user [27]. There is an ethical discussion as to whether apps that are targeted as mental health support should have a duty of care for users [34]. However, the context of this study, abiding by research ethics and university principles, meant that we needed to ensure all student users were aware of professional services and how to contact them if needed.

In conducting this study and reflecting on the findings in the context of previous literature, there is evidence of marked similarity in what young people want from digital mental health support between multiple different studies and reviews [12,14,15,33]. What this suggests is twofold: first, researchers working in this space need to do more to learn and build on preexisting research when they are designing and conducting projects in this space [35]. However, and conversely, this reflects the fact that the internet has created a rapidly changing social and political landscape where the factors that make a platform accessible and sustainable are constantly evolving [36]. One reason researchers repeat these elements of codevelopment is that while the overarching advice from young people may be the same, for example, ease of use or age-appropriate language, the specifics of this may vary according to context, be it geographical or cultural [37]. Including the target audience, especially in interventions aimed at young people, in mapping out the intervention theory and development of prototypes is crucial to creating DMHIs that have sustained benefits [28,35].

We placed our joint adaptation of the i-Spero intervention as a level 4 within Shier's participation framework: the student advisors were involved in the decision-making, but they did not share the responsibility for the ultimate decision (level 5) [15]. Shier emphasizes that his framework is not hierarchical, that different levels of participation are appropriate in different contexts [15]. However, there are increasing concerns that the growing prevalence of coproduction occurring without a critical and evaluative lens on power and decision making may be detrimental to the original aim of producing "socially robust" research outcomes [19]. In the case of DMHIs, this specifically means that placing limits on the extent of coproduction results in a product that may not fit user requirements. What our study highlights further, however, is the often-competing agendas that are at play in codeveloping DMHIs, especially in the context of research. First, where software developers have existing designs or researchers have existing research aims, this creates areas where those with lived experience have to be told "no." When considering working relationships, this builds a level of power imbalance where the advisors may lose faith in the project and their motivation to contribute wanes. A fully coproduced project, where people with lived experience colead or even lead

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the process of designing and delivering a DMHI, would avoid these challenges, but would take far more time and resources. Further research in this field would be to compare the impact of DMHIs that are fully coproduced with people with lived experience, as compared to ones which only have user-testing elements, both on mental health outcomes for users and costs and resources.

There were strengths in our extended joint adaptation process of i-Spero with university students, including the rigor and transparency in the researcher and advisor feedback process [18]. Additionally, a reflection of the process as we have presented in this paper is crucial for effective participatory research [38]. However, there were some limitations. First, while the student advisors were the target audience in that they were university students, they had joined the advisory group because they had an interest in student well-being, not necessarily because they themselves were experiencing mental health challenges or seeking support. Hence, they may not have been the students that the intervention was designed for. Another limitation was that we only used focus groups or written feedback; more inventive or creative approaches could have garnered more detailed insights [15,28]. Additionally, as discussed above, while i-Spero was initially developed with co-design and research methodologies, by the time we were adapting the platform, there were some aspects that could not be changed within the research timeframe and budget.

Conclusions

To conclude, inductive analysis of our records of the joint adaptation process generated 3 key themes for designing DMHIs for young people: “Relevance and Usefulness,” “Simplicity and Clarity,” and “Accessibility and Inclusiveness.” While these are concepts that have been identified in other studies, it is important to recognize that they are also constantly changing entities. Hence, co-design with users from the inception of a digital intervention idea is key to ensuring effective and sustainable digital mental health support. However, there is a need for more research exploring the impact of different levels of user participation in codevelopment on intervention outcomes.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization: JD (lead) and EW (equal)
Data curation: JD
Formal analysis: JD (lead) and NA (supporting)
Funding acquisition: EW
Investigation: JD
Methodology: JD
Project administration: JD
Resources: EW
Supervision: EW
Validation: NA
Visualization: JD
Writing – original draft: JD
Writing – review and editing: NA and EW

Conflicts of Interest

None declared.

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Abbreviations

DMHI: digital mental health intervention
GAD-7: Generalized Anxiety Disorder 7
GP: general practitioner
NHS: National Health Service
PHQ-9: Patient Health Questionnaire-9
SAG: student advisory group

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Co-Designing and Evaluating a Multimodal Digital Application to Enable People With Dementia to Self-Report Quality of Life Patient-Reported Outcome Measures: Co-Design Study and Summative Evaluation

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Abstract

Background: Worldwide, there are an estimated 55 million people living with dementia, with an estimated cost to society of US $1.3 trillion a year. These numbers are predicted to rise, with the dementia population doubling every 20 years, reaching an estimated 152 million by 2050. There is currently no cure for dementia, with the condition having a significant impact on people's independence and quality of life (QoL). It is therefore vital that people living with dementia are given the support that helps them to manage these impacts and optimizes their QoL. To do this, a more personalized and detailed understanding of a patient's daily life is needed. Patient-reported outcome measures (PROMs) have long been associated with significant benefits in other domains, though the use of PROMs in routine dementia care is lacking. Factors such as platform design, literacy, language proficiency, and physical and mental capability can all severely impact the ability of people living with dementia to complete PROMs routinely.

Objective: This study aims to co-design and evaluate a novel multimodal digital application to enable people living with dementia to regularly self-report QoL PROMs. The research questions were (1) What features, questions, and modalities do people living with dementia prefer when interacting with a digital application that enables them to self-report QoL PROMs? (2) What are the design considerations and specifications for a digital application to enable people living with dementia to self-report QoL data via PROMs?

Methods: People living with dementia, informal caregivers (ICs), and health care professionals (HCPs) participated in iterative co-design workshops and a final summative evaluation to co-design a multimodal digital application from initial concepts to a functional prototype. Prototypes were presented using cognitive walkthroughs and think-aloud protocols, and data were analyzed following framework analysis using interaction design and features voted for by participants using MoSCoW (Must Have, Should Have, Could Have, Won't Have).

Results: A total of 25 participants took part in this study (people living with dementia=9, ICs=4, and HCPs=12) developing and evaluating a total of 34 prototypes into a single final functional multimodal prototype that can collect PROMs using text, visuals, and voice.

Conclusions: A functional prototype for a novel digital application was developed that enables people living with dementia to regularly self-report QoL PROMs, which was then successfully evaluated by people living with dementia, ICs, and HCPs. The prototype was co-designed with direct involvement from people living with dementia during every stage of development, and this is one of the first studies to evaluate perceptions from key stakeholders (including people living with dementia, ICs, and HCPs) regarding the use of electronic patient-reported outcome measures for dementia in routine care.

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KEYWORDS

dementia; patient-reported outcomes; co-design; ePROMs; multimodal; accessibility; mobile phone; electronic patient-reported outcome measure

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Introduction

Background

Worldwide, there are an estimated 55 million people living with dementia (people living with dementia), with the condition now the 7th leading cause of mortality [1]. These numbers are predicted to rise, with the dementia population doubling every 20 years, reaching an estimated 152 million by 2050 [2]. There is currently no cure for dementia, with the condition having a significant impact on people's independence and quality of life (QoL) [3]. It is therefore vital that people living with dementia are given the support to manage these impacts and optimize their QoL with health and care services that focus on delivering person-centered care. The nature of dementia requires health care professionals (HCP) to recognize and monitor individuals' changing needs throughout the disease's progression and adjust care and practices accordingly while preserving the individual's personhood [4,5].

One such tool to monitor an individual's changing needs is patient-reported outcome measures (PROMs). These are questionnaires used to measure subjective outcomes relating to a patient's health, QoL, or functional status associated with health care or treatment, reported directly by patients without interpretation from HCP or other parties [6]. Traditional PROMs take the form of paper questionnaires, though electronic patient-reported outcome measures (ePROMs), digital PROMs that can be completed remotely on various internet-connected devices and collated automatically, offer an efficient method of data collection with a comparable level of response compared to traditional methods [7] as well as reducing times and associated costs [8].

PROMs and ePROMs are increasingly recognized as an important tool for fostering clinician-patient communication, informing direct care decisions, and improving the quality of care [9,10]. PROMs continue to see greater use in routine care delivery to assess patients' experiences, evaluate outcomes, and encourage shared decision-making [11], with many patients welcoming the use of PROMs and believing they should be used more routinely [12]. Despite this, implementation of PROMs is lacking, with significant barriers including patient inability to complete PROMs, the perceived irrelevance of PROMs and their lack of value to the patient, as well as difficulty using electronic devices to complete PROMs [13]. This difficulty in completing PROMs is compounded for individuals with cognitive impairments, where the content, layout, and procedures of the PROM can pose barriers if PROMs are implemented without cognitive accessible designs in mind [14,15].

One solution would be to develop PROMs that are better designed and more accessible for people living with dementia in their day-to-day environment. While such PROMs have existed for decades [16], their usage is almost exclusively limited to research studies [17]. QoL measures are often used as proxies instead of dementia-specific PROMs [18], though these often do not capture benefits and issues specific and meaningful to people living with dementia [19] and are not designed with cognitive accessibility in mind [14]. This issue is compounded by the lack of high-quality QoL PROMs that are validated for use in a home environment [20].

Despite the challenges, PROMs could provide a largely unrealized potential for advocating the needs and measuring the QoL of people living with dementia in a scalable manner [17]. It is therefore vital that the voice of the people living with dementia is enabled to be heard, as it is "a fundamental right of all patients and individuals living with long-term conditions to be included in the decisions and be in control of their own care and support" [21].

Aims and Objectives

This study aims to co-design and evaluate a novel digital application to enable people living with dementia to self-report QoL PROMs. To achieve this, the following research questions were answered: (1) What features, questions, and modalities do people living with dementia prefer when interacting with a digital application that enables them to self-report QoL PROMs? (2) What are the design considerations and specifications for a digital application to enable people living with dementia to self-report QoL data via PROMs?

Methods

Study Design

This iterative qualitative study invited people living with dementia and informal caregivers (ICs) to co-design and test prototypes for a novel application during 4 cycles of online workshops that developed a final functional prototype (FFP) before a final summative evaluation cycle involved all stakeholders to review and evaluate the FFP. Before this study, a short patient and public involvement and engagement phase allowed stakeholders to voice their expectations and recommendations for the prototype, which were used to develop the initial prototypes. People living with dementia and ICs were then invited to review and refine these prototypes during the co-design phase, where they directly contributed to the look, design, and functionality of the application, as well as the type of PROM questions asked, and the modality of interaction. All stakeholders were then invited to evaluate the FFP during the summative evaluation phase.

Questions and responses used in the prototypes were originally taken from the quality of life in Alzheimer disease (QoL-AD) PROM questionnaire [22] using the "participant version" and the verbal questions from "instructions for the interviewer" [23]. QoL-AD was chosen on recommendation from the health care and charity professional partners, and for having validated questions for both text-based and voice-based modalities. Early prototypes used these questions and responses verbatim. The prototypes were designed to be web-based for use on computers, laptops, and large-screen tablets following the preferences of participants during initial patient and public involvement, engagement research, and prior literature research [15,24-29].

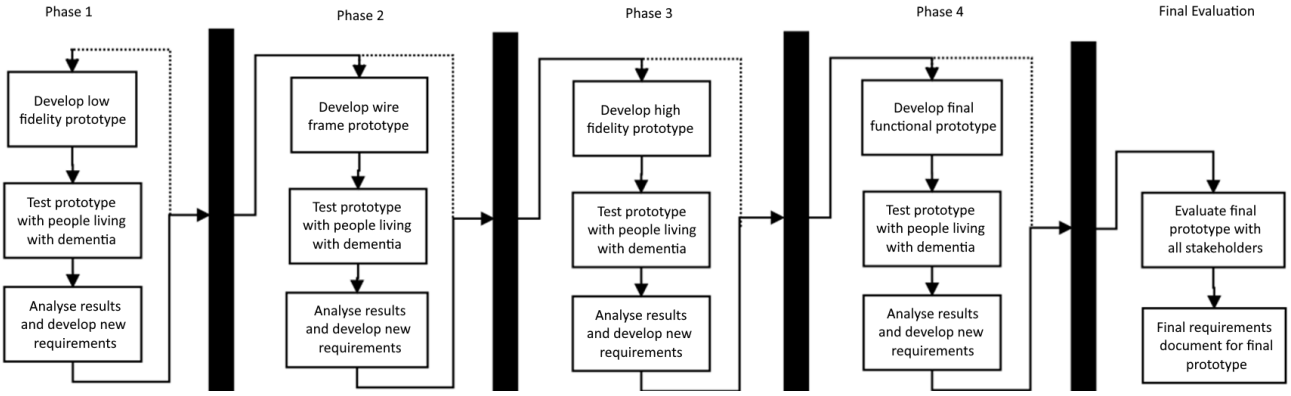
Co-Design Phase

We present four interlinked iterative cycles, with each cycle consisting of 3 agile sprints involving development, testing, and analysis (Figure 1). Cycle 1 focused on the development, testing,

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and analysis of a low-fidelity prototype (LFP). Cycle 2 developed the LFP into a wireframe prototype (WFP). Cycle 3 improved WFP into high-fidelity prototypes (HFP) with cycle 4 culminating in an FFP. Between each workshop, participants voted on several features they felt should be prioritized for the next prototype.

Figure 1. Prototype development phases. WFP: wireframe prototype.



Summative Evaluation

A final summative evaluation phase concluded this study, with all stakeholders evaluating the functional prototype for its feasibility, usability, and utility.

During cycles 1‐3, author DK performed cognitive walkthroughs [30] with participants, detailing the features and differences of each prototype concept to participants who provided their opinions and recommendations on how they can be improved. During cycle 4, DK led participants in a think-aloud protocol [31] using the FFP while relaying their experiences and opinions. All workshops were recorded and overseen by an HCP and an experienced researcher (KE or RM) who ensured the needs of participants were always met. Participants were also offered regular breaks during workshops and were reminded that if they were struggling with cognitive or emotional issues, they should inform the experienced researchers. Audio from the workshops was fully transcribed into text using a combination of Microsoft Stream (Microsoft Corp) and human transcription by DK. These transcriptions were analyzed by DK along with notes taken by KE and RM using NVivo (Lumivero) with major themes extracted using framework analysis [32] following the 5 dimensions of interaction design to determine what features should be improved, removed, or added [33]. These themes were then presented to participants via an online poll where they voted on what features they want prioritized using the MoSCoW (Must Have, Should Have, Could Have, Won't Have) prioritization method [34]. This informed the sprint product backlog for the next iterative cycle, where the prototype was redeveloped into a higher fidelity version and presented to participants for usability testing during the next workshop. During cycle 1, general feedback collected in notes written by the researchers was used for analysis, as well as the results of the MoSCoW. This was due to unforeseen technical issues that resulted in no usable recordings or transcripts for cycle 1.

Ethical Considerations

Ethical approval was granted by the National Health Service (NHS) Health Research Authority (IRAS Project ID: 273039). Participants received no compensation. Informed consent was collected from all participants who were provided a participant information sheet detailing the study details including their right to withdraw at any time, as well as a consent form that could be completed via written consent or recorded verbal consent. All identifiable data collected was anonymized.

Results

Recruitment

A total of 25 individual participants took part in the entire study. Of these, 7 took part in the co-design phase and 20 in the summative evaluation. Two participants took part in both phases.

Co-Design Phase

A total of 7 participants (people living with dementia and IC) were recruited from various charities and NHS partners across Scotland to take part in 4 online co-design workshops conducted between October 2021 and May 2022 (Table 1). For participants who completed the demographic questionnaire (n=5), a total of 4 identified themselves as “somewhat or very confident” using technology, with 1 participant “somewhat unconfident.” Participants identified themselves as having access to a wide variety of commercial technology, including laptop computers (80%, 4/5), e-readers (80%, 4/5), tablets (60%, 3/5), smartphones (60%, 3/5), smart speakers (20%, 1/5), and smartwatches (20%, 1/5).

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Table . Participant details for both phases.

Characteristics	Co-design phase (N=7)	Evaluation phase (N=20)
Gender, n (%)		
Woman	4/7 (57)	10/20 (50)
Man	3/7 (43)	10/20 (50)
Race, n (%)		
White	7/7 (100)	18/20 (90)
Asian	N/A[a]	2/20 (10)
Role type, n (%)		
Person with dementia	5/7 (71)	6/20 (30)[b]
Informal caregiver	2/7 (29)	2/20 (10)
Health care professionals, n (%)		12/20 (60)[c]
Manager or lead	—[d]	3/20 (15)
Doctor or consultant	—	3/20 (15)
Nurse	—	2/20 (10)
Not stated	—	4/20 (20)

[a]N/A: not applicable.

[b]Two previously participated in the co-design phase.

[c]Two took part in the MoSCoW (Must Have, Should Have, Could Have, Won't Have) but could not attend the workshops.

[d]Not available.

Summative Evaluation

For the summative evaluation phase, a total of 20 participants took part. This included 12 HCPs recruited via the NHS and 8 participants (people living with dementia and IC) recruited via Alzheimer's Scotland (including 2 returning from the co-design phase), who took part in the summative evaluation cycle over 3 separate workshops in May 2022.

A total of 34 prototypes were developed over the course of 4 iterative co-design workshop cycles (Figure 2, Multimedia Appendix 1). Features from these prototypes were combined and refined over the course of the workshops into an FFP (Figure S38 in Multimedia Appendix 2). The results of the MoSCoW for each phase are displayed and ranked in Tables 2-5.

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Figure 2. Prototype development class chart. DEMQOL: dementia quality of life; QOL-AD: quality of life in Alzheimer's disease.

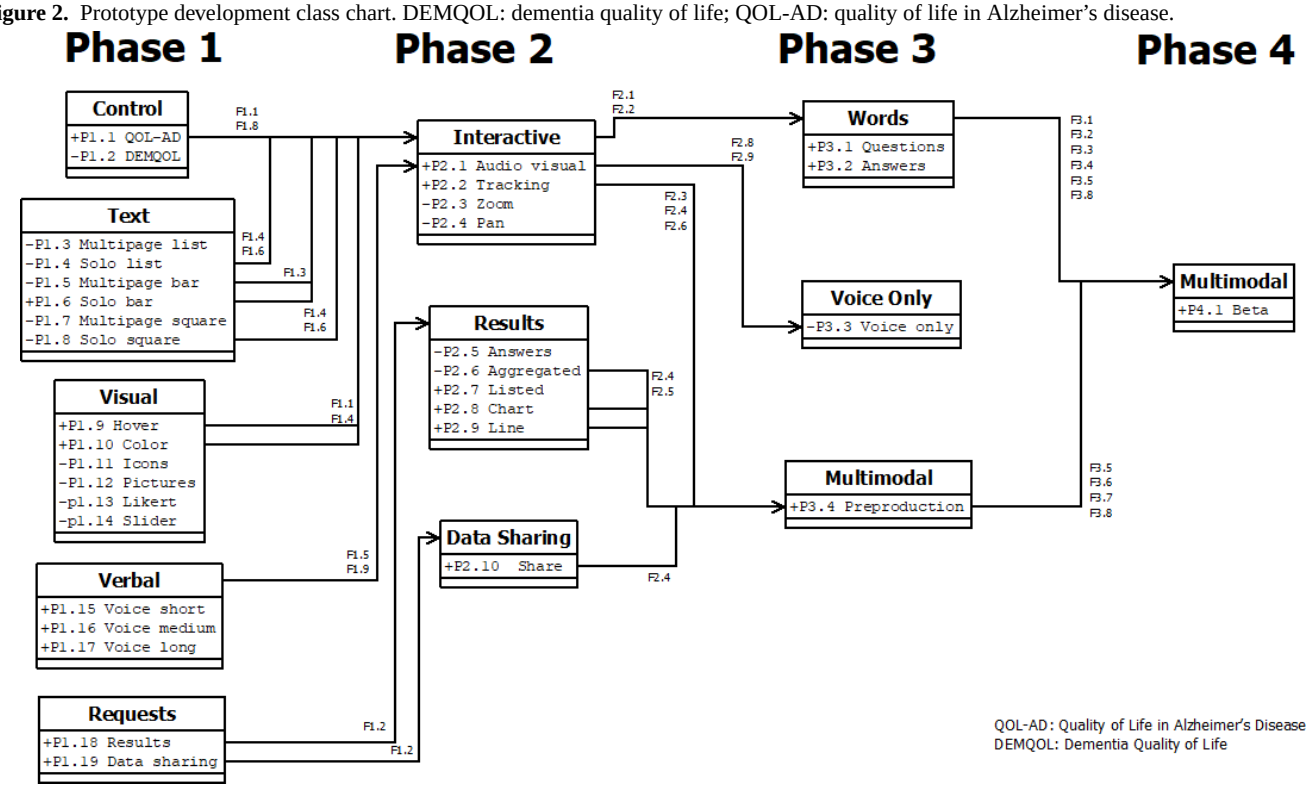


Table . Workshop 1 MoSCoW[a] results.

ID	Features	MoSCoW score	Will not include	Priority
F1.1	Larger font and bolder fonts	1.95	0	High
F1.2	Results page for participants to see their own responses	1.8	1	High
F1.3	Options displayed in boxes	1.55	1	High
F1.4	Automatically move to the next page	1.5	0	High
F1.5	Actor's voice recording	1.45	3	Moderate
F1.6	One question on each page	1.35	0	Moderate
F1.7	All questions on 1 page	1	2	Low
F1.8	More detailed questions and explanations	0.85	1	Low
F1.9	Visual prompt with verbal questions	0.85	1	Low

[a]MoSCoW: Must Have, Should Have, Could Have, Won't Have.

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Table . Workshop 2 MoSCoW[a] results.

ID	Features	MoSCoW score	Will not include	Priority
F2.1	Adjust some of the words to be more inclusive (such as changing “spouse“ to “partner,“ “decreased“ to “reduced,“ “stayed the same“ to “no change“)	2.35	0	Very high
F2.2	Make the questions less ambiguous and more relevant to me	1.8	0	High
F2.3	Show my previous answers after I submit them, and let me change them	1.7	0	High
F2.4	Option to turn colors on or off	1.6	0	High
F2.5	Have a drop-down menu for the results page that goes into more detail	1.6	0	High
F2.6	Show reminders of what kind of questions have been asked (such as ”mood“ instead of “question 3”)	1.1	0	Moderate
F2.7	Option to add notes to your answers so I can provide more details	1.1	0	Moderate
F2.8	Let me answer using my voice instead of touching the screen	0.6	1	Low
F2.9	Have the results be spoken using audio instead of reading	0.6	2	Low
F2.10	Use animations and screen transitions between questions	0.3	2	None

[a]MoSCoW: Must Have, Should Have, Could Have, Won't Have.

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Table . Workshop 3 MoSCoW[a] results.

ID	Features	MoSCoW score	Will not include	Priority
F3.1	Shorten and simplify longer questions	1.8	1	High
F3.2	Remove terms such as “lately“ and be more precise with time frames	1.8	1	High
F3.3	Mark sensitive questions (such as marriage or friends) as optional and not asked if not relevant.	1.35	1	Moderate
F3.4	Change unclear questions that start with “how about“	1.1	1	Moderate
F3.5	Add comment boxes to questions to add our own notes	1.05	2	Moderate
F3.6	Allow us to add people we can share the data with ourselves	0.75	2	Low
F3.7	Allow us to answer using just our voice	0.25	1	Low
F3.8	Provide an option to skip questions	0.15	0	Low
F3.9	A voice-only option that will run on a device such as Siri (Amazon.com, Inc) or Amazon Echo (Amazon.com, Inc)	0	0	None

[a]MoSCoW: Must Have, Should Have, Could Have, Won't Have.

Table . Workshop 4 MoSCoW[a] Results.

ID	Features	MoSCoW score	Will not include	Priority
F4.1	A button at the end to end the session	2.6	0	Very high
F4.2	Questions automatically move to the next when answered	2.3	0	Very high
F4.3	A comment section to add your own notes	2	0	High
F4.4	A button to print out the results	1.6	0	High
F4.5	A mobile version of the application	1.2	1	Moderate
F4.6	Thicker lines and larger fonts are used on the line graph	1	1	Moderate
F4.7	More visible buttons on the ”share with“ page	0.85	1	Low
F4.8	Voice feature that reads out questions and allows you to answer with your voice	0.6	2	Low

[a]MoSCoW: Must Have, Should Have, Could Have, Won't Have.

The FFP was designed to be used by people living with dementia in a home environment, either independently or supported by IC. The prototype is accessible via a web link that is sent to the user and presents users with a home screen with options to

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answer the questionnaire, view their previous results, or adjust settings such as the color display or voice modality. The questionnaire asks 12 questions modified from QoL-AD, with the option to have them read out using a digital voice. Once the questionnaire is completed, users are presented with their responses and the opportunity to update them. Users can then choose who to share this information with. Once completed, users are returned to the main menu with the option to review their results in multiple charts and over various periods of time.

Cycle 1

During cycle 1, which focused on the development, testing, and analysis of LFPs during online workshops, the highest priority features related to the visual dimension of interaction design, with 3 of the top priority features relating to that dimension (F1.1, F1.2, and F1.3), with the time dimension and space dimension also scoring moderately. "Larger font and bolder fonts" took the highest priority for users, which reflects one of the main talking points during the session. Users complained that the font display was far too small. Prototypes had to be magnified 150% of normal size to allow participants to clearly see and read. Participants were keen to have questions automatically move to the next once answered (F1.4), with 1 question displayed per page (F1.6). While participants were interested in actors' voice recordings being used in future prototypes (F1.5), the feasibility of this during the prototyping phase was limited and out of scope for this study. Another feature heavily discussed in the workshop that scored highly was related to ownership of data and participants being able to see their own results (F1.2), as well as the ability to take ownership of this data and be able to show it to relevant people and professionals. No prototypes had been developed for these features, so prototypes for this were implemented in cycle 2 (P2.5-P2.10).

Cycle 2

For cycle 2, which aimed to develop the LFPs into WFPs, the MoSCoW response had the highest priority features related to the word dimension (F2.1 and F2.2), in particular, the choice of words and phrasing used in the questions. Terminology was the highest priority issue raised (F2.1), with many participants taking umbrage at the use of "marriage" on the results page. While this topic was not discussed as heavily during the workshop as the issue of ambiguity, it scored significantly higher in the MoSCoW feedback. The next priority feature regarding questions was their ambiguity and lack of relevance (F2.2) with much criticism raised against the format of the questions and the predefined response options. Additionally, many participants voiced confusion about why a question about physical health was being asked as part of a dementia PROM and felt the question in its current form was irrelevant to them and their dementia. Participants queried the use of the word "lately," criticizing that with dementia, many found it hard to gauge periods of time coherently.

Ambiguity

Much criticism was raised against the format of the questions and the predefined response options. Participants found the phrasing of the questions to be inappropriately positive when discussing a topic of dementia, especially with 1 response being "excellent." Participants also noted that the combination of some questions and responses was grammatically incorrect. The first question using the term "physical health" was deemed to be ambiguous, with participants unsure whether it was asking about their physical activity, their physical health overall, specifically regarding their dementia, or how their physical health is being treated. Additionally, 1 participant voiced confusion about why a question about physical health was being asked as part of a dementia PROM and felt the question in its current form was irrelevant to them and their dementia. Participants also criticized the use of the word "lately" in some of the questions, noting that with dementia, many found it hard to gauge periods of time coherently, and the vague use of "lately" made them unsure on whether they were thinking of today, the past week, or since the last questionnaire. Many stated that their response could fluctuate significantly over any given period of time and that they would prefer questions that were asked in the moment.

> *I I'm not, I'm not. Trying to be obstructive, but I would have thought the great majority of people who have dementia don't feel good about it [dementia]. Don't feel. Don't feel fair about it [Dementia].* [PWD3]

> *Yeah, I, I mean I just. Think that you come along. You are a stranger. You ask me how I am about my physical health, yeah. And erm. It just does not. It's, it is just the word. Best word is ambiguous… this it is not a good question.* [PWD3]

> *Are you asking about dementia? or how [is] the rest of me?* [PWD5]

> *I need to be honest and say I think it's a silly question for somebody with dementia. The reason I've been diagnosed with dementia is that I have a poor memory.* [PWD2]

Relevance

Participants also raised issues with the relevance of the fourth QoL-AD question, which asked about the users' living situation [23]. The question was intended to gauge users' satisfaction with their home environment, though the phrasing and use of "now" was interpreted by participants as indicating that their home environment had changed. Many found this inappropriate for a frequent questionnaire and did not foresee it changing bar from significant changes in circumstances. Participants felt the phrasing of the question needed to be changed, or to ask a prequestion asking if their living situation had changed before asking their response. Further, 1 participant also questioned the relevance of questions asking about users' memories and found it to be "a silly question for somebody with dementia."

> ***PWD5:*** *That's not likely to change week from week. I'd have thought, yeah. So, I don't quite see the point of it. In a weekly questionnaire.*

> ***PWD2:*** *I see what PWD5 means, mean. my situation wouldn't change at all. unless the worst happened.*

> ***PWD2:*** *You can get into a care home or something. But it's not on a weekly basis. It's not something that I think would necessarily change.*

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PWD3: *I feel the addition of the word "now" yeah. Uhm? Alters the meaning of the rest of the question ahead. How do you feel about the place you live now? It is implying that.*

PWD5: *You changed?*

Terminology

Participants were vocal about the terminology used in the questions. Even with prototypes (P2.1, P2.2, P2.3, and P2.4) developed to showcase features relating to other dimensions (visual, space, or time), participants would often cycle back to criticize the terminology of the questions. Participants did not like, for example, the use of "marriage" on the results page. Participants correctly pointed out that marriage would exclude participants who are unwed, in civil partnerships, or in other partnerships, with many participants requesting a change to "partner."

PWD2: *I struggle with the word marriage. Can that be change to partnership?*

PWD5: *That should actually.*

PWD2: *cause I'm in a same sex relationship.*

PWD5: *Yeah, it should be. Yeah, it should be changed.*

PWD2: *So, it doesn't really accommodate me.*

PWD2: *I'd like to switch spouse for partner. And also have an option for no one.*

PWD5: *I think you'd have to.*

Misread and Tonally Incorrect

Additional requests regarding the word dimension were changing words that could be misread or were seen as tonally incorrect, such as "decreased," which could be misread as "deceased," and "excellent" being replaced for being far too positive a response.

PWD5: *With my dementia, I saw deceased.*

PWD4: *Oh.*

PWD5: *So, I think, if possible, could you change that.*

PWD4: *Yeah.*

PWD2: *Deceased! ha-ha.*

PWD5: *Yeah, you do get funnier things with my dementia.*

Cycle 3

The top priority during cycle 3, which aimed to improve by changing WFPs into HFPs, was the word dimension, with 3 of the top 4 prioritized themes (F3.1, F3.2, and F3.4) belonging to this dimension. A significant amount of priority was also set for the behavior dimension (F3.3, F3.5, and F3.6). Matching the framework analysis results for workshop 3, MoSCoW results recognized shortening and simplifying the longer questions (F3.1) as well as updating the terminology that asks about time (F3.2) as being the top priority. Participants also wanted to see grammar updated to remove the use of questions starting with "how about" for greater clarity (F3.4). Regarding question sensitivity, participants had a significant preference for unnecessary or sensitive questions to not be shown at all to participants (F3.3) rather than just the option to skip (F3.9). While participants were open to the idea of being able to skip questions entirely in the workshop, this was a rather low priority. Participants also showed interest in providing greater input using the application. A free-text comment box for some questions would allow them to provide additional context along with their answers (F3.5), and the ability to nominate people with whom the data are shared directly into the application (F3.6) was also pitched. As with previous MoSCoW results, voice modality features were of limited priority (F3.7 and F3.9).

Complexity of Questions

A particular barrier highlighted was the length and complexity of questions. Most QoL-AD questions [23] were deemed far too long and multifaceted to read, or the questions were asked in a way that did not align with the responses available. Several questions were noted to be too long, especially those that posed multiple facets for a single question (Q2 and Q3). Some questions were deemed too large in their scope for participants to consider (Q6), and questions where a yes or no answer seemed more appropriate than a 4-point scale (Q4). Further, 1 participant found the short headings used above each question to be enough and easy to read at a glance. Finally, participants noted that some questions (Q6 and Q7) could be combined as the overlap between family and partners would be hard for them to separate.

I think it's difficult because there are 3 answers[Q3], it's not as, not as focused as I'd expect it to be? [PWD3]

I think questions 6 and the other [Q7] can be put together. Or maybe have parts to put the family members with different options but I don't think it needs to be separate questions. [PWD4]

Yes, I'd be able to answer it, but I also think that's there's too much there, the headings enough [Q9] [PWD4]

Terminology

Another area of significant comment related to the frequent use of certain terminology. As raised in cycle 2 (F2.2), participants disliked questions that asked users to consider a period of time, especially with the term "lately," which they found imprecise. This was once again raised in cycle 3 when reviewing all the questions with participants, noting the term was "difficult" to gauge what period of time the question wanted you to consider. Participants also commented on questions starting with "how about" (Q4, Q5, and Q6). Participant PWD2 noted the grammar was incorrect, which made some questions unanswerable with the responses available, and participants much preferred a more personal question, such as "how do you feel," which was easier to interpret. While these terminology issues may appear minor, participants appeared to be fixated on these issues, with half of the entire workshop's runtime spent discussing the questions.

I think the use of the term lately is perhaps difficult, does that mean yesterday and today or in the last fortnight? [PWD2]

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Depends if you're thinking about the present time? And is it like a regular question so you monitor it? [IC2]

PWD2: *I'm not sure about "how about your memory" as that's not really a question.*

PWD2: *Again, I don't want to be difficult but again I don't know what the question is. It starts with how about? What is the answer to "how about"?*

Yeah, I'd probably bin it [QoL-AD] to be honest, sorry to be so straight forward. [PWD2]

Sensitivity

One theme that arose was how many of the questions asked about participants' personal lives that could be insensitive, upsetting, or rude. Participants queried if people who were widowed, had no family, or did not have friends would be asked these questions. PWD2 also asked if information about a person's situation could be collected before the initial setup of the app, so these questions can be omitted from the questionnaire on a user-by-user basis. Participants were also keen on the option to skip questions.

What do you do if you're answering the questions, and your spouse is dead? [PWD3]

PWD2: *I think the option to skip would be useful. Because of my situation I don't have children and I'm an only child and have no nieces or nephews so be able to skip the question without refusing me to continue like the census [The Scottish census which was discussed prior to recording] did.*

PWD2: *And I think PWD3's point that if someone's been widowed, if we are gathering that type of information before we are starting the questionnaire process then a flag that says don't ask questions about marriage or a partner if they've been widowed or bereaved, that would be helpful.*

I'm aware I'm talking as if I am "tommy no mates" but there are some people who see themselves as not having a circle of friends and being asked this question could be a trigger for some emotion around the fact, I am "tommy no mates" and I have got nobody. [PWD2]

Free Text Input

Participants also showed interest in having additional input options when using the FFP. Numerous times when discussing the questions, participants requested a free-text comment box to be added so they could provide additional context along with their answers.

If it was on a comment, so instead of putting a yes or no, then a bit for a comment where you can put your own wee bit in. [PWD4]

I think there is an assumption that people can. Maybe the question should be are you able to do things that you enjoy and then a comment box for you to list what they are rather than again this "how about." Sorry I was an English teacher so start a question with how about? How about what? What's the answer to how about? [PWD2]

Data Sharing and Autonomy

A consistent theme that arose again during cycle 3 was regarding data autonomy. This was raised in cycle 1 with participants wanting to access their results and in cycle 2 with participants requesting greater control of who the data is shared with. In cycle 3, participants were keen on the ability to easily print results on headed paper so they could take this with them to appointments and to show to their HCPs. Participants also wished for the feature to nominate their own people that the data would be shared with.

Would you be able to make it so you could go to the doctor or hospital and take that [printed results]? [PWD4]

PWD2: *Would you be able to add someone to that list?*

PWD4: *I think it would be useful to be able to add it yourself. Yeah.*

PWD3: *I agree with the discussion and thinks it's all fine.*

Voice

As with cycles 1 and 2, the use of voice was of very limited interest to participants, with the voice-only prototype (P3.5) receiving universal dislike. Participants unanimously agreed that if voice is to be implemented, it must be accompanied by a visual or textual prompt that displays the question asked and the answer responses, as many said they would struggle to remember these using voice only.

PWD4: *I think even with the verbal one, although the voice is saying Good, Fair, Etcetera, I think its need to be on the page because depending on people's memory, they might not remember what the answers were spoken.*

DK: *So, you definitely prefer a visual experience or a visual prompt alongside the audio?*

PWD4: *Yes*

PWD2: *Or instead of!*

Cycle 4

For the final co-design workshops, which aimed to culminate the HFPs into an FFP, time was the most prioritized dimension (F4.1 and F4.2), followed by behavior (F4.3 and F4.4). Participants wished to see a definitive end to the application with an "end session" button that would close it when completed, reassuring them that it is finished. Due to the way the FFP (P4.1) handled data in its database, an earlier feature, which automatically moved to the next page once an option was selected (F1.4), did not function correctly. While the feature did not come up in discussion during the cycle 4 workshop, it was included in the MoSCoW survey, where participants gave significant priority for it to be reinstated (F4.2). The MoSCoW results also showed priority for a comment box to be added (F4.3) so users could add additional context to their responses, as well as a print option being added inside the application

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(F4.4). Participants also requested some minor visual adjustments, though these were of relatively low priority. Finally, participants had moderate interest in the app being developed for mobile (F4.5), though once again, they had little interest in implementing voice modalities (F4.8).

End Session

Some users were not aware of what to do once they had completed the questionnaire and reviewed their results. While the webpage can be closed at any time, the lack of a prompt to do this caused minor confusion with 1 participant. It was therefore requested that the inclusion of an "end session" button to be displayed at the end.

> *I've done that, I'm now back at the screen that says, "your dementia app. Thank you for submitting the questionnaire." There's nothing that tells me how to close it.* [PWD2]
>
> *The only thing for me is at this stage is a button to see close or end session.* [PWD2]

Free Text Input

Participants were concerned that some of the questions did not provide enough context, with just 4 response options. For example, if the user had an argument earlier that day, this could affect their response to how they feel about friends or family. Adding an optional free-text input at the end of the questionnaire would allow users to include such context. This theme was previously raised in cycle 3 (F3.5), but after further discussion, it was decided that a single comment at the end of the questionnaire was better than a per-question basis.

> ***PWD2:*** *I think some of the questions I'm just a bit concerned that. Your answer is going to be specific to the day that you do the questionnaire. … And if you've had a row with somebody first thing in the morning, and you do this in the afternoon, yeah. That might affect how you answer.*
>
> ***PWD4:*** *You know, even if they have [had an argument] a comments box somewhere, yeah, you know to put in comments if you needed too, you know?*
>
> *[in response to being asked "any other features"]*
>
> ***PWD4:*** *And the comments box!*
>
> ***IC2:*** *And it would be optional, wouldn't it? So, you comment if you wish?*

Frequency

Participants were keen to have the option to choose the frequency of the questionnaire. Most participants seemed to favor monthly delivery for the PROM. One participant did request once a week, and this feature was previously raised as it would be better for building up a routine and make it harder to forget.

> ***PWD2:*** *I think making it once a month would be more likely to encourage people to use it than once a week.*
>
> ***PWD4:*** *Hmmm, yeah, I think you should have the option to do it weekly because I think if it was. Monthly. And. I might forget what I did, yeah? Or even 2 weeks ago? Yeah no. So, I would need to do weekly.*

Data Autonomy and Ownership

One participant inquired if their data could be saved and with the functionality to print their results. While this feature does exist natively for most web browsers, the participant was keen to have this feature built into the application for easy use. This feature was previously raised in cycle 3 and would be useful to have where participants wished to have results printed on headed paper that they could take with them to appointments and share with their HCPs.

> *Would that be printable?* [PWD2]
>
> *Would I also be able to save that?* [PWD2]

Mobile

Participants were indifferent to the prototype being developed for mobile devices. Some thought it may be useful to have as an option, though most agreed that a mobile screen is far too small to comfortably use for this purpose.

> ***DK:*** *Anyone be interested in seeing it on a smaller device like a mobile phone?*
>
> ***IC2:*** *Urmmmmmm.*
>
> ***PWD2:*** *I'm not sure on that.*
>
> ***PWD4:*** *Well, I would like the option.*
>
> ***IC2:*** *I think too small. There's just not, not manageable.*
>
> ***PWD2:*** *I think the options there I'd probably not take the option. Yeah, if it's there, it's there.*
>
> *No, I think phone things are too small.* [PWD5]

Setup

Participants were confident in their ability to set up the prototype themselves, as well as being in control of who the data is shared with. Participants who could access the prototype were able to access the questionnaire and all the features independently and quickly. One participant mentioned they would feel uncomfortable with having someone else, such as an HCP setting up the questionnaire, especially regarding questions about finance that they would not like to have raised with an HCP.

> ***IC2:*** *Set it up myself, I think.*
>
> ***PWD4:*** *I think so.*
>
> ***PWD2:*** *I think so too, yes.*
>
> *I think that is probably quite a good idea, I wouldn't want my doctor to know too much about my personal life.* [PWD5]

Summative Evaluation

A total of 3 workshops were conducted as part of the summative evaluation workshops involving 2 major stakeholder groups, the first 2 workshops involved HCPs from NHS (n=12, Table 6), and the final workshop involved people living with dementia and IC from the charity Alzheimer's Scotland (n=8, Table 7).

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Table . NHS[a] MoSCoW[b] results.

ID	Themes	Theme covered	MoSCoW score	Will not include	Priority
F5.1	Implementation of a text message or SMS-based system to send the questionnaire	Behavior	2.7	0	Very high
F5.2	Further research into mobile-friendly and application versions	Space	1.85	0	High
F5.3	How to encourage user participation, especially during certain periods of their journey	Behavior	1.65	0	High
F5.4	Expand testing to those with later and more severe stages of dementia	Behavior	1.5	1	Moderate
F5.5	Rebuild inside existing systems using the established and approved tools	Space	1.45	0	Moderate
F5.6	Offer greater breakdown and filter options for how data is displayed to all users	Visuals	1.25	1	Moderate
F5.7	Look into interoperability and how the data can be shared and stored in established systems	Space	1.15	0	Moderate
F5.8	Avoid changes to questions and restore the original QoL-AD[c]/DEMQOL[d] questions	Word	0.75	2	Low
F5.9	Further research into voice systems, such as Alexa (Amazon.com, Inc) devices	Word	0.7	0	Low

[a]NHS: National Health Service.

[b]MoSCoW: MoSCoW (Must Have, Should Have, Could Have, Won't Have) prioritization method.

[c]QoL-AD: quality of life in Alzheimer disease questionnaire.

[d]DEMQOL: DEMQOL (dementia quality of life) questionnaire.

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Table . Alzheimer's Scotland MoSCoW[a] results.

ID	Themes	Theme covered	MoSCoW score	Will not include	Priority
F6.1	Test the reliability and validity of the questionnaire and results	Word	High	0	2.45
F6.2	Review the use of certain words and colors for better usability	Word	High	0	2.4
F6.3	Ensure GPs[b] and HCPs[c] are on board with using this system	Behavior	High	0	2.3
F6.4	Further research into mobile-friendly and application versions	Space	Moderate	0	1.75
F6.5	How to encourage user participation, especially during certain periods of their journey	Behavior	Moderate	1	1.7
F6.6	Further research into voice systems, such as Alexa devices	Space	Low	1	0.7
F6.7	Avoid changes to questions and restore the original questionnaire	Word	Low	1	0.65

[a]MoSCoW: MoSCoW (Must Have, Should Have, Could Have, Won't Have) prioritization method.

[b]GP: general practitioner.

[c]HCP: health care professional.

NHS Evaluation

Analysis from the NHS evaluation showed the highest priority features related to the space or behavior dimension, with the top 5 features all relating to those dimensions (F5.1, F5.2, F5.3, F5.4, and F5.5). The behavior dimension was also heavily prioritized in cycle 4. The space dimension, on the other hand, proved to be a notable dimension for HCP, who took particular interest in the feasibility and technology being implemented, particularly in relation to their existing systems and processes.

The delivery method was the top priority for HCP, with them inquiring if the application could be delivered via text or SMS message (F5.1) and whether further research could be performed to develop a mobile-friendly version of the prototype (F5.2).

> *Just about the email aspect. I'm not sure if that many of the patients use email. Sort of experience from clinics. I think sometimes the carers do but even that's quite rare and the patients, I think seldom use email.* [HCP2]

> *Did you look at like phone numbers to send the link? … Instead of the email, yeah, use their phone numbers and you know. And then they can access it.* [HCP4]

> *I think we are quite used to receiving text messages from the NHS because I am I just got 1 today… so I think patients might be quite used to that because they're already getting that from their surgeries. And I think that might be something to explore if there is a better way of linking it to your questionnaire.* [HCP1]

The next prioritized features involved investigating ways to encourage user participation throughout the different stages of their treatment journey (F5.3), including expanding the testing of the prototype to people with later and more severe stages of dementia (F5.4) to understand the app's usability at stages where problematic behavior is more prevalent. They also recommended revisiting icons and images, as other patients may find the use of visual aids helps those who are less digitally skilled or have a more severe diagnosis of dementia to better interpret the questions being asked.

> *I think it's a really good way to measure somebody's response to medication to care treatments and things like that on a week-by-week basis. So, I actually think it's really good and the simplicity of it for people who are obviously coping in public they appear, but they're a very stressed period in their life… I would actually incorporate that into my assessments, review feedback to the consultant.* [HCP3]

> *I guess it's about kind of envisioning which group would be using it? And then the frequency kind of comes into lawful purpose. I mean it is almost at the early stages of dementia, so if you think of immediately post diagnosis, is this about trying to kind of get some sort of early detection of somebody's QoL starting to sail off?... Actually, if a dementia outreach team were seeing somebody for quite an*

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> *intense period of work, more frequently might be useful.* [HCP1]
>
> *You could change it depending on the execution so like the crisis team, so they might want the weekly because their engagement is good, yeah? Very short term but doctors would be monthly, or you know something along those lines to get the data.* [HCP4]

The topic of delivery also extended to the possibility of rebuilding the application inside existing systems that are established and approved (F5.5). This comes with several complexities, as many NHS systems will have their own independent and legacy systems, which would require rebuilding multiple apps for multiple systems to multiple standards and requirements. It was also noted that, as the prototype is web-based, most existing NHS systems would be able to access it with ease, and keeping it as a separate standalone app would benefit it more than direct integration. An HCP-specific feature that arose regarding how HCPs would access the data collected and how it can be used to benefit their existing processes. One feature would be the ability to break down and filter options for how data is displayed to all users (F5.6). They also raised consideration into the interoperability of the data and how it can be shared and stored in established systems (F5.7), with concerns regarding data governance and how different layouts and structures in existing systems may make integration very difficult.

> *How will healthcare staff access this information? In particular, if you're accessing an application or whatever in terms of not only the confidentiality, but how that will mesh, and if it will play nicely with the NHS systems?* [HCP6]
>
> *I guess the difficulties that you have is across the country. Is that different people have different electronic records and some of them have got more advanced patient portals than others and…not even so much the technical bits, it's the information government side about the data sharing with NHS systems and who gets to keep it where, yeah?* [HCP1]

Alzheimer's Scotland Evaluation

Analysis from people living with dementia and IC in the Alzheimer's Scotland workshop (n=8) showed a significant departure in priorities and topics when compared to the HCP in the NHS workshops. While the NHS evaluation focused significantly on the behavior dimension, participants of Alzheimer's Scotland were far more concerned with the word dimension, particularly regarding the choice of questions that were used.

Participants' main priority was regarding the reliability and validity of the questions and answers, and they were keen to get the new questions validated (F6.1). While participants did have concerns with the validity of the updated questions, there was very little call for restoring the original QoL-AD PROM questionnaire (F6.7).

> *How do you know that? When somebody says they're not, their "Fair," their "fair" is somebody else's "good"?* [IC3]
>
> *Sorry, so just thinking it's very subjective and if you look at what you feel like today. And yes, it could change that, you know, and so how reliable is it?* [PWD7]
>
> *I just think there's so much. Relating to reliability and validity. Measuring what you say you are and then validity in the actual meaning of everything of each word, and so on. I have a lot of concerns, with that.* [IC3]

The next priority regarded the usability of the interface regarding layout, font sizes, and use of colors, as well as some of the terminology used (F6.2). Some participants found the use of colors distracting, though they were pleased at the option to turn colors off. Participants also found the text and line graphs to be far too small and thin to see and would prefer to see their size increased.

> *Yeah, for me I would like to see just plain black and white really.* [PWD8]
>
> *I think the colours are actually distracting, yeah.* [PWD7]
>
> *Hey DK how would that work with the graph that comes at the end that shows you know the variation in health and mood? In that the colours are helpful.* [IC2]
>
> *Yes, yeah, but would you be able to read the words below the drawings. You know you've got this line graph like Oh yeah, yeah. And were supposed to be able to read them. They're tiny?* [PWD7]

The next priority for the Alzheimer's Scotland group was ensuring HCPs and general practitioners (GPs) were on board with using the system (F6.3). Participants vented frustration that the level of interaction with their GPs was minimal. Therefore, it is paramount that future researchers ensure cooperation and involvement from GPs and HCPs to use the system before implementing, as the data would be useless if they do not use it.

> *Yeah, and also how practical is it? I've not seen a doctor for quite a while. I actually had a phone call with her last week and there is just not the time to do something like that.* [PWD8]
>
> *I was thinking also, but in terms of GP, GPs aren't even doing an annual review. So, the prospect of him trying to get only a GP and take this along and look at it. Yeah, you know it's. I don't think you know. 1 of the missions are things we have to change the attitude of GPs as well to looking after people even say once a year. yeah.* [IC3]
>
> *I don't want to be pessimistic. But yeah, the time factor just wouldn't allow it.* [PWD8]

A theme was added to the MoSCoW questionnaire due to its significance in the NHS workshop, regarding further research into mobile-friendly and application versions of the prototype (F6.4). The MoSCoW response showed a moderately high interest in the prototype to be designed for this, though the topic itself did not arise during the workshop.

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As with earlier phases, participants disliked the use of a voice modality (F6.6), with participants finding it overly robotic and 1 participant describing the voice having "disturbed" them and felt the voice sounded "manipulative." While participants did recognize the usefulness of having a voice option for people who may struggle to read, each participant would choose to disable the voice feature if given the option.

> *Are you going to use that voice? Why is it an American accent?* [PWD7]
>
> *I just feel. Disturbed by being manipulated about my deepest things by Alexa [Digital Voice assistant].* [PWD3]
>
> *Is it and it just feels like totally manipulative of everything. Hmm, yeah. Yeah, definitely don't want you, don't want you expect when you're dealing with intimate things where you when you look at the sensitivity.* [PWD3]
>
> *You know they would be nice to have that option. Especially because then PWD8 speaks about, you know, just difficulty they you know seeing you know the words and reading due to Alzheimer's that if you had the voice activation option. Yeah, it could read the question, but I do agree. I think in that robot version. Yeah, it is. Yeah, it's not so clear and things as well, but I think there's more options that they have to have that.* [PWD10]

Finally, on the topic of encouraging user participation (F6.5), people living with dementia who attended the workshop without an IC stated they would have no issues completing the prototype themselves regularly, though 80% of participants who completed the demographic questionnaire described themselves as being "somewhat or very confident" using technology. People living with dementia who attended with an IC stated they would likely need help from their IC to complete.

> *I think I would be comfortable doing it myself.* [PWD2]
>
> *Oh, I'd do it myself. I think it mustn't be very difficult, different for Everybody.* [PWD8]
>
> ***IC2:*** *Would you need my support to fill in the questionnaire? To this. If this was sent to you. Would you feel happy just to do it or would you like me to be there to help you?*
>
> ***PWD3:*** *I would, I would need support, yeah.*
>
> ***IC3:*** *Well, my husband would certainly need my support.*

Discussion

Principal Findings

The purpose of this study was to co-design a novel digital application to enable people living with dementia to regularly self-report QoL PROMs. This aim was successfully achieved as demonstrated with a co-designed FFP that adheres to modern web standards [35,36] and DEEP (Dementia Engagement and Empowerment Project) guidelines [37-39]. The prototype was co-designed with direct involvement from people living with dementia during every stage of development and was evaluated by key stakeholders (including people living with dementia, ICs, and HCPs) around features, questions, and modalities alongside design considerations, which are discussed below.

What Features, Questions, and Modalities Do People Living With Dementia Prefer When Interacting With a Digital Application That Enables Them to Self-Report QoL PROMs?

Existing PROM terminology was deemed inappropriate and noninclusive, with the format of certain questions being overtly long, ambiguous, irrelevant, and confusing. Participants requested frequent changes to the questions over the course of the prototype development. Regarding modalities, participants preferred text-based modalities, describing visuals, icons, and animations as distracting, with the use of colors being divisive among participants. Voice modalities were universally disliked and seen as intrusive, aggravating, and "just bad."

Use of Dementia PROM Questions

Existing PROM terminology was deemed inappropriate, with participants reporting these questionnaires to be noninclusive, overtly long, ambiguous, irrelevant, and confusing. While QoL-AD is a well-established and validated tool designed specifically for people living with dementia [40], it has seen limited clinical use with many studies opting for more generic PROMs [17,18]. These studies did not report a reason for using generic PROMS over those designed for people living with dementia, though these studies also lacked involvement from people living with dementia in a co-design capacity. This study's findings show a need to review existing PROMs developed for people living with dementia. Many of these PROMS were originally developed as only paper-based questionnaires to be used in a clinical setting and delivered by an HCP [17], with very few high-quality QoL PROMs validated for use in a home environment [20]. With the rise in ePROMs [41] and the convenience of online questionnaires [42] with comparable response rates compared to traditional methods [7], it becomes clear that more needs to be done to update dementia PROMs for digital use.

Preferred Modalities

Participants showed a significant preference for text-based modalities, with visual modalities often resulting in indifference or conflict, and voice modalities being significantly disliked. This is to be expected, as since their inception, PROMs have been primarily text-based [12], with the concept of multimedia PROMs and protocols for it still being relatively new [43]. While there are several paper-based PROMs that use visual elements [44,45], the use of images and icons was deemed patronizing and unprofessional by people living with dementia participants during cycle 1. Such patronizing actions can have a dehumanizing effect on people living with dementia that reinforces negative stereotypes and should be avoided [46]. Participants, therefore, preferred visual flourishes that focus on larger and bolder text fonts (F1.1) and the use of visuals to highlight interactive elements (F1.3). These statements are backed up by other literature that notes that culture and language play a key role in the use of PROMs, and issues with

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misinterpretation can impact their reliability and validity [47]. Finally, while voice modalities were universally disliked, they have been shown to work as an effective interaction method for people living with dementia, with voice assistant technology being recognized as being mature enough to support health care delivery [48]. The type and style of voice used should be explored to appeal to participants keen to use a voice modality [49], as well as concerns about understanding accents as a major recognized weakness of speech recognition technology [50]. More research is therefore needed for voice modalities to be effective.

What Are the Design Considerations and Specifications for a Digital Application to Enable People Living With Dementia to Self-Report QoL Data via PROMs?

Overall, participants enjoyed the layout and design of the prototype, finding it highly accessible, and envisioned using it at home without needing assistance. Participants lauded the importance of personalization and optionality. Rather than having fixed features, participants requested the ability to turn features such as color or modality on or off, as well as the ability to skip questions. Participants were also keen on being in control of their own data, requesting access rights to their results as well as the ability to choose with whom and when to share the data.

Personalization and Optionality

A key feature that arose multiple times during the workshops was the importance of personalization and optionality of the prototype. This matches the background research, which notes the importance of individuality for people living with dementia and how technology interventions need to be adaptable and adjusted to specific users [18] and how engaging early with people living with dementia in the design process to make such adjustments can benefit a variety of different technologies during the development process [51]. Current policies for the future of digital health technologies highlight the importance of personalized approaches tailored to patients' needs [52], with HCPs increasingly encouraged to implement more personalized approaches in all facets of medicine and treatment [53], including dementia care [54]. Lack of personalization and adaptation is already a recognized issue with existing technology "designed for people living with dementia" [55,56], which is compounded by the lack of involvement and inclusion of people living with dementia in developing technologies which are meant to serve them [57]. Technology that is not designed with personalization in mind may struggle to be adopted as users in all domains will have vastly different needs, perceptions, and capabilities, meaning that implementing any modern technology solution requires consideration of this user diversity [58]. A "one size fits all" solution would not work, and with an already high and increasingly aging population impacted by dementia, there is a risk of the "digital divide" expanding even further, with increasing social inequalities in this domain being driven by technology that excludes people living with dementia and other vulnerable members of society by being inaccessible or not adaptable to their needs [26,59]. This, of course, does increase the level of complexity of an application and the work required to develop, test, and support it. Having too many features and options can result in feature fatigue for users, which can overwhelm them and make an application more difficult to use [60]. Therefore, a careful balance must be struck between optionality and complexity.

Data Ownership and Autonomy

Another feature was the importance of data ownership and autonomy. Patient autonomy has long been a vital aspect of health care, with HCP respecting patients' opinions and offering them the opportunity to make informed decisions about their medical treatment [61]. People living with dementia are increasingly being encouraged to be involved in such decision-making [62] with the goal of using technologies to provide medical treatments remotely that will enable patients to stay at home for longer [52,63] well into the later stages of dementia [54]. The danger here is that such technology in a home environment can be intrusive, collecting sensitive and personal data on patients who may not be willing to give or be aware of such a thing, which could be risks for privacy violations or data breaches [64,65]. It is therefore critical that patients have the autonomy to access and control their data and how it is used. Privacy concerns remain one of the top barriers to technology adoption among the over fifties [66], with polls showing almost half (49%) of older adults raising privacy concerns with telemedicine delivery [67]. Regardless, an extended effort should be made to enable and encourage data autonomy among patients. This approach has seen significant success in Estonia, where the Estonian eHealth Patient Portal enables patients to access all health care data regarding them on request and allows them to deny access to their data to any or all care providers [68]. This enables an unprecedented level of patient engagement and trust, with Estonia recognized as having one of the leading eHealth solutions in Europe [69].

Conclusions

While this study did successfully develop and evaluate a multimodal digital application to enable people living with dementia to regularly self-report QoL PROMs, this work opens further discussion about the wider changes that are required to facilitate regular use of PROMs in routine postdiagnostic dementia care. More research is needed to update preexisting dementia PROMs or validate new dementia PROMs that are designed with digital delivery in mind; solutions should prioritize text-based modalities and avoid voice-only modalities; any technology solution developed for people living with dementia should be designed with personalization and optionality in mind; and data autonomy for people living with dementia should be considered as a top priority, for applications developed to collect QoL data, with people living with dementia given access and control of how this data is shared and used.

Strengths and Limitations of This Study

The main strength of this study was that the novel application was co-designed with people living with dementia from the outset, with people living with dementia involved directly throughout every stage of development. By including people living with dementia in the entire development of the prototype, we were able to include and remove features and create a prototype that was far more likely to be acceptable and adopted

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by people living with dementia and serve their needs. We also believe this is one of the first studies to evaluate perceptions from all key stakeholders, including people living with dementia, ICs, and HCPs, regarding the use of ePROMs for dementia in routine care.

The main limitation of our study came as a result of needing to perform entirely online. This caused significant issues with recruitment. Multiple potential participants excluded themselves from this study due to it being online. Many people living with dementia and IC reported not feeling confident enough to take part in an online study, or felt that spending any extended length of time on their computer was exhausting. HCP also reported that many possible participants were overfatigued by online meetings during the pandemic and would not wish to participate in further online meetings. This resulted in a small and homogeneous participant group that likely does not represent the population at large. This itself was an additional limitation as our co-design group and most of our evaluation group were White and native English speakers and did not adequately represent participants from different cultural and language backgrounds. A further limitation was that, as people living with dementia were the central focus of co-designing the prototypes, the voice of IC may not have been heard. While ICs were involved in every stage of development, it may be fruitful in the future to investigate the specific perceptions of ICs. Finally, the inclusion criteria did not permit people living with dementia in later stages of the condition to take part. This was a pragmatic choice as this would have added significant additional complexity to this study, especially regarding the ethical approval required for participants who cannot provide informed consent, and the additional resources needed to ensure their safekeeping and well-being. This was therefore outside the scope of this study and is something to investigate further in the future.

Future Research

With a functional prototype, the next stage for this project would be a pilot in a real-world environment. Future participants with early stages of dementia would be encouraged to self-report the QoL questionnaire using the novel application remotely using their own device in their home environment, while HCPs access the data and evaluate its clinical utility. Future research would also strive to revisit and test the prototypes on participants with later stages of dementia to gain insight into understanding the app's usability at stages where problematic behavior is more prevalent, to see if the prototype fits their use case. If this proves viable, new features could be developed for this particular population. We would also aim to recruit participants from a wider range of backgrounds, especially those from ethnic backgrounds or where English is not their first language. We would also seek to investigate further opinions from IC and recruit an expanded pool of them, such as extended family and friends who may offer greater insight and observation from a home environment, especially when piloting the novel application remotely. Finally, more research is needed into ePROMs that are designed to enable people living with dementia to self-report QoL data. The novel application is a good proof of concept for people living with dementia self-reporting QoL data using digital technology, so the next step would be to see if we could validate our questionnaire or create a new ePROM designed to enable people living with dementia to self-report using new technologies.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Overview of prototypes.
[DOCX File, 2946 KB - jopm_v18i1e87565_app1.docx]

Multimedia Appendix 2
Video demo of final functional prototype.
[MP4 File, 8637 KB - jopm_v18i1e87565_app2.mp4]

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Abbreviations

DEEP: Dementia Engagement and Empowerment Project
ePROM: electronic patient-reported outcome measure
FFP: final functional prototype
GP: general practitioner
HCP: health care professional
HFP: high-fidelity prototype
IC: informal caregiver
LFP: low-fidelity prototype
MoSCoW: Must Have, Should Have, Could Have, Won't Have
NHS : National Health Service

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PROM: patient-reported outcome measure
QoL: quality of life
QoL-AD: quality of life in Alzheimer disease
WFP: wireframe prototype

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Participatory System Mapping of a Hospice Care System With Hospice Stakeholders: Hybrid Design Workshop Study

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Abstract

Background: Palliative and end-of-life care (PEoLC) systems are expanding across services, settings, and stakeholders, increasing their complexity and the need for systemic understanding to support patient outcomes and service delivery. Hospice care is central to the future of PEoLC, as hospices provide holistic services and engage diverse stakeholders. Participatory system mapping offers a way to collectively understand and visualize complex dynamics with those who live and work within these systems.

Objective: This study aims to capture hospice system dynamics and preliminary leverage points via participatory causal loop diagram (CLD) mapping while evaluating method suitability through 3 research questions: (RQ1) What key variables and causal interrelationships do stakeholders identify in a hospice through participatory system mapping workshops? (RQ2) What preliminary leverage points emerge from the system map? and (RQ3) How effective are participatory system mapping workshops for capturing hospice dynamics?

Methods: We developed and iteratively refined an innovative hybrid, asynchronous, multimodal design workshop series in a hospice in North West England. Stakeholders were introduced to core concepts in technology, design, systems thinking, and CLDs before engaging in participatory system mapping focused on the hospice experience quality. CLDs generated in workshops and through asynchronous participation were consolidated into a composite hospice system map. Twenty-seven participants, including patients, health care professionals, volunteers, managers, maintenance staff, and chaplaincy, contributed to the mapping process. The resulting map was analyzed using quantitative network analysis (in-degree, out-degree, betweenness, and closeness centrality) alongside qualitative interpretation of key system dynamics.

Results: The participatory hospice system map contained 84 variables connected by 175 causal links. Network analysis highlighted patient experience (highest in-degree, 20), advanced care planning (highest out-degree, 8), fundraising (highest betweenness centrality, 0.19), and relationships with community organizations and external stakeholders (highest closeness centrality, 0.23) as central elements in the map. Qualitative analysis illuminated important dynamics, including the impact of hospital admissions and hospice stereotypes, as well as uncertainties around how advanced care planning is shaped and enacted in practice.

Conclusions: Participatory system mapping with hospice stakeholders was feasible in a time-pressured setting and generated a nuanced, stakeholder-led representation of hospice system dynamics. The hybrid, multimodal workshop model enhanced access and flexibility, supporting diverse engagement. Network analysis of the CLD suggested preliminary structural and conceptual leverage points and revealed gaps in shared understanding, indicating candidate areas for service development, policy attention, and further research. Future work should examine the replicability of this approach across PEoLC settings and integrate context-specific processes to validate and act on candidate leverage points.

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KEYWORDS

palliative and end-of-life care; participatory system mapping; design workshops; stakeholder engagement; participatory research methods

Introduction

Hospice as a Research Setting

In England, palliative and end-of-life care (PEoLC) refers to care that enables people of all ages to live well in the last years, months, weeks, days, and hours of life, with “end of life” specifically referring to the final year of life. These terms are often combined to describe the broad services that provide PEoLC [1], which is the term used here. PEoLC systems face intensifying pressures, with aging populations driving demand while services expand multidimensionally to address patient needs [2-6], in-person and digital services [3,7-11], diverse care environments [7,12], its changing societal value [13,14], and a person-centered care approach [15]. PEoLC definitions are evolving through "upstream migration," as services integrate

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earlier into primary and hospital care rather than being limited solely to end-of-life, expanding the range of illnesses included [16,17]. Hospice care, as a core pillar of PEoLC, reflects this expansion, evolving from single-site cancer relief to multifaceted inpatient and community services within regional networks (Multimedia Appendix 1 summarizes these expansions across dimensions). This expansion and complexity have received recognition from both within and outside the field to approach it on a systemic level [18-22]. Current understanding lags behind these developments, risking reactive services rather than proactive redesign.

Systemic design addresses such complexity with place-based, stakeholder-involved mapping for collective understanding and person-centered interventions [23-25]. Participatory system mapping via causal loop diagrams (CLDs) visualizes this by constructing dynamics for discovery and leverage identification, building joint understanding, and leading to greater trust and sustainability of interventions [26,27]. Distinct from expert group model building (GMB), it engages end users (patients or carers) via directional variable maps for whole-system experience perspectives [28-32]. Participatory system mapping, as a flexible method, is more closely aligned to the format of CLDs, which are directional system maps of variables and their causal relations [33]. By making visible the variables, relationships, and gaps that shape hospice care, participatory CLD mapping can support a more holistic understanding of how services, staff, patients, families, and wider networks interact, thereby identifying points where more coordinated and person-centered care may be strengthened.

Health care participatory design principles and approaches that involve stakeholders are increasing in policy prominence and are seen as enriching the research process, producing better outcomes [34-37]. The National Health Service (NHS) has embedded co-design principles in its “Long Term Plan”; however, they risk tokenism, lack standardization and designers in the process, and are unable to adapt to time or ethical barriers [20,24,25,38,39].

Hospices provide an ideal setting for the exploration of participatory design methods and for researching PEoLC dynamics and operations, compared with alternative locations, by providing access to the core of PEoLC operations and its branching specialist services. This study has selected a hospice operating as a branch of a national hospice care charitable organization in the United Kingdom, which provides robust ground for a holistic, granular, and place-based understanding of hospice care as a complex system. The particular hospice was selected based on several factors, including proximity, willingness for interdisciplinary collaboration, a strong research culture, and support for the researchers in navigating the system and engaging stakeholders.

Objectives and Research Questions

Our objective is to capture hospice system dynamics and preliminary leverage points via participatory CLD mapping while evaluating method suitability. We have devised 3 research questions in order to achieve this objective: RQ1. What key variables and causal interrelationships do stakeholders identify in a hospice via participatory system mapping workshops? RQ2. What preliminary leverage points emerge from the system map? RQ3. How effective are participatory system mapping workshops in capturing hospice dynamics?

Methods

Ethical Considerations

This study formed part of a doctoral research project and received ethical approval from the University of Liverpool, Central University Research Ethics Committee (Ref: 10901; approval document and protocol in Multimedia Appendices 2 and 3). Informed consent was obtained from all participants.

Participatory System Mapping Approach

Participatory approaches toward system mapping in health care are assessed as overall positive, with methodological challenges and barriers involved [40,41]. Jun et al [41] note the adaptation of action research methods due to the time constraints of stakeholders in time-limited, one-off workshop settings, as well as the recruitment and retention of busy and geographically distributed stakeholders.

Hospice care is treated here as a focal subsystem of PEoLC because it brings together inpatient, community, bereavement, volunteer, and organizational functions, making it a useful microcosm of broader PEoLC system dynamics. Using participatory research methods in this setting introduces advantages and known barriers similar to those in broader health care settings. The advantages include incorporating many voices collaboratively, as well as reflexive and adaptive approaches that can feed into working groups, continuous improvement, and wider service innovation. The barriers include the high cost of implementation; the time required to conduct research and build productive relationships between researchers and participants; ethical considerations around including patients in sensitive topics; and the challenges of initiating and sustaining participation [35,36,41-44]. This focus allows the study to examine how broader PEoLC dynamics are expressed in a service setting where clinical, community, and organizational congregate.

Adopting the recommendations of Hockley et al [42] and Borgstrom and Barclay [44], the researchers attempted to gain managerial buy-in early on, be reflexive and responsive to participants’ needs, and enable equitable engagement during workshops through effective facilitation. The study adopted a participatory system mapping of CLD through an asynchronous workshop format to allow for flexible, enhanced, and inclusive engagement. CLD was selected because its mapping rules were simple, and once learned, a CLD could be easily understood and built upon by other participants in a nonexpert workshop setting.

Advanced Workshop Design and Development Approach: Developing Participatory, Hybrid Multimodal System Mapping Workshops With Stakeholders

Four consecutive 1-hour workshop sessions were developed. A design approach was adopted, and the participatory system mapping was framed, introduced, and delivered as part of a

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wider design workshop series for system stakeholders (hospice staff and patients). The content of the workshops aimed to first increase participants' literacy and confidence in the meaning, potential value, and role of technology, design, and systems in hospice care, and then conduct participatory mapping of the hospice system with participants using a CLD. The wider design-led approach to first engage with and understand the relevance and importance of systems design in future hospice care is argued to build contextual relevance and offer value and meaning to participants, thereby increasing meaningful engagement.

"Hospice experience quality" was selected as the central variable for cocreation of the CLD by workshop participants, as it was considered a relevant and important area of priority for all hospice stakeholders, including patients and staff, due to its direct impact on the overall care and well-being of individuals at the end of life.

Accessible and jargon-free language was used in all content, and any potentially new concepts were explained. An information poster was designed for each workshop, outlining its remit and summarizing its content. The language, accessibility, and functionality of all print and digital material were assessed by a patient-facing staff member with no previous familiarity with the topic or content, and improvements were made accordingly. Enhanced engagement and interaction were encouraged by displaying the information poster from the previous workshop in a public space within the hospice, with the ability for participants to add to the discussion via a large notepad, Post-it notes, and pens. Table 1 provides a summary of the 4 workshops, outlining content, aims, and activities.

Table . Workshop design—content, aims, and activities.

Workshops	Content and aim	Activity
Workshop 1: technology	• Content: The most recent technological advancements selected for their perceived importance to future hospice care (robotics and artificial intelligence) [10] • Aim: To consider challenges and opportunities for using technologies in the context of hospice care	Discussing pros, cons, opportunities, and concerns of technologies in hospice care.
Workshop 2: design	• Content: The definition of design, an introduction to human-centered design and design thinking principles, and 4 orders of design [45] • Aim: To provide a broad perspective of design and a general understanding of the value and role of design in hospice care	Open discussion about what design is, design processes, design connection to PEoLC[a], and the impact of design on the world, with a neutral stance presenting good and bad examples.
Workshop 3: understanding complexity	• Content: An introduction to systemic design, its remit and application, and how to make and read a CLD[b] • Aim: To understand the aim, processes, and applications of systems design and to understand CLD	Filling out a CLD template (reinforcing and balancing loop diagram) individually.
Workshop 4: mapping complexity	• Content: A brief reintroduction to CLD. Discussion of CLD outcomes at the end of the workshop • Aim: To create a CLD around the variable of "hospice experience quality"	Participatory system mapping using CLD and building a map as a group using paper, pens, and Post-it notes.

[a]PEoLC: palliative and end-of-life care.

[b]CLD: causal loop diagrams.

The workshops were conducted over a period of 3 months in a space accessible to staff, patients, and family members within the hospice, facilitated by an experienced design researcher. At the time of running the workshops, the researcher had spent 8 months in the hospice as part of their designer-in-residence role, conducting observations and interviews, and had developed a good level of familiarity with staff and patients.

The workshop format took shape iteratively throughout the research, exploring the most suitable formats in a high-pressure and sensitive health care setting for participants with very limited time and mental space to engage. This required flexibility in a highly responsive, patient-facing workplace with immediate and fluctuating patient care needs.

Workshop Iteration 1: Asynchronous and In-Person, With an Emphasis on Physical Interactions

The first iteration was informed theoretically by the work of Davis et al [46] and empirically by the format of an existing well-attended 1-hour weekly journal club for hospice staff. Staff engagement helped suggest and later verify a 1-hour duration, a set time slot, and a daily in-person physical format as optimal for attendance and interaction. Four daily 1-hour workshops were delivered consecutively over 1 week, at a consistent time.

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However, workshop attendance revealed several barriers to participation. Overall, 8 staff members were able to engage over the week, 1 staff member attended all workshops, and no patients participated. Feedback collected from the staff and patients, focused primarily on format and timing, is outlined in Textbox 1.

Textbox 1. The first iteration of the participatory system mapping workshop—format, barriers, and suggestions.

Iteration 1

- Format
  - Four daily 1-hour workshops delivered consecutively over 1 week, at a consistent time
  - Each workshop had a printed poster summary and an assigned activity, made available to participants unable to attend the live workshop, to allow asynchronous engagement with the content
- Barriers
  - Staff's inconsistent attendance and nonattendance due to unavoidable reasons (eg, immediate patient care needs, overrunning shifts, or unplanned external visits)
  - Patients' nonattendance due to fluctuating health and care needs and physical and mental capacity
- Suggestions
  - More accessible and flexible options for workshop interaction were as follows:
    - An online space where audiovisual presentations of information could be easily accessed, paused, and resumed
    - Online spaces where activities could be completed online at the participant's convenience
    - Options for individual or small-team sessions at flexible times

Workshop Iteration 2: Asynchronous, Extended, and Multimodal Hybrid, With an Emphasis on Flexible Engagement and Interaction

Iterative Refinement of the Workshop Format

Building on the feedback, the workshop format was iterated to include 4 core characteristics around content, modes of activity, advertising, and access:

- Online content: A website was designed containing all the written content of the workshops, accompanied by podcast-style audio narration for asynchronous engagement.
- Multimodal activities: An online version of the workshop activities was developed. A physical space for mapping was created, which would be mirrored for online engagement using kumu.io virtual platform.
- Diverse advertising: Posters were created and visibly showcased in a dedicated space in a high-traffic area of the hospice. The posters contained all the content of the workshops, prompts, and a QR code that linked to the themes corresponding to the website page. Recruitment emails and face-to-face interactions were also used to promote participation.
- Extended flexible access: The workshop content was made available for 4 weeks, allowing participants greater flexibility, with the workshop facilitator available for drop-ins or scheduled one-to-one and group sessions.

Participant Recruitment and Data Collection

Textbox 2 outlines participant inclusion and exclusion criteria. Ethical approval was granted, as well as staff and patient participants were recruited through a combination of methods which evolved from iteration 1 to iteration 2. In workshop iteration 1, participants were recruited through advertising posters exhibited in the hospice, emails, and face-to-face interactions. The same-time daily format was expected to build momentum among those who attended. However, the passive advertising approach to engagement, that is, posters and emails proved ineffective, although it raised wider awareness of the workshops among hospice staff and patients.

In workshop iteration 2, a more direct yet flexible recruitment strategy was adopted, considering potential participants already had some level of awareness about the content and remit of the workshops through iteration 1 recruitment activities. For patient recruitment, staff were briefed to identify receptive groups and introduce the project after their regular activities, allowing interested patient participants to engage without disrupting their planned medical and care routines. For staff recruitment, the researcher coordinated directly or through line managers to schedule group or individual sessions, offering rescheduling options when needed.

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Textbox 2. Participant inclusion and exclusion criteria.

Inclusion

- A person who has had experiences with the hospice, including, but not limited to, patients, family members of current or past patients, staff, and volunteers
- For patient participants, a gatekeeper or ward sister team must confirm that the individual is willing and able to consent and participate in the workshops
- Participants must be able to provide informed consent independently
- Participants must be 18 years of age or older
- Participants must be able to communicate effectively in English to engage in workshop discussions
- Participants must be willing and able to commit to the time required for workshop participation

Exclusion

- A person who has limited or no interaction with the hospice, including, but not limited to, mail delivery person, third-party contractor
- For patient participants, if a gatekeeper declares that a person is unable to consent to being a part of the study or is too vulnerable to participate
- Persons unable to provide informed consent independently, as determined by a designated gatekeeper or ward sister
- Individuals under 18 years of age
- Individuals with cognitive impairments that would prevent them from meaningfully engaging in the workshop activities
- Individuals who cannot communicate effectively in English to engage in workshop discussions

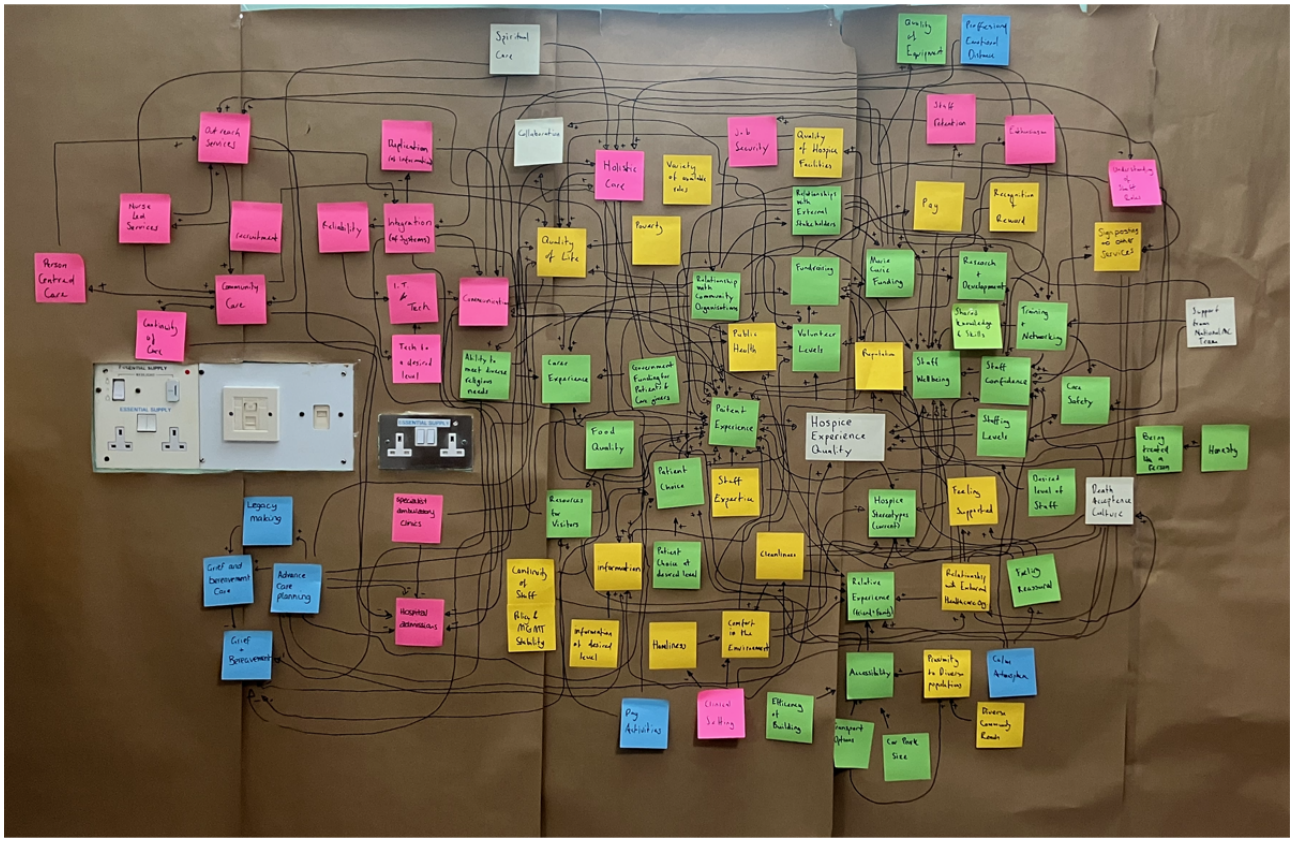
Results

Participant Characteristics and Overview of the Hospice System Map

Overall, 27 participants representing 12 diverse and distinct hospice stakeholder groups attended the workshops. The participating stakeholder groups included patients, doctors, health care assistants and nurses, community nurses, volunteers, management, chaplaincy, well-being team, therapy team, research team, maintenance team, and patient and family support team. This was considered a highly representative sample of hospice care stakeholders. Figures 1 and 2 represent the physical and digital versions of the participatory hospice system map, respectively, codeveloped by hospice stakeholders as workshop participants. The system map contains 84 variables with 175 connections and a network density of 0.03, meaning that the network contains 3% of the possible edges (connections) expected in a completely interconnected network, indicating a relatively sparse network structure compared with a fully connected system.

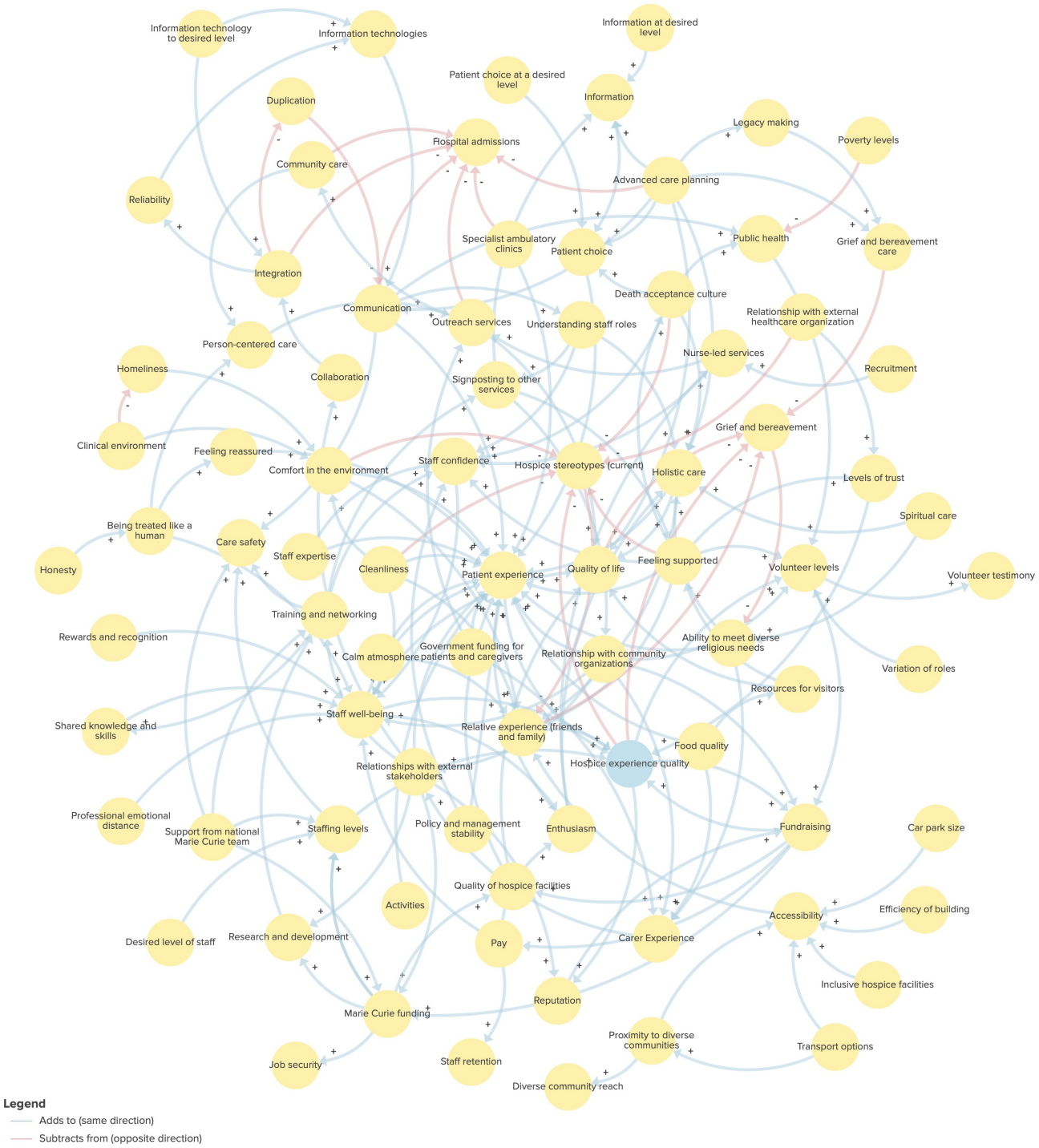
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Figure 1. The physical causal loop diagrams (CLD) codeveloped by hospice stakeholders as system mapping workshop participants.



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Figure 2. The online version of the participatory causal loop diagrams (CLD).



The participatory and iterative mapping process meant that the hospice system map was validated iteratively and incrementally through each round of stakeholder participation. Participants were asked to both add to the map and check whether the existing variables and their connections on the map were correct, complete, and well explained according to their stakeholder view of the hospice system. In the later stages of map codevelopment, a saturation point was reached where participants describing the effect of a variable could find that connection already represented on the map.

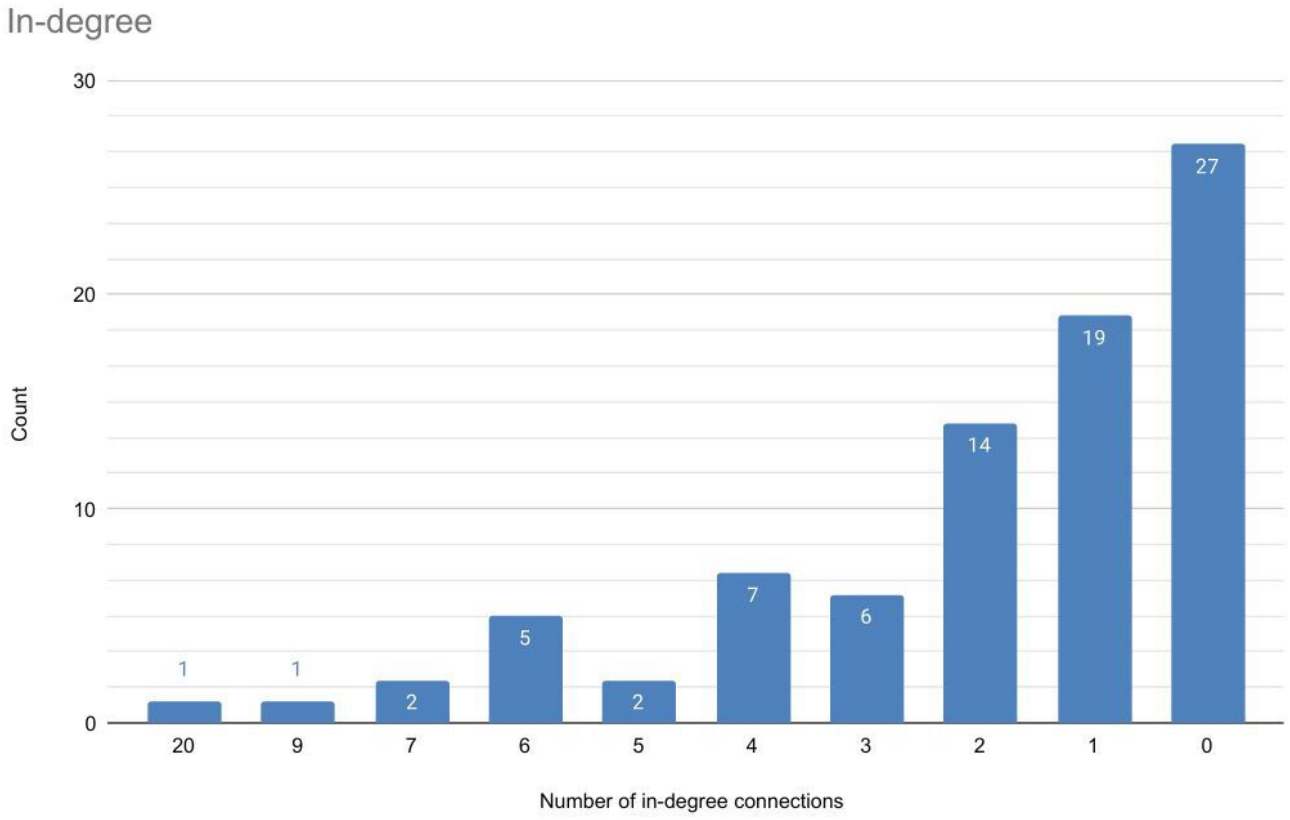
CLDs offer the potential for mixed-method analysis, contributing to a composite understanding of complex systems both quantitatively and qualitatively. The findings presented here are preliminary and represent the outcomes of this process rather than fully articulated results. Further review for missed connections and redundancies, alongside triangulation with other methods or literature, is required for a more rigorous causal understanding of the system. Quantitative and qualitative findings at this stage are presented using network analysis and qualitative interpretation.

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Network Analysis Findings: Key Variables and Causal Interrelationships in the Hospice System According to Participatory Stakeholder Mapping

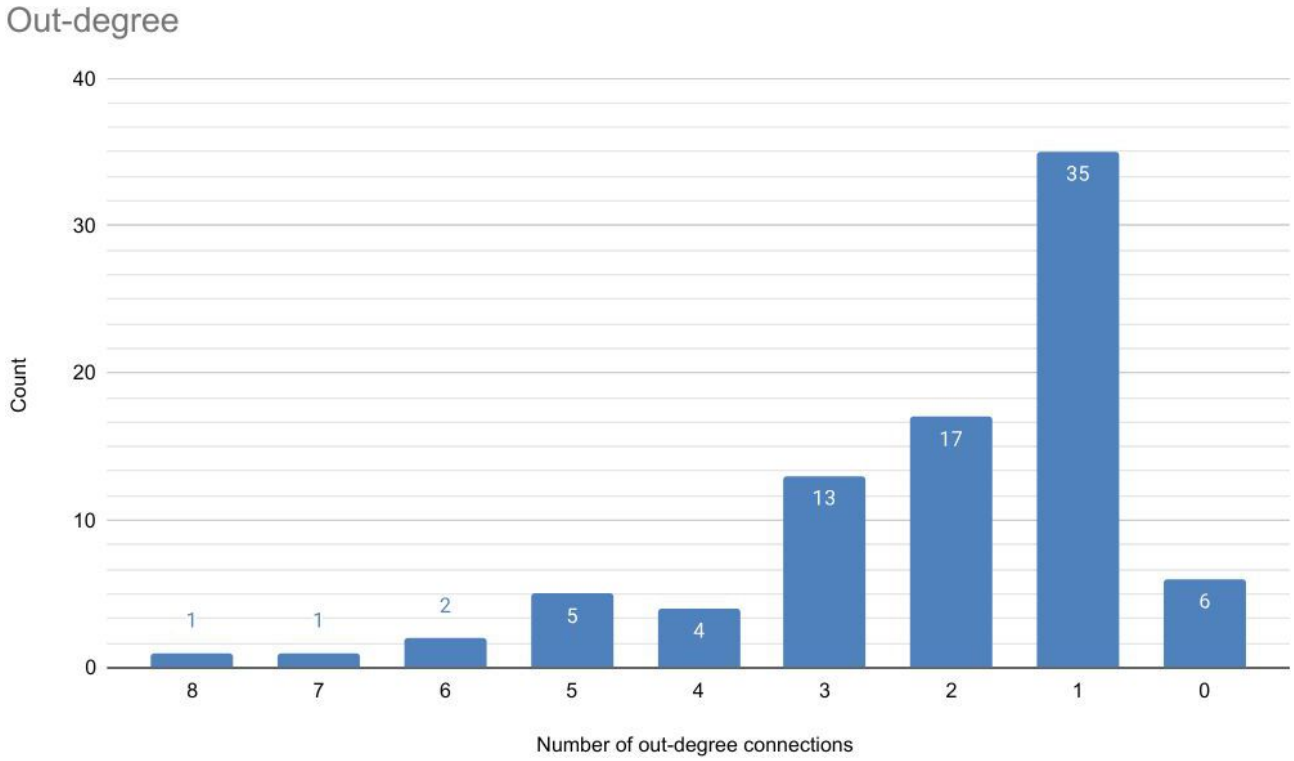
Network analysis enables the quantification of the structure of a network and provides insights into the influence and importance of variables on and within the structure, as well as the flow of information within the network [47]. Four commonly used metrics in network analysis, that is, in-degree, out-degree, betweenness centrality, and closeness centrality, were captured. In-degree measures the number of incoming connections for a variable. Variables with high in-degrees are impacted by multiple other variables. An in-degree of 0 means a variable is not impacted by anything in the system. Out-degree measures the number of outgoing connections for a variable. High out-degree variables can influence more in the system. Variables with a 0 out-degree will not directly impact the system. The codeveloped hospice system map demonstrated in-degree variables ranging from 20 to 0 (Figure 3) and out-degree variables ranging from 8 to 0 (Figure 4).

Figure 3. Number of in-degree connections.



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Figure 4. Number of out-degree connections.



Betweenness centrality measures a variable's frequency on the shortest path between 2 other variables. Variables with high betweenness have more control over the flow of information and act as key bridges within the network, referred to as "Mediators" [47]. Closeness centrality measures the distance each variable is from all other variables. In general, variables with high closeness can spread information to the rest of the network most easily and usually have high visibility into what is happening across the network [48]. However, centrality measurements are to be viewed critically. As pointed out by Crielaard et al [49], centrality has been found to vary in results with an adjustment of the positioning of variables in mental models especially as it is a directionless measurement in a directioned map. Table 2 presents the top 3 variables with the highest out-degree, in-degree, betweenness centrality, and closeness centrality out of 84 variables identified. The complete table providing full details is available in Multimedia Appendix 4.

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Table . Network analysis results according to out-degree, in-degree, betweenness centrality, and closeness centrality.

Variable	Out-degree	In-degree	Betweenness	Closeness
Top 3 out-degree				
Advanced care planning	8	0	0.00	0.22
Feeling supported	7	2	0.04	0.21
Relationships with external stakeholders	6	2	0.13	0.23
Relationship with community organizations	6	1	0.02	0.23
Top 3 in-degree				
Patient experience	1	20	0.11	0.14
Staff well-being	4	9	0.08	0.18
Relative experience (friends+family)	2	7	0.08	0.15
Staff confidence	1	7	0.03	0.13
Top 3 betweenness				
Fundraising	4	4	0.19	0.20
Ability to meet diverse religious needs	3	2	0.14	0.17
Grief and bereavement	1	4	0.14	0.13
Relationships with external stakeholders	6	2	0.13	0.23
Top 3 closeness				
Relationships with external stakeholders	6	2	0.13	0.23
Relationship with community organizations	6	1	0.02	0.23
Advanced care planning	8	0	0.00	0.22
Signposting to other services	3	2	0.09	0.21
Feeling supported	7	2	0.04	0.21

According to the network analysis of CLDs, a key variable is considered one that has a high degree of connectivity, influences multiple other variables, or bridges different parts of the system and, therefore, is identified using the "in-degree," "out-degree," "closeness," and "betweenness" measures. Key causal interrelationships are considered ones that form feedback loops, connect otherwise disparate parts of the system (*betweenness*), or have a significant influence on the system's behavior over time.

A leverage point is defined as a variable or relationship in the system where a small change could lead to large shifts in the system's behavior. According to network analysis, these include the *highest out-degree*, *highest closeness*, *and highest betweenness* [47]. *Highest out-degree* affects a lot in a system; therefore, changing it should see an effect on many elements quickly. The highest betweenness signifies a bottleneck between clusters, and changing it should see greater connections between variables in the system. The highest closeness affects and reflects the health of the whole system, and changes in it should see a reciprocal effect across the system. Table 3 outlines key variables, causal interrelationships (RQ1), and leverage points (RQ2) in the hospice care system as identified through participatory system mapping with stakeholders.

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Table . Identified key variables, causal interrelationships, and leverage points in the hospice system.

Variables	Variables, causal interrelationships, and leverage points
Key variables and causal interrelationships	
Highest in-degree	Patient experience (20)
Highest out-degree	ACP[a] (8)
Highest betweenness	Fundraising (0.19)
Highest closeness	Relationships with community organizations (0.23); relationships with external stakeholders (0.23)
Highest number of subtractive connections	Hospice stereotypes (6); hospital admissions (6)
Key leverage points	
Highest out-degree	ACP
Highest betweenness	Fundraising
Highest closeness	Relationships with community organizations and relationships with external stakeholders
A mindset variable that affects many stakeholder variables	Feeling supported
A mindset to how we view the role of stakeholders in a system	Stakeholder terminology

[a]ACP: advanced care planning.

Qualitative Findings: Systemic Support and Role Perception

Limitations of Centrality Measures

While network analysis can provide valuable quantitative insights, it has its limitations. Using betweenness and closeness centrality measures to identify leverage points can lead to incorrect inferences [49]. Furthermore, higher leverage points, such as mental models as described by Meadows [50], would not be shown as a single or group of variables within a CLD system map but are identified through an understanding of the whole. Understanding these limitations and informed by the results from network analysis, the discussion section qualitatively and critically examines the system through a lens of stakeholder values, discovering key variables, and their influence and importance within the system.

Feeling Supported

"Feeling supported" emerged as a highly connected variable in the hospice care system, with positive effects on patient and relative experiences, staff confidence, volunteer levels, levels of trust, and death acceptance culture, while also reducing hospice stereotypes. The map does not show how each stakeholder group experienced support, especially where patients' and staff's understandings may differ, so this remains an area for future focused interrogation and causal analysis.

The broader significance of this variable is that it points to a more holistic role for hospices, not only in relation to patients but across all stakeholders. If the aim is to help people feel supported beyond treatment, cure, or care for them, the emphasis shifts toward a more collaborative and autonomous interaction rather than a one-directional staff-to-patient action. This is not to suggest we change the terminology of care but to explore alternative mindsets for how PEoLC service systems enact care and for whom. This also aligns with the discussion by Sawyer et al [51] of palliative care as a "shared social process," in which death, dying, and loss are shaped through relationships between services, communities, and individuals. The ethics of care proposed by Tronto [52] offers a further relational lens, as it foregrounds care as a set of relationships shaped by power, dependency, and responsiveness, and may help frame this emergent leverage point for further analysis.

Stakeholder Characteristics

Analysis of how participants described stakeholder variables revealed distinct mindsets that highlight potential system leverage points and areas for further research. Patients, families, and carers were associated with "experiences," staff with "well-being," volunteers with "levels," and organizations and community stakeholders with "relationships." These differences reflect implicit assumptions about the roles and values assigned to each stakeholder group within the hospice care system.

Examining the values and mindsets attached to these variables may uncover underrecognized contributions and support a re-evaluation of stakeholder roles. For example, reframing volunteers through the lens of "experience" rather than "levels," as suggested by the NHS Volunteering Taskforce [53], could alter how their role is perceived and designed within the system. This shift could move volunteers from being viewed mainly as a source of labor toward being seen as people with whom relationships are actively built.

This does not require changing the terminology of care itself, but it does suggest the value of extending person-centered principles to other stakeholders. In that sense, the variable names themselves point to a broader reimagining of power dynamics and responsibilities across the hospice system.

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Discussion

Key Variables and Causal Interrelationships in the Hospice System (RQ1)

Key variables and their causal relationships, according to the CLD network analysis metrics, are discussed below.

Patient Experience (Highest In-Degree)

Patient experience had the highest in-degree connections (20), showing that the system focuses on improving it, with its sole out-degree connection to central hospice experience quality. Stakeholders mapped hospice experience quality as influencing hospice stereotypes, grief or bereavement, reputation, fundraising, and volunteer levels. Negative public perceptions (hospices as a place of death and sadness) persist, but positive patient experiences challenge these, motivating volunteering and fundraising among direct beneficiaries, though broader outreach is needed to reshape stereotypes beyond service users.

Advanced Care Planning (Highest Out-Degree)

Advanced care planning (ACP) showed the second-highest out-degree connections (8), reaching 37% of system variables and ranking third in closeness centrality. It linked positively to quality of life or holistic care and negatively to hospital admissions, aligning with the findings of Brinkman-Stoppelenburg et al [54] that ACP improves end-of-life care, increases hospice use, and reduces hospitalizations.

Critically, ACP had no in-degree connections, revealing stakeholder uncertainty about its implementation drivers, echoing the documented cultural and operational barriers reported by Lund et al [55] and Jimenez et al [56] despite recognized benefits. This gap underscores the need for reexamining ACP aims, delivery, and suitability within hospice settings.

Fundraising and Relationships With Community Organizations and External Stakeholders (Highest Centrality Outcomes—Betweenness and Closeness)

Fundraising ranked highest for betweenness centrality (0.19, excluding the central variable), indicating a system bottleneck and a single point of failure. This is corroborated by UK Parliament evidence calling current PEoLC funding "not fit for purpose," requiring commissioning reform [57].

Relationships with community organizations (1st closeness, 0.23) and external stakeholders (2nd) suggest a broad reach, though site-specific. Findings align with the literature on hospice-nursing home collaborations, hospice-university networks, clinician-researcher partnerships, and compassionate communities building resilient PEoLC networks [7,58-60].

Hospice Stereotypes and Hospital Admissions (Highest Variables With Subtractive Interrelationships)

Stakeholders mapped hospice stereotypes and hospital admissions for reduction (combined 12 negative in-degrees, 1 out-degree), showing clear drivers but limited understanding of downstream effects—risking the perpetuation of existing behaviors.

Review by Robinson et al [39] confirms hospitals' poor PEoLC fit: high symptom burden, poor communication impairing family decisions, noisy and busy environments despite occasional dignified care.

Leverage Points in the Hospice System (RQ2)

Structural and Conceptual Leverage Points

Leverage points are system locations where small shifts yield significant changes. Meadows [50] hierarchy ranges from shallow (parameters) to deep (paradigms) interventions.

Network analysis identified structural leverage through the *highest out-degree*, *closeness*, and *betweenness centralities*. Complementary qualitative analysis revealed conceptual leverage points, combining context-agnostic metrics with stakeholder-specific insights for a comprehensive understanding of the hospice system and intervention opportunities.

Fundraising

Network analysis identified fundraising as leverage across Meadows hierarchy. Shallow interventions could expand activities and sources to increase fundraising, while deep paradigm shifts might diversify income beyond the current UK hybrid NHS and charity model. Recent parliamentary calls and PEoLC manifestos recognize funding pressures [3,61], aligning with the Health and Care Act 2022 [62] commissioning mandate and palliative care's human rights framing, making full government funding a compelling ethical and systemic solution.

Relationships With Community Organizations and External Stakeholders

The importance of relationships with community organizations and external stakeholders suggests that greater integration of care across NHS services and into the community could strengthen the wider PEoLC system. Public health and community models of palliative care aim to improve end-of-life experiences by combining palliative principles with public health strategies and community services. These approaches recognize that care for people with life-limiting illnesses extends beyond traditional health care, and existing evidence suggests benefits including more deaths at home, fewer emergency department presentations, higher patient and carer satisfaction, shorter hospital stays, and fewer admissions and readmissions [51,63,64].

Advanced Care Planning

There are multiple levels at which ACP could be leveraged. At a practical level, this could include better identification of patients, earlier documentation, and expanding who initiates and records ACP beyond medical professionals. At a deeper level, it could involve a mindset shift, reframing ACP as "Advanced Care Preparation" so that it is understood as preparation for end-of-life care rather than as a fixed planning exercise [65]. Beyond this, Morrison et al [66] argue that ACP may not be the best model at all if it continues to fail its intended aims, and that alternative ways of communicating current, rather than future, end-of-life care plans may be more valuable.

Beyond the numerical analysis and the more formulaic, context-agnostic use of network analysis, other factors, such as

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the number of stakeholder links and the characteristics of each variable, were also considered. This helped identify 2 further leverage points in the hospice system map.

Methods for Mapping Hospice Systems (RQ3)

Participatory system mapping, as part of a design workshop series with hospice stakeholders, proved to be an effective method overall for capturing complex system dynamics in a hospice setting. The research resulted in the iterative development of a hybrid multimodal extended asynchronous method, which improved interaction with participants; accommodated a range of participant preferences in engagement style and digital literacy levels; and allowed for spatiotemporal barriers to be elevated to a degree. The method's strengths lie in its ability to engage diverse stakeholders, capture in-depth perspectives, and adapt to the unique constraints of the hospice environment. However, challenges related to time constraints, engagement with complex visual data, and the need for researcher guidance in novel tasks suggest areas for refinement or further examination. Future applications should consider a balanced approach between face-to-face and online interactions, with careful attention to spatial and temporal factors unique to each hospice setting. Multimedia Appendix 5 outlines the key strengths and challenges of hybrid asynchronous extended design workshops as a method for participatory system mapping with stakeholders in a hospice setting.

Suitability of Data Collection Method

Participatory system mapping offers advantages and disadvantages when compared with alternative systemic mapping methods such as interviews [67], GMB [68], and rich picture mapping [69]. While interviews may provide greater depth into individual perspectives, participatory system mapping supports a collective understanding using participants' own language, with ideas refined through an ongoing cocreation process rather than filtered solely through researcher interpretation, making it useful as a foundation for continued participatory development, such as co-design. Unlike traditional GMB, the asynchronous approach may increase overall engagement, although it may sacrifice some of the insights generated through real-time group discussion. Rich picture mapping differs from CLD by offering a more open and expressive format, but it may provide less direct structure for systemic analysis.

While the network analysis does not directly demonstrate how to improve patient outcomes, it helps identify where communication, coordination, support, and resource pathways may be strengthened within the hospice system, offering a starting point for more holistic and participatory service investigation and development in PEoLC. Overall, participatory system mapping using CLD provides a balance between accessibility, collective insight, and structured representation of system dynamics, making it well suited to system mapping in sensitive health care settings. Multimedia Appendix 6 summarizes the strengths and weaknesses of the method used in this study compared with alternative approaches.

Limitations and Future Work

CLD-based system mapping has inherent capabilities and limitations in terms of the information it can provide on the what, how, and why of a system's variables and interrelations. In terms of generalizability and thoroughness, this participatory system map provides a snapshot of a single hospice system in an urban context in Northwest England and is solely defined based on the existing understanding and implicit assumptions of its participating stakeholders. Future work could attempt research triangulation by mapping the same system through distinct complementary methods, for example, observations and interviews, thereby enhancing validity and advancing methodological granularity and comparison.

In terms of representativeness and completeness, all identified hospice stakeholder groups were successfully engaged in codevelopment of the system map, apart from the patient family members who could not engage in workshops due to multiple factors. The qualitative interpretation of a CLD is inherently subjective and could be influenced by researcher bias; hence, the combination of quantitative and qualitative CLD analysis in this study.

A CLD system map acts as an analytical canvas, enabling open-ended, multivariable, and granular analysis and interpretation of the whole or parts of a system, depending on the questions being asked about that system. This paper explored key variables, interrelationships, and leverage points of a hospice system as a first step, laying the foundations for the use of CLD in understanding complex hospice system dynamics, and further question-specific discussion of findings could be included.

A greater understanding of the importance of variables and connections could be discovered using Barbrook-Johnson and Penn's [33] suggestion of weighted connections. However, this would introduce greater complexity and time demands for the workshop activities and facilitation, and it should be approached as a trade-off. The researcher-participant dynamic, through the facilitation of the workshops, may have positively influenced the willingness of participants to share sensitive information, with a nonmedical researcher who lacks the authority to implement changes to the organization directly.

Conclusions

This study developed an innovative hybrid, asynchronous multimodal design workshop to engage 27 diverse hospice stakeholders in participatory system mapping, creating a composite representation of a hospice care system consisting of 84 variables with 175 connections. Key methodological contributions include a reflexive and responsive participatory approach and method that was mostly successful in overcoming challenges common to researching in PEoLC environments, thereby developing a potentially replicable model for ethically engaging diverse stakeholders.

Empirical contributions, derived through mixed-method analysis, reveal structural leverage points discovered in funding, a system bottleneck, and the importance of community organizations and external stakeholder relationships to the system. Further conceptual leverage points identified include reimagining stakeholder roles and expanding the principle of "feeling

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supported" holistically to the stakeholders of the system. These findings reflect current initiatives found in literature, health care practice, and policy [3,7,53,57,62]. These findings reflect sector-wide challenges and developments reflected from a single site; however, with an absence of family member participants, we lack a critical perspective for a more holistic understanding.

In conclusion, this research provides an informed framework for future participatory studies in PEoLC environments and potentially in broader health care contexts. It demonstrates how accessible participatory methods can produce a holistic understanding of complex systems, generating actionable and grounded insights. Future research could explore the replicability and application of this approach across diverse health care settings aiming to create stakeholder-informed system changes.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
An overview of expansion of palliative and end-of-life care.
[XLSX File, 7 KB - jopm_v18i1e69746_app1.xlsx]

Multimedia Appendix 2
Study protocol describing the study design, participant recruitment, consent procedures, and eligibility criteria.
[DOCX File, 14 KB - jopm_v18i1e69746_app2.docx]

Multimedia Appendix 3
Ethics acceptance letter.
[PDF File, 176 KB - jopm_v18i1e69746_app3.pdf]

Multimedia Appendix 4
Full network analysis results for, out-degree, in-degree, betweenness centrality, and closeness centrality.
[XLSX File, 20 KB - jopm_v18i1e69746_app4.xlsx]

Multimedia Appendix 5
Key strengths and challenges of the participatory system mapping workshop method.
[XLSX File, 6 KB - jopm_v18i1e69746_app5.xlsx]

Multimedia Appendix 6
Strengths and weaknesses of the participatory system mapping workshop method compared to alternative mapping methods.
[XLSX File, 6 KB - jopm_v18i1e69746_app6.xlsx]

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Abbreviations

ACP: advanced care planning
CLD: causal loop diagram
GMB: group model building
NHS: National Health Service
PEoLC: palliative and end-of-life care

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Original Paper

A Parent-Facing Decision Aid About Childhood Vaccination: Co-development Study Adapting a Shared Decision-Making Approach to Support Evidence-Guided Decision-Making

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Abstract

Background: Childhood vaccination rates are declining, and more parents are becoming hesitant about vaccinating their children. Higher levels of vaccine hesitancy occur among parents with lower levels of educational attainment, who are also likely to have lower levels of health literacy.

Objective: We aimed to develop a web-based decision aid, considered a shared decision-making (SDM) approach, to inform and support Dutch parents in their decision-making about routine childhood vaccination, prioritizing the needs of hesitant parents and those with lower health literacy. We adapted the traditional SDM approach by balancing the ethical tension between the collective responsibility for public health and individual autonomy in vaccination decisions and focused the decision aid on evidence-guided (rather than preference-sensitive) decision-making.

Methods: The development process involved content development and web application development. We adopted a user-centered approach by actively engaging stakeholders, including parents, health professionals, and other experts. Participating stakeholders were purposefully selected and engaged through different routes to include a variety of perspectives. The general concept of vaccination as an evidence-based intervention to promote health at the individual and societal levels remained central throughout the development process.

Results: We conducted this project in the Netherlands from early 2023 through the end of 2024. We identified parental needs through interviews with 18 parents and a literature assessment. Parental needs, evidence-based information about vaccination, and how to communicate about vaccination informed the initial content of the decision aid. After feedback from the advisory group and subject matter experts, we refined the draft. At this stage, the textual content was inserted into a prototype web application. We subjected this prototype to 3 iterative cycles of testing, review, and adaptation. We analyzed and discussed the issues identified during testing and recommended adaptations to improve the design, structure, and content of the decision aid. These adaptations were subsequently discussed with the advisory group before being implemented. In response to the issues raised, we shortened the text blocks, replaced written information with visual elements, and restructured the layout to improve navigation. The final prototype consisted of the modules “Information” and “Decision Support.”

Conclusions: We co-developed a parent-facing decision aid (PDA) for childhood vaccination tailored to the needs of hesitant parents and those with lower health literacy. Through this intervention, we adapted an SDM approach to evidence-guided decision-making, creating space for individual concerns and deliberations without compromising evidence-based recommendations.

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Future research should focus on the timing of the intervention and the optimal window for offering the PDA in relation to the parents' decision-making process.

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KEYWORDS

routine childhood vaccination; decision-making; vaccine hesitancy; user-centered design; decision aid

Introduction

In March 2025, the World Health Organization (WHO) reported the highest number of measles cases in more than 25 years [1]. This increase is attributed to falling vaccination coverage rates, which are inadequate to reach group immunity. Lower public confidence in the safety and necessity of vaccination has led to vaccine hesitancy and decreasing uptake [2]. This poses a significant public health concern because individual decisions to decline vaccination have a broader impact by reducing group immunity [3]. In particular, vulnerable groups, such as very young or ill children, benefit from group immunity for their protection. Promoting these societal aspects of vaccination when discussing individual vaccination decisions may contribute to closing these immunity gaps [4,5]. Besides societal aspects, it is also important to consider cognitive and emotional aspects when developing strategies to address vaccine hesitancy [6].

Decision aids (DAs) are tools developed to support health decisions about prevention, screening, and treatment. When using these tools, people are better informed and more aware of their personal risks and preferences [7]. Vaccination-specific DAs support an active role in decision-making, increase vaccine uptake, and are recommended as interventions to address vaccine hesitancy [8,9]. So far, DAs for vaccination have primarily focused on single vaccinations [10]. However, childhood vaccinations are typically offered as a series of combined vaccines using a timetabled schedule rather than being offered on a one-by-one basis. Yet, few DAs address childhood vaccination as a general concept. Therefore, there is a mismatch between these DAs and the reality of how childhood vaccination is organized and delivered. We considered this an opportunity to develop a web-based parent-facing DA (PDA) that covers all vaccinations offered through the Dutch National Immunization Program (NIP) to children aged ≤4 years.

DAs are originally designed to support shared decision-making (SDM), a collaborative process between patients and health care professionals to reach evidence-based and value-aligned decisions [11]. Typically, DAs present different options in a balanced manner without steering users toward a predetermined outcome, which is suitable for preference-sensitive decisions that primarily affect the individual [12]. However, this approach does not align with the context of routine childhood vaccination, where there is a strong public health imperative. Vaccination is a public health intervention for which the evidence of benefits outweighs the evidence of risks for both individuals and populations. We therefore argue that vaccination decisions, as they are not neutral from a public health perspective, should be evidence-guided rather than focused on individual preferences. This fundamental difference should be reflected in DAs about vaccination by presenting evidence-based individual- and population-level information while allowing space to explore individual concerns and deliberations without compromising evidence-guided decision-making [13].

Since the COVID-19 pandemic, parents have become increasingly concerned about vaccinating their children [14]. In the Dutch context, 27% of parents report hesitancy about their vaccination decisions [15]. Given these rising levels of vaccine hesitancy, parents might benefit from a DA about childhood vaccination. As vaccine hesitancy levels are higher among parents with lower levels of educational attainment and lower health literacy, we aimed to tailor the DA to this group [16,17]. To achieve this, we applied a user-centered approach by involving relevant stakeholders throughout the development of the PDA.

We developed a PDA to support informed and deliberate decision-making about childhood vaccination for Dutch parents. Because decision-making about vaccination is likely to start before a baby is born, we also considered prospective parents to be part of the target group [18]. In this article, we describe the evidence base, guiding principles, stakeholder involvement, and the various steps in the development of this PDA, following the Guidance for the Reporting of Intervention Development (GUIDED) framework [19].

Methods

Context of the Intervention

The Dutch NIP is coordinated by the National Institute of Public Health in the Netherlands and executed by nurses and clinicians working at community-based preventive child and youth health care (CYH) centers. Vaccination services are integrated with routine health visits from childbirth onward at CYH centers to monitor growth and development from birth. Up to 95% of parents attend routine CYH center visits. Other health care professionals, such as midwives or general practitioners, are not involved in providing education or counseling about childhood vaccination.

Purpose and Target Population

We aimed to develop the PDA to support parents in making informed and deliberate decisions about childhood vaccination. The target group consisted of prospective parents and parents of children aged ≤4 years. We targeted this broad and heterogeneous group with a particular focus on those who were hesitant or had lower levels of educational attainment.

Guiding Principles

The first guiding principle in the development of this intervention was to address vaccination as a public health approach. We aimed to convey accurate scientific knowledge

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about the role of vaccination in preventing diseases for individuals and across populations. A range of stakeholders guided us in determining how best to present these concepts to vaccine-hesitant parents.

A second principle was to address childhood vaccination as a general concept rather than focusing on single vaccines. We described childhood vaccination as a timed schedule of single-disease and combined vaccines, as offered in the Netherlands.

The third principle was to consider parents' wider needs beyond information. Other factors such as personal values and others' experiences and advice play a role in vaccination decisions [20,21].

As a final principle, we prioritized the needs of hesitant parents or those with lower health literacy skills when faced with conflicting advice from stakeholders.

Use of Components From an Existing Intervention

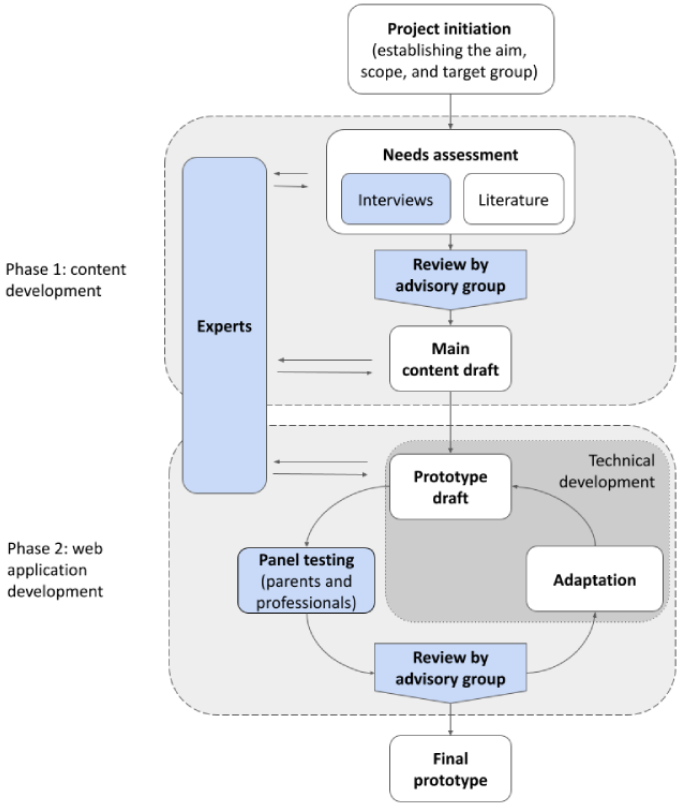
For our proposed PDA, we adapted a software template previously developed for a DA on human papillomavirus vaccination [22]. The template has also been used to develop other DAs for vaccination [23,24] and allowed us to make adjustments, redesign the layout, and remove or add features.

Development Approach and Stakeholder Contributions

Overview

The process was guided by systematic development protocols for DAs [25,26] and involved two main phases: (1) drafting the main content and (2) iterative web application development. Our user-centered approach involved engaging stakeholders across different phases. The flowchart in Figure 1 provides an overview of the phases and the involvement of stakeholders.

Figure 1. Flowchart of the development process. Steps involving active stakeholder participation are highlighted in blue.



We formed an advisory group of stakeholders to provide guidance and input throughout the development process. On the basis of the recommendations of Elwyn et al [26], we aimed for a stakeholder group of 6 to 10 members with balanced representation across our stakeholder groups. These groups included the target group (parents), CYH professionals providing vaccination services, medical advisers from the NIP hosted by the National Institute of Public Health, and experts in communication and DA development. Additionally, subject matter experts were consulted on an ad hoc basis whenever specialized expertise was needed. The stakeholder group members and experts were purposefully selected through the research team's professional network.

Phase 1: Content Development

During the first phase, we based the content of the PDA on the results of a needs assessment. This consisted of a review of relevant literature and interviews to identify parents' questions, information needs, and decision-making needs. We searched for relevant literature in the PubMed database using the keywords "childhood vaccination," "information needs," "decision-making needs," and "parents" and searched for additional literature using the snowball method. After reviewing the search results, we prioritized key papers that contained relevant information and were applicable to our setting. We extracted the described information and decision-making needs.

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Additionally, we conducted brief informal interviews with parents visiting a CYH clinic to explore their information and decision-making needs. Parents were approached at 2 different clinics before their appointment and received verbal information about participation. When parents agreed, a brief informal interview was conducted in person at the respective clinic by a member of the research team (DB-V) and took 10 to 20 minutes. During the interviews, notes were taken, no recording was made, and no personal identifying details were collected. On the basis of the notes, parental needs were summarized, and interviews were continued until no new topics came up. The findings from the literature and interviews were triangulated with a CYH clinician who was highly experienced in counseling parents with vaccine hesitancy. During the triangulation process, the identified needs were grouped into main topics and prioritized. We chose this approach because we aimed to provide a concise and clear overview of the most important topics and to cover the main needs rather than answer every detailed need. Some needs were highly individual and competed with those of other individuals, and integrating these would compromise the accessibility and readability of the DA. The main topics were subsequently reviewed by the advisory group and then used to inform the first draft of the PDA's content. We also involved a health literacy expert and a CYH clinician as subject matter experts to thoroughly review the first version of the PDA draft; they were both recruited through the research team's professional network.

Phase 2: Iterative Web Application Development

In the second phase, a company was contracted to undertake the technical realization of the draft content into a prototype web application. As we used a software template previously developed for a vaccination DA, we collaborated with the same design company and its user experience (UX) professional and could thereby benefit from their expertise in this field.

The prototype was evaluated by panels of both parents and professionals and adapted in iterative cycles. We used different routes to engage panelists as we sought to include a variety of perspectives. We invited professionals involved in routine childhood vaccination care through a newsletter call at 2 different regional CYH organizations and selected both physicians and nurses. Additionally, we invited parents through a call in a childcare service newsletter and through collaboration with an existing low socioeconomic parent panel [27].

First, we focused on general use and navigation through the app and invited a broad group of panelists to conduct a robust evaluation of the prototype. Panelists reviewed the prototype individually online via Microsoft Teams, with a member of the research team taking notes. These sessions took approximately 30 to 40 minutes. In this cycle, we verbally administered the System Usability Scale (SUS) to assess the level of usability [28]. We analyzed session notes to identify issues with the PDA's design, content, and structure and discussed them within the research team. Additional review sessions with new panelists were planned until no new issues were identified. On the basis of the panelists' experiences with the prototype, we formulated adaptations to improve the design, structure, and content of the PDA. These were subsequently discussed with the advisory group and implemented. From the second cycle of review sessions onward, we focused on fine-tuning the suitability of the prototype for users with lower health literacy skills. The prototype was evaluated in person at a more detailed level with members from the low socioeconomic parent panel who had low or medium levels of educational attainment. These sessions took approximately 60 minutes. Similar to the previous cycle, we analyzed session notes, recommended adaptations, and reviewed the adaptations with the advisory group before implementation. We planned a final round of test sessions to evaluate if the adaptations had the expected result.

Ethical Considerations

This project was carried out in accordance with institutional and national guidelines. The consulted stakeholders gave verbal consent to participate and, as compensation, they received a gift voucher. No personal identifying details were collected. We described the methods for the development of the DA as part of a larger project that also included a feasibility study. This study protocol was submitted to our ethics review board and deemed exempt from full review (2024-17606).

Results

Phase 1: Content Development

Needs Assessment

We assessed the available literature from 2012 to 2022 addressing the needs of parents when making decisions about childhood vaccination. Additionally, interviews with 18 parents conducted between May and June 2023, along with triangulation with a CYH clinician, confirmed and added to the findings of the literature assessment.

We grouped the identified needs into the 5 topics shown in Textbox 1: disease descriptions, vaccination schedule, practical information, factual, balanced, reliable information, and discussion and deliberation.

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Textbox 1. Parental needs identified during the needs assessment.

Disease descriptions

Parents expressed the need to receive information about the diseases that vaccinations aim to prevent, including the risk of contracting these diseases, the necessity of vaccination, and the effectiveness, side effects, and safety of the vaccine itself [29-31]. Most parents indicated that their baseline knowledge was limited. This was not necessarily experienced as problematic, and preferences for the level of detail varied greatly, ranging from highlighting key information to requesting an extensive representation of risks.

Vaccination schedule

Parents also indicated a need for information about the timing and rationale of the vaccination schedule. This included an explanation for combining multiple vaccines and the need for administering multiple doses of the same vaccine at different points in time [29].

Practical information

Parents requested information about the administration of vaccines, including the injection site and care for children after vaccination [29]. They also requested practical guidance on how to reduce discomfort after vaccination.

Factual, balanced, reliable information

Parents expressed the need to receive balanced, accurate, reliable information in a neutral tone, written in an understandable manner, preferably from independent sources, and presented in a nondirective manner [29,32]. Some parents also indicated that, to achieve the right balance, details about severe disease outcomes should be left out.

Discussion and deliberation

Parents indicated the need to deliberate on and discuss the decision with others, such as health care professionals, relatives, or friends [32-34]. Additionally, parents wanted to hear the views and decisions of other parents.

Review by the Advisory Group

The findings of the needs assessment were reviewed by the advisory group. This group was permanently composed of 7 members, including experts, parents, CYH professionals, and representatives of the National Institute of Public Health. This group endorsed the guiding principles and identified needs but did not support the request to omit details of illness that can be prevented by vaccination. Members also wanted to include upcoming changes to the NIP and recommended referring parents to health care professionals and/or their CYH centers if they had questions after using the PDA.

Main Content Draft of the PDA

We based the main content of the PDA on the identified parental needs, evidence-based information about vaccination, and how to communicate about vaccination. We designed 2 modules. One module provided information to support an informed choice, and the other module promoted reflection on values and the views of other parents to support a deliberate choice. The initial draft covered all 5 topics identified in the needs assessment (Textbox 1). In November 2023, a health literacy expert suggested readability improvements, a reduction in the volume of information, and visual elements to support the text. At the same time, the content was reviewed by a CYH clinician for accuracy, tone, and alignment with practice. Table 1 shows illustrative examples of adaptations following their advice.

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Table 1. Illustrative examples of adaptations to the PDA based on expert consultation.

Expertise and advice	Adaptations
Health literacy	
Use active voice consistently	• Changed "Children receive vaccinations to protect them from illness" (passive voice) to "Vaccinations protect children from illness" (active voice)
Avoid complex sentence constructions and abstract words	• Changed "Vaccination contributes to public health" to "vaccination helps keep people healthy" • Changed "A vaccine protects against a combination of multiple diseases at the same time" to "a vaccine protects against multiple diseases" • Changed "airways" to "lungs"
Explain the purpose of each text section	• Added the following to the introduction of the decision support module: "Have you read enough information about vaccinations for your child? Continue here to organize your thoughts. At the end, you will get an overview of what is important to you."
CYH[a]	
Align terminology to avoid confusion	• Referred to the "National Immunization Program"
Consider including a reference to other tools used in practice	• Included a reference to a tool parents can use to chat with a CYH nurse
Include practical information about vaccination appointments	• Added information about vaccination invitations and routine vaccination services
User experience	
Limit the number of levels in the tool that users can navigate through	• Restructured the design to three main layers: (1) welcome page, (2) modules page, and (3) specific information page or feature
Use a professional yet warm and calm style	• Placed more detailed information in drop-down panels • Selected a color palette and main images

[a]CYH: child and youth health care.

A significant challenge was how best to present probabilities. A general recommendation for DAs is to provide numerical information in a consistent format [35]. This was difficult for the childhood vaccination PDA, as the range of probabilities varies for each of the 12 diseases and depends on many other factors, such as overall population vaccination coverage and the child's age. Presenting probabilities using scenarios of best, worst, and most likely outcomes was a possible solution [36]. In the first draft of the PDA, we included both numerical and scenario-based information so that we could seek guidance from our stakeholders.

Phase 2: Iterative Web Application Development

Design and Technical Development of the First DA Prototype Draft

The hired company created a prototype, and a UX professional supported us in designing a layout that was appealing, professional, user-friendly, and easy to navigate. Illustrative examples of subsequent adjustments are shown in Table 1. Additionally, we added a read-aloud feature to support better text comprehension.

Iterative Cycles of Panel Testing, Review by the Advisory Group, and Adaptations

We subjected the prototype draft to iterative cycles of testing, review, and adaptation (Figure 1). During the first cycle, we focused on evaluating usability and content through online testing sessions with panelists, including parents and professionals. We observed how they used the prototype through screen sharing and encouraged them to think aloud. This gave us insights into how users navigated the PDA. Their overall impression was positive. They found the scenario-based format of risk representation (best-case and worst-case scenarios) clear and concise, although some preferred numerical risks. Panelists also found the overview of considerations provided in the decision support module helpful.

The level of usability according to the SUS ranged from 68 to 93 (out of 100), with an average of 78, indicating good usability [28]. In subsequent test cycles, we focused on parents with lower health literacy skills. We evaluated their UX using in-person test sessions and observed how they used the prototype. These parents found some words confusing, and we made changes to address this issue.

After each cycle, we discussed adaptations with the advisory group. Table 2 shows the characteristics of the panels, illustrative examples of comments and feedback provided by the panels, and subsequent adaptations made in each cycle. A key editorial decision involved reducing the amount of information, categorizing the information into essential and additional topics (refer to Final PDA Prototype section), and simplifying the navigation within the decision support module.

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Table 2. Illustrative examples of adaptations to the PDA based on panel consultation.

Cycles, panel characteristics, and comments	Adaptations
Cycle 1[a]	
General	
"It is not clear which organization has created and who made this decision aid."	We improved logo visibility and added information about the team that created the DA in the "About us" section.
"Overall, this is a lot of information."	We critically reviewed the topics covered by the DA and prioritized information needed for decision-making. For example, practical information on the administration of vaccines was removed.
"The large amount of text makes it difficult and also a bit boring. Pictures, videos, and a personal story are missing."	We made adaptations to reduce the length of text blocks and replaced text with visual elements, including infographics and videos. For example, educational videos and a video with a clinician sharing experiences with parents' vaccination decision-making were added.
"The social aspect of vaccination is a bit forced here, this is really too much for me. I prefer the DA to focus on my personal situation."	As it was an important principle to convey the societal aspects of vaccination, we did not make any adaptations.
Information module	
"The info on risks and safety is limited and does not address concerns that parents may have."	Information on this topic was spread over several tiles. We merged and consolidated this information under 1 tile.
"The info about diseases is quite a list and not inviting to read."	We restructured this information, grouped diseases by vaccine, and placed text blocks in drop-down sections.
Decision support module	
"The statements are difficult to read."	The wording and visual representation of the statements were improved.
"Disappointing that the [value clarification] exercise only gives an overview of what is important in my decision, but does not give advice based on my input."	It is neither feasible nor desirable to generate tailored advice based on user input, as the advice for every parent is to vaccinate their child. The exercise aims to clarify which values are important to parents in their decision-making. We adjusted the wording at the start of the module to manage expectations. At the end of the exercise, we explicitly advised users to discuss the results with a health care professional.
Cycle 2[b]	
General	
"The links to a different website are confusing, I don't like to be directed to another website."	We reduced the number of links directing users to other websites. Where such links were still present, this was explicitly indicated to simplify navigation.
"The information on how vaccines work is not clear. It now seems that children make antibodies against diseases even without vaccination. I now think that vaccines are not needed."	The information on how vaccines work was simplified and adjusted to capture the main message.
"The information on how to find reliable information is not helpful. I expect to find examples of other reliable sources."	We adopted this suggestion and presented links to key websites with reliable information.
Cycle 3[c]	
General	
"The information on the different diseases that children are vaccinated against, gives a nice and good overview. I would like a bit more background information on how common these diseases are elsewhere in the world."	On the basis of previous feedback that the information was too much and the subsequent reduction of content, we decided not to include additional background information on diseases.

[a]n=13; 9 parents (mothers of children aged ≤4 years) with a high level of educational attainment and 4 CYH professionals involved in vaccination care for children aged ≤4 years (1 physician and 3 nurses) from 2 CYH organizations.

[b]n=4; 4 parents with lower educational attainment.

[c]n=3; 3 parents with lower educational attainment.

Final PDA Prototype

Overview

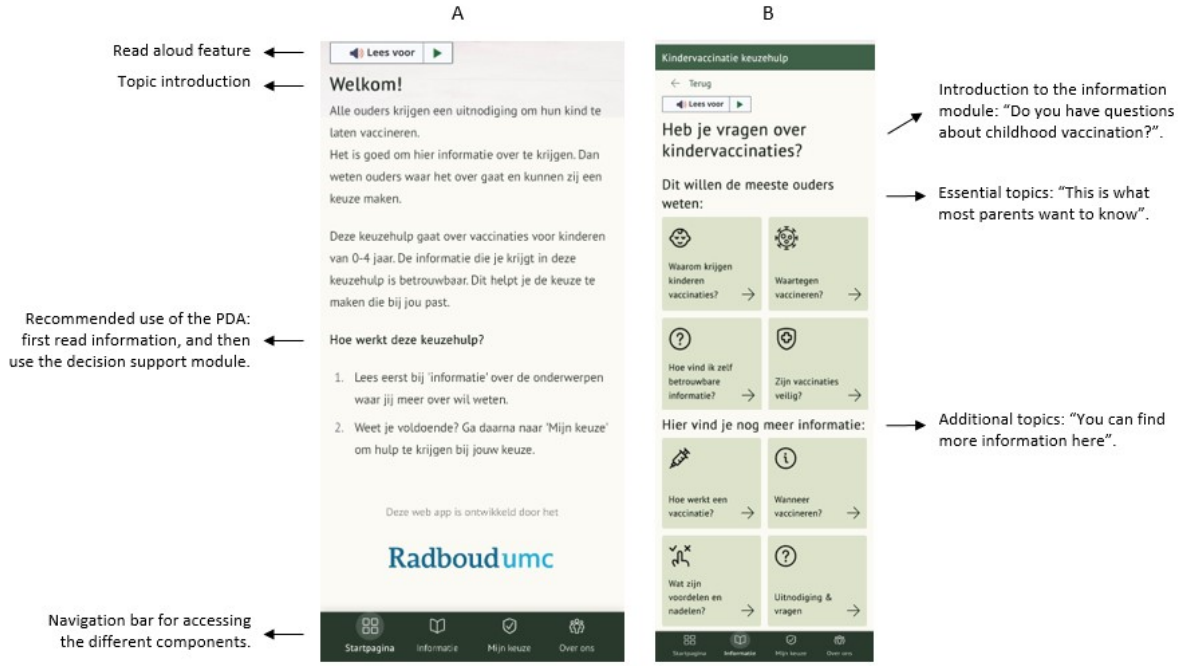
We considered the prototype final when the panel sessions did not yield any new feedback and when users could navigate the PDA easily. The Dutch Foundation for Easy Reading assessed the final content and awarded a certificate recognizing its use of plain and ordinary Dutch. The final PDA prototype consists of the following components.

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Welcome Page

The PDA begins with a welcome page that explains what the PDA is, who it is intended for, and how to use it (Figure 2A). From the navigation bar, users can navigate to the different components.

Figure 2. Screenshots of the welcome page (A) and information module (B). The arrows indicate the main elements of the PDA. The screenshots were taken using a mobile display of the PDA, images are not shown due to potential copyright concerns. The full translation of the text shown in this figure is provided in the multimedia appendix.



Information Module

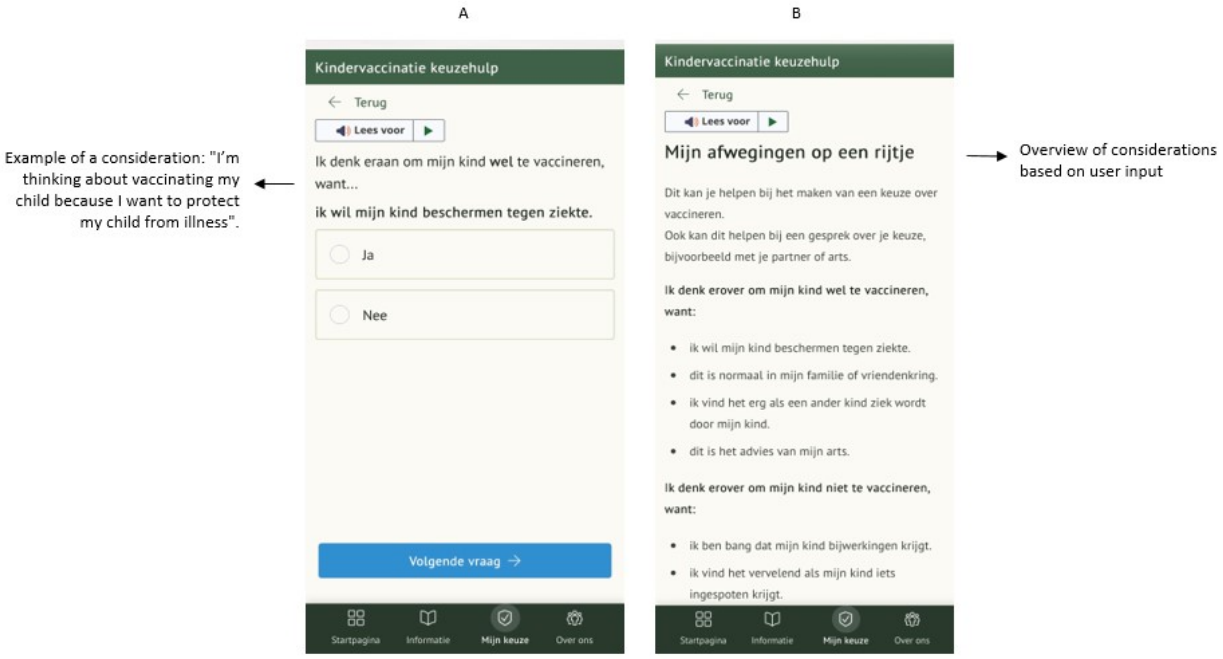
This module features a tiled architecture that organizes topics into 2 categories: essential information titled "This is what most parents want to know" and additional information titled "You can find more information here" (Figure 2B). Each tile links to a question and its answer, presented in the form of text and/or visual information. The essential topics cover the individual and societal aspects of vaccination, the diseases that vaccines are designed to prevent, how to find reliable information, and vaccine safety. The additional topics include how vaccines work, the vaccination schedule, the advantages and disadvantages of vaccination, and details about the vaccine invitation.

Decision Support Module "My Choice"

The main page of the decision support module features an explanation of the different steps in the decision-making process and a video of a clinician's experience in assisting parents through this process. This page links to "The choice of others," with perspectives of other parents on vaccination, along with an icon array visualizing vaccination coverage. Within this module, users can also access the value clarification exercise ("My Choice"). This exercise allows users to reflect on their values and considerations related to their vaccination decision. Users are invited to agree or disagree with various considerations regarding their vaccination decision and can also add their own. Figure 3A shows an example of a consideration. At the end of the exercise, a customized overview of considerations relevant to each user is generated (Figure 3B). This overview can serve as a basis for a conversation with a health care professional.

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Figure 3. Screenshots of the value clarification exercise in the decision support module, showing (A) an example of a consideration and (B) an overview of considerations relevant to the user, presented at the end of the exercise. The screenshots were taken using a mobile display of the PDA, images are not shown due to potential copyright concerns. The full translation of the text shown in this figure is provided in the multimedia appendix.



About Us Page

To clarify who designed the PDA, we included an information page that introduces the project team members and briefly explains the evidence on which the PDA is based.

Discussion

Principal Findings

We co-developed a PDA that addresses both the individual and societal aspects of childhood vaccination within the Dutch immunization program. In doing so, we aimed to address cognitive, emotional, and societal aspects of vaccine hesitancy [6]. Parents who participated in the co-development process expressed that they felt this PDA was needed and emphasized that it should be tailored to meet the needs of parents with lower levels of educational attainment.

Our user-centered approach is the main strength of this project. This allowed us to tailor the PDA to the needs of our target group, a critical step in developing potentially effective interventions that address hesitancy [37]. We prioritized the interests of hesitant parents and those with lower health literacy, who probably will benefit most from a decisional support intervention [16,38]. For example, parents with lower levels of educational attainment had difficulty understanding the key message about how vaccines work (refer to cycle 2 described in Table 2). We subsequently made adjustments to improve clarity and evaluated them in the next cycle. Another strength is that we used a systematic and cyclical approach, combining various methods (expert consultation, user evaluation, and readability assessment) to ensure the suitability of the PDA in practice. In addition, in line with our guiding principles, we combined elements of risk communication ("Information" module) with value clarification ("My Choice" module), which are more likely to be effective in supporting those who are hesitant than information alone [39].

A limitation of this project is that we developed the PDA in Dutch. Professionals and parents requested that the PDA be made available in other languages as well. It is important to explore if this would increase its future reach within the Dutch population. Another limitation is that we were not able to address all needs. For example, some parents preferred very detailed disease-specific information (refer to cycle 3 described in Table 2). This conflicted with our focus on vaccination as a general concept and our prioritization of the needs of parents with lower health literacy. Consequently, we opted for short text blocks alternating with visual elements instead of extensive written information. This indicates that a PDA alone will not satisfy all users' needs and should be used alongside other interventions, such as educational materials and conversations with health care professionals. Another limitation is that we could have involved a more diverse group of stakeholders in this project. When we evaluated the PDA with parents, we asked them to reflect on the period when they were pregnant but did not include prospective parents during pregnancy in our panel evaluations. We could also have involved our stakeholders more, for instance, when designing the structure and layout of the PDA. Although we mitigated this by evaluating these aspects with panelists afterward, we recommend a diverse group of stakeholders to participate actively in each development step.

SDM and the Role of the PDA

When developing this PDA, we considered the guidelines and criteria of the International Patient Decision Aid Standards (IPDAS) Collaboration [12]. These guidelines emphasize a balanced representation of the risks and benefits of different

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options for the individual. However, in the case of vaccination, individual choices also have a wider societal impact through group immunity. Therefore, we considered it vital to address the societal aspect of vaccination in our PDA. Some panelists experienced this as coercive and favored focusing only on their individual perspective (refer to cycle 1 described in Table 2). As this was clearly contrary to our principles, we did not adopt this suggestion. This illustrates that although stakeholder input guided the development, it was subject to certain limits. This also illustrates how we adapted the traditional SDM approach to fit decision-making about routine childhood vaccination. Alternative criteria are needed to guide the development of DAs to support similar evidence-guided decision-making in a public health context. When carefully adapted, an SDM approach could contribute to patient engagement, support informed decision-making, and foster dialogue with health care professionals, even in a public health context.

Supporting decision-making about childhood vaccination warrants a complex balance between strong evidence-based recommendations for accepting vaccination and its population-level benefits, while also considering benefits, harms, and preferences at the individual level. This means allowing space for individual concerns and considerations without compromising the scientific evidence supporting population-level interventions. Throughout the development of this PDA, we carefully sought this balance by (1) providing evidence-based information in an accessible format to help hesitant parents navigate their way through the vaccination information landscape and (2) providing decisional support, allowing parents to inventorize their individual values and considerations as input for further conversation with a health care professional.

Conclusions

Interventions aimed at addressing vaccine hesitancy have primarily concentrated on mass-media communication and on interactions between parents and health care providers. By introducing this PDA about childhood vaccination, prospective parents and parents can use it in a way and at a time that best suits their decision-making process. Future research should focus on the best timing for using this PDA to support informed and deliberate decisions. As more vaccines are being added to the NIP at a very young age and vaccination decisions are likely to start before childbirth [18], we recommend evaluating this PDA from pregnancy onward.

Acknowledgments

The authors thank Kelli Tiggelman and Dr Corine Meppelink for their valuable advice, as well as the stakeholder group, panelists, and experts for their meaningful contributions throughout the development process. Additionally, the authors thank Gerda Wink for facilitating the successful collaboration with the parent panel.

Data Availability

The data supporting the development of the DA are included in this published article. The needs assessment and advisory group meetings were not transcribed and therefore no raw data are available.

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Authors' Contributions

All authors contributed to the design of this project. DB-V, LV, and JLAH developed the decision aid, supervised by MEJLH and GE. DB-V drafted the original manuscript, which was reviewed and edited by all authors. All authors approved the final version and agreed to be accountable for all aspects of the work.

Conflicts of Interest

None declared.

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Abbreviations

CYH: child and youth health care
DA: decision aid
GUIDED: Guidance for the Reporting of Intervention Development
IPDAS: International Patient Decision Aid Standards
NIP: National Immunization Program
PDA: parent-facing decision aid
SDM: shared decision-making
SUS: System Usability Scale
UX: user experience
WHO: World Health Organization

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Investigation of the Content Validity, Feasibility, Internal Consistency, and Construct Validity of 5 Patient-Reported Outcome Questions on Patient Involvement in Care Among Adolescents With Type 1 Diabetes: Multimethods Study

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Abstract

Background: Validated measurement tools that focus solely on assessing adolescents' involvement in their treatment are scarce.

Objective: The study aimed to validate 5 patient-reported outcome (PRO) questions regarding patient involvement in care among adolescents with type 1 diabetes.

Methods: A multimethod and questionnaire design was used. A total of 447 adolescents (aged 11 - 18 y) completed a short questionnaire that included 5 PRO questions regarding patient involvement in their care. In total, 25 interviews were conducted with 20 adolescents, as some adolescents were interviewed twice. The content validity, feasibility, internal consistency, and construct validity of the PRO questions were analyzed.

Results: Assessment of validity revealed that most participants encountered no or minor difficulties comprehending the PRO questions. The interviews demonstrated that all participants showed a satisfactory understanding of 3 of the 5 PRO questions. However, the terms "appropriate" and "experiences" posed a challenge for 3 out of 20 participants. Using data from the questionnaire, the feasibility, internal consistency, and construct validity analyses uncovered only 2 limitations in validity. First, the clinical use of the questions limits anonymity, potentially introducing bias. Second, adolescents younger than the age of 15 years had more difficulty with the item "I talked to the health care staff about the questions or concerns I had."

Conclusions: The PRO questions are valid for measuring patient involvement among adolescents with type 1 diabetes. Respondents stated that the PRO questions were easy to understand, relevant, and comprehensive. There should be awareness when using the PRO questions, as they are most robust for those aged 15 years or older. Therefore, using these PRO questions in both clinical settings and research demands thoughtful consideration regarding their application and setup, particularly when considering the age of respondents and circumstances. It is worth noting that these PRO questions may pose validity challenges for use among adolescents younger than the age of 15 years with type 1 diabetes.

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KEYWORDS

children; patient involvement; indicator measures; patient-reported outcome; PRO; patient and public involvement; validation; cognitive interview; diabetes; adolescent

Introduction

Involving patients in their health care, for example, in planning and decision-making regarding their disease, has been shown to positively impact treatment outcomes [1,2]. This is also important for children and adolescents. Studies have shown that most adolescents want to take part in their care, but they can also feel pressured when involved in it [3]. Patient involvement refers to the patient's rights and benefits from having a central position in their health care. Patient involvement builds on a patient-clinician partnership characterized by dialogue, mutual trust, respect, and shared decision-making [4]. According to the "Convention on the Rights of the Child," adolescents have a right to express their opinions [5]. Given this, over the past 20 years, there has been an increased focus on the importance of

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effective communication and adolescents' involvement in their health care [6,7]. When involving children and adolescents in their health care, it is important to consider the verbal and sociocognitive differences across this age group, as well as the sociocultural and clinical context. Studies have shown that these factors affect their ability to participate and self-report, especially before the age of 12 years but also between 12 and 18 years [8]. Studies show that adolescents with chronic diseases like diabetes want to be involved in their care [9]. Adolescents especially desire to gain more control over their lives by being more involved in decision-making about managing their illness [3,9]. Hence, it is important to involve adolescents with diabetes in their care, as their experiences and attitudes may affect the quality of care [10,11]. Despite this, including a patient-reported outcome (PRO) questionnaire of patient involvement in the development and evaluation of health care interventions, as well as in clinical practice, is still limited among adolescent health care [12]. Furthermore, PRO questions are equal to PRO measures, which are defined as any report of the status of a person's health condition, for example, their general well-being or diabetes distress, that comes directly from the person without interpretation of their response [13]. This means that PROs are used as an umbrella term, involving both person-reported outcome measures, such as physical functioning and mental health, and person-reported experience measures, for example, communication with clinicians and partnership [13,14]. Based on the above, we define PRO questions of patient involvement as questions that reflect the degree to which the person feels involved in their care. Most questionnaires that incorporate adolescents' viewpoints regarding their involvement in their care do so implicitly by asking about their condition and perceptions of the quality of care [12]. Concerning adolescents with diabetes, both generic and disease-specific questionnaires exist [15,16], which implicitly include this. This perspective is included in questionnaires, such as the Child Depression Inventory–Short [17], Barriers to Diabetes Adherence [18], Readiness for Emerging Adults with Diabetes in Youth [15], and World Health Organization–5 (WHO-5) Well-Being Index [19]. Other PRO questionnaires have incorporated one or more questions regarding involvement, along with questions focusing on symptoms or treatment outcomes [20]. A scoping review identified 23 PRO questionnaires used to measure different kinds of treatment involvement among adolescents with type 1 diabetes, for example, communication with clinicians, clinicians' commitment, and shared decision-making. This included, for example, the generic questionnaire Chronic Illness, Resource Survey or the diabetes-specific Diabetes Family Conflict Scale [20]. Still, to our knowledge, no validated PRO questions precisely assess patient involvement among adolescents. Such PRO questions could be important to offer feedback to the clinical team and support the implementation of new involvement initiatives to meet the goals, as well as to uncover the effects of new patient-involving initiatives for adolescents. In an adult (aged >18 y) context, 5 PRO questions for patient involvement have been developed and validated [21]. These PRO questions can be used across patient groups and for various health services [21]. The PRO questions were developed to measure the degree of user involvement intervention and provide feedback to health care professionals regarding the quality of care [22]. Hence, they were developed as PRO questions to be used anonymously in research or development projects, not for clinical practice [23]. The development shows that the questions had a skewed distribution and high interitem correlation. Furthermore, the development and validation of the PRO questions showed that classic background variables such as gender, age, and education have a limited impact on patients' responses. The most significant effect relates to the patients' "self-perceived health"; the more ill a patient perceives themselves to be, the more critical they are regarding the experience of involvement. Furthermore, validating the significance of the background factors for how vital the 5 PRO questions are for different patient groups showed that age had a limited influence. In particular, the questions are less significant for patients older than 80 years. Additionally, there is a tendency for involvement to be more important for women than for men, and the longer the patient's education, the more emphasis is placed on involvement. Also, there was no difference in the importance of the questions for patients with somatic and psychiatric conditions. Furthermore, it holds that the more involvement a patient desires, the more significant the involvement questions become. Taking this into account, we rely on the development and validation of the PRO questions among adults [21,22]. The content and wording of these PRO questions were deemed appropriate for assessing patient involvement in adolescents with diabetes (aged 11 - 18 years) in a clinical setting. Although not originally developed for adolescents and not previously used as PRO questions in clinical practice [21], this study aims to validate the PRO questions in adolescents with diabetes. Furthermore, we hypothesize that validity may be affected by the adolescents' differences in metabolic regulation, hemoglobin A1c (HbA_{1c}), age, and gender, as well as their desire for involvement.

Methods

Design

This study uses a multimethod design, drawing on a questionnaire and interviews to collect data from adolescents with type 1 diabetes and secondary diabetes in an outpatient hospital setting. This design allows researchers to gather data at a single point in time, which is suitable for evaluating the psychometric properties of the questions, including internal consistency and construct validity. The study used the COSMIN (Consensus-Based Standards for the Selection of Health Measurement Instruments) [24] checklist (Checklist 1) and the analytical model from Murphy et al [25] study on the Primary Care Outcomes Questionnaire to select measurement instruments and guide reporting on measurement properties. Together, this is characterized by a psychometric approach designed to validate reliability, validity, and sensitivity in measuring user involvement. To establish content validity and identify and correct challenges, we conducted semistructured interviews [26] with adolescents with diabetes. The interviews were used to evaluate the quality of responses and to determine whether the questions elicited the information the author intended. This was combined with a statistical analysis of the 5 PRO questions. These analyses assessed feasibility using the amount and patterns of missing data and construct validity by testing

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prespecified hypotheses about the correlations between the questions. Through the analyses, we focused on age and gender, the potential effect of age on the pattern and content of participants' responses, and, finally, whether the validity of the questions depended on age. Consequently, we performed all statistical analyses on the group, stratified by age (≥11 - 15 y and >15 - 18 y) and gender. In other words, the strength of the interviews is that they provide in-depth information regarding face validity in a narrow sample. In contrast, the strength of the statistical analyses lies in their ability to examine the broader population systematically. During the analytical process, we also involved patient and public (PP) partners.

Ethical Considerations

The interview participants were informed verbally and in writing about the study. Written informed consent was obtained before the interviews. Permission to collect questionnaire data from the medical records was given by the Central Denmark Regional Legal Office (record 1-45-70-21-21). The study was registered in the Central Denmark Regional database (record 663160). All procedures performed were in accordance with the ethical standards of the National Research Committee and the Declaration of Helsinki [27]. The Science and Legal Office, Central Denmark Regional Office, assessed the study 1-16-02-326-19.

Study Participants

The study was conducted among adolescents with type 1 diabetes and secondary diabetes aged 11 to 18 years, with a diabetes duration of more than 1 year. Secondary diabetes refers to diabetes that develops due to another medical condition or as a side effect of certain medications, rather than from autoimmune processes (as in type 1 diabetes). Examples of common causes of secondary diabetes include cystic fibrosis or medical treatment following a transplant. The participants came from 4 pediatric departments in the Central Denmark Region and were recruited between May 2019 and March 2022. All participants had internet access to answer the short questionnaire and could understand, read, and write Danish. For the first interviews, participants were purposively sampled to ensure variation in age and gender. The purposive sampling by gender was chosen because girls' and boys' physical, mental, and social development occur at different stages [28]. Convenience sampling was used for the second interview, and 5 prior participants were interviewed again. Participants for the interview came from the outpatient clinic at Steno Diabetes Center Aarhus, and the health care professional assisted in the recruitment.

PRO Questions for Patient Involvement and Clinical PRO-Context

Before their annual consultation at the clinic, participants completed a short questionnaire assessing symptoms of disordered eating using the Diabetes Eating Problem Survey–Revised (16 items) [29,30], the generic WHO-5 Well-Being Index [19], patients' overall satisfaction [31], and PRO questions for patient involvement [21]. The short questionnaire was part of standard care and was conducted using AmbuFlex telePRO solutions (Center for Patient-Reported Outcomes), a web-based platform for patients to answer PRO questions. When patients responded to the short questionnaire, their responses were directly accessible in their electronic health record [32]. The PRO questions consist of a 5-item questionnaire measuring the degree of agreement with statements on a 5-point scale, ranging from 0 ("Not at all") to 5 ("A very high degree"), with an additional option to select "Don't know" (Textbox 1). Multimedia Appendix 1 outlines the 5 PRO questions and the question concerning patients' overall satisfaction, which was included in the validation. The question regarding patients' overall satisfaction is also used in the Danish National Health Survey [31].

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Textbox 1. Indicator measurement regarding patients' experience of involvement (PRO: patient-reported outcome).

These questions are about to what degree you have felt involved in your treatment? **(Select only one answer for each statement) [Disse spørgsmål handler om, hvordan du har følt dig medinddraget i din behandling? (sæt kun en markering ud fra hvert udsagn)]**

- The healthcare staff inquired about my own experiences with my illness/condition.

[Sundhedspersonalet spurgte ind til mine egne erfaringer med min sygdom/tilstand]

- I talked with the healthcare staff about the questions or concerns I had [Jeg fik talt med sundhedspersonalet om de spørgsmål eller bekymringer, jeg havde]
- The healthcare staff encouraged me to ask questions or talk about my concerns [Sundhedspersonalet opfordrede mig til at stille spørgsmål eller tale om bekymringer]
- I was involved in the decisions about what was going to happen. [Jeg var med på råd, når der blev truffet beslutninger om det, der skulle ske]
- I have had an appropriate number of conversations with the healthcare staff about how I can best handle my illness/condition. [Jeg har i passende omfang haft samtaler med sundhedspersonalet om, hvordan jeg bedst håndterer min sygdom/tilstand]
- All in all, I am satisfied with my last visit to the outpatient clinic [Jeg er alt i alt tilfreds med mit sidste besøg i ambulatoriet]

Response categories: Not applicable, Not at all, To a slight degree, To some degree, To a high degree

To a very high degree, Don't know [Ikke relevant, slet ikke, I mindre grad, I nogen grad, I høj grad, I meget høj grad, Ved ikke]

The English translation of the Danish PRO questions [Danish version.], has been guided by the protocol and guidelines from the International Society for Pharmacoeconomics and Outcome Research (ISPOR) [33].

Data Collection

Data collection was conducted iteratively and consisted of semistructured interviews and data from the short questionnaire described in the previous subsection.

The semistructured interviews were conducted from December 2020 to October 2021 (20 interviews) and from May 2022 to August 2022 (5 interviews). All 25 interviews were performed by the second author (20 interviews) or the third author (CBA; 5 interviews). The interviews took place in the clinic (n=2), by telephone at home (n=21), or via video (n=2). The interviews were audio-recorded and lasted between 11 and 48 minutes (mean 31 minutes). They were transcribed verbatim. A total of two semistructured interview guides were developed, focusing on (1) how participants constructed their answers, (2) what they interpreted the questions to mean, (3) whether they experienced any difficulties in answering, and (4) other aspects that shed light on the broader circumstances upon which their answers were based [26]. The first interview guide included four topics: (1) practical aspects of completing the short questionnaire (eg, "Tell me about the last time you completed the short questionnaire"), (2) short questionnaire content (eg, "How do you understand this question?"; selected questions from the short questionnaire were read to participants), (3) experiences with assessing their own condition and needs (eg,"What do you think about asking questions regarding the health care professionals' ability to involve you in your treatment?"), and (4) use of the short questionnaire in consultations (eg, "Tell me about how the short questionnaire was used in the conversation with your doctor/nurse") (Multimedia Appendix 1). The second interview guide focused solely on the use and value of the 5 PRO questions. These interviews were conducted to gather more data on participants' experiences with the PRO questions. Participants were asked to express their understanding of all 5 PRO questions and explain what they meant in clinical practice. For example, they were asked what it would mean to "Have had an appropriate number of talks with the health care staff about how I can best handle my illness/condition." Furthermore, participants were asked to describe whether they found it relevant to ask and use questions regarding adolescent user involvement (Multimedia Appendix 1). During the interviews, think-aloud and cognitive interview techniques were used. These are recommended techniques for investigating content validity [33,34]. The quantitative data for statistical analyses were collected from electronic health records in March 2022, covering participants' data from May 2019 to February 2021. The data consisted of the 5 PRO questions and 1 question on the patient's overall satisfaction, which was part of the short questionnaire used in participants' standard care (described in the "PRO Questions for Patient Involvement and Clinical PRO-Context" section). Furthermore, the data included participants' age, gender, HbA_{1c}, treatment, duration of diabetes, and diabetes type.

Data Analysis

The analysis of the PRO questions included content validity, feasibility, internal consistency, and construct validity.

Content validity was assessed through an analysis of all the interviews. This was an inductive process using the interpretive description methodology [35]. An important feature of this part of the analysis was the participation of PP partners in the process. The value of including PP partners in research is recognized and recommended, with benefits such as patient perspectives improving both research processes and outcomes to ensure they are patient-centered and focused on relevant patients' needs [36,37]. The PP partners involved in the analytical process were 2 adolescents (one younger than 15 years and one older than 15 years) with type 1 diabetes. They

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were recruited from the adolescents' user panel at the outpatient clinic at Aarhus University Hospital. They had experience with consultations at the outpatient clinic but no experience answering the questionnaires. Multimedia Appendix 2 outlines the PP partners' participation in the analytical process.

The first part of the content validity analysis consisted of sorting data into broadly coded categories. The categories formed codes related to the 5 PRO questions, participants' experiences with answering the short and PRO questions, how they valued the PRO questions, and challenges with using them. Further analysis investigated how the different statements were interlinked and highlighted similarities and differences within and between the interviews, looking for patterns, associations, and connections across the data. The first and last authors carried out this initial step. This process led to the first interpretation of the PRO questions' validity. In this analysis stage, the PP partners were involved (Multimedia Appendix 2). The involvement of PP partners revealed no differences in the interpretation of the data. However, PP partners stressed that even though the participants understood the PRO questions, they preferred to use terms more commonly used by adolescents, for example, replacing "outpatient clinic" with the clinic's name. After the involvement of PP partners, the results were discussed with the rest of the research team, and final interpretations were made, leading to a description of the dominant characteristics of how participants experienced the use and content of the PRO questions. NVivo (Lumivero) supported the organization, coding, and analytical queries across participants' characteristics.

The COSMIN checklist guides the statistical analysis of the qualitative data, but some steps were omitted due to data limitations. The main limitation was that there was only 1 question per theoretical item. The statistical analysis focused on how age groups differentiated and was divided into those aged more or less than 15 years. The statistical analysis of structural validity tested 2 hypotheses using the Kendall τ-b correlation coefficient. The difference between the age groups is tested in the proportion missing by a 2-sample test for equality of proportions with continuity correction. The difference between means was tested with the Welch 2-sample 2-tailed *t* test. All analyses were performed using R version 4.0.2 (R Foundation for Statistical Computing).

Results

Participants

Questionnaires from 447 adolescents were included, and 20 of the adolescents participated in the interviews. Participants with secondary diabetes (n=3) were included due to their similar treatment approaches to participants with type 1 diabetes. Participants' demographic and clinical characteristics are described in Table 1. Compared to the overall demographic population in the Central Denmark Region regarding age, gender, duration of diabetes, diabetes type, and HbA_{1c}, there are no significant differences [38]. All participants in the interviews reported experience answering questionnaires in school or in a health care setting. They indicated it took 5 to 20 minutes to answer the short questionnaire. Half of the participants had responded to the questionnaires alone, while the rest had support from either parents or a health care professional.

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Table . Demographic and clinical characteristics of the participants (N=447).

	Participants attending interview (n=20)	Participants answering questionnaires (N=447)
Age (y), mean (range)		
11 - 18	15 (11-18)	14 (11-18)
Age (y), n (%)		
>11 - 15	11 (55)	229 (51)
>15 - 18	9 (45)	218 (49)
Gender, n (%)		
Woman	11 (55)	229 (51)
Man	9 (45)	218 (49)
Diabetes type, n (%)		
Type 1	18 (90)	444 (99)
Secondary diabetes	2 (10)	3 (1)
Duration of diabetes (y), n (%)		
<5	8 (40)	247 (55)
≥5	12 (60)	200 (44)
Diabetes treatment, n (%)		
Insulin pump	20 (100)	345 (77)
Sensor	20 (100)	102 (23)
HbA_{1c}[a] measurement, mean (range)		
HbA_{1c} (%)	7.0 (5.0-8.6)	7.6 (4.8-18.2)
HbA_{1c} (mmol/mol)	53.4 (31-71)	59.4 (29-175)
Context of treating hospital, n (%)		
Aarhus University hospital	20 (100)	216 (48)
Regional Hospital West Jutland	0 (0)	76 (17)
Regional Hospital Randers	0 (0)	62 (14)
Regional Hospital Viborg	0 (0)	93 (21)

[a]HbA_{1c}: hemoglobin A1c.

Questionnaire Responses

Of the 447 questionnaire responses, 258 (58%) respondents completed all involvement questions, while 189 (42%) were missing at least one of the involvement items. Responses such as “Don’t know” and “Not relevant” were treated as missing in the analyses. The indicators are individually scored from 1 to 5, with higher scores indicating greater involvement. As a total score, they are summarized into a simple summative index and rescaled to range from 0 to 100.

The preliminary analysis shows (Table 2) that each item has a mean above the middle of the scale and an SD of around 1 point. Together, these findings indicate that the scale of the answers is skewed, with responses concentrated at the positive end. It also shows that individuals aged older than 15 years have a significantly higher mean score on 3 of the 5 involvement items and the total index. When grouping by other factors, we observe no significant differences in gender, HbA_{1c} regulation, or WHO-5 Well-Being Index.

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Table . General statistics about the items divided into age groups at age older than 15 years.

Item	Age group (y)				Difference	
	≥11 - 15[a]		>15 - 18[b]		*P* value missing	*P* value mean
	Missing (%)	Mean (SD)	Missing (%)	Mean (SD)		
The health care staff asked questions about my own experiences with my illness/condition	21.21	3.92 (1.01)	21.76	3.94 (0.96)	.89	.87
I talked to the health care staff about the questions or concerns I had	28.14	3.85 (1.19)	14.35	4.02 (1.07)	<.001	.16
The health care staff encouraged me to ask questions or talk about my concerns	18.61	3.54 (1.24)	15.74	3.99 (0.98)	.42	<.001
I was involved when decisions were made about what was to take place	13.42	3.76 (1.18)	12.50	4.13 (0.88)	.77	<.001
I have had an appropriate number of talks with the health care staff about how I can best handle my illness/condition	12.99	3.88 (1.07)	10.65	4.23 (0.78)	.44	<.001
Total involvement score (summative index of all 5 questions scaled 0 - 100).	50	72.93 (20.81)	34	79.33 (16.14)	.12	.007

[a]Mean interitem correlation=0.490; Cronbach α=0.827.

[b]Mean interitem correlation=0.471; Cronbach α=0.815.

Content Validity

Content validity is assessed through the analysis of the interviews, examining whether respondents understood the questions as intended. Most participants had no or only minor challenges in understanding the PRO questions. The PRO questions “The health care staff encouraged me to ask questions or talk about my concerns” and “I was involved when decisions were made about what was to take place” were understood by all participants. As one participant expressed regarding the first of the questions mentioned above, “Well, it’s like that if they ask you to ask questions or something like that” (ID 11).

In the PRO question, “I have had an appropriate number of talks with the health care staff about how I can best handle my illness/condition,” understanding the term “appropriate” was challenging for 2 participants (ID 1 and ID 2). Additionally, understanding the word “experiences” was challenging for 2 participants (ID 3 and ID 4) in the PRO question, “The health care staff asked questions about my own experiences with my illness/condition.” The PRO question, “I talked to the health care staff about the questions or concerns I had,” was understood

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by all the participants. However, many of them found it irrelevant to answer, as they described having no questions or concerns. Consequently, they answered, “Not relevant.”

Other words like “concerns” and “health care staff” were not a problem for the participants to understand, as 1 participant explained:

> *I think using health care staff is fine because you do not specifically refer to a doctor. It may also be a nurse.* [ID 5]

All participants appreciated being asked about their involvement in their care. As 1 participant explained:

> *I think it’s pretty good because it just means that you care and that we feel good about coming to the hospital. It just shows that you're not indifferent, and you actually want to do something about it if there is something wrong.* [ID 6]

Furthermore, being able to complete the questions before their consultation made them reflect more on their care and condition. They expressed that “you must be honest with yourself when answering the questionnaire because if you report a problem, you will be confronted with it during the consultation.” This was viewed positively, but also as a challenge that they believed health care professionals should be aware of:

> *It can also be cool enough to have the opportunity to be honest. But I could also imagine that many would not answer them genuinely because it is very direct.* [ID 5]

Since the questionnaire was completed before the consultation, participants had to recall and base their responses on the previous consultation 3 months earlier. Most participants expressed that this was a challenge. When asked by the interviewer, “When you answer the questions, what do you think back on?" 1 participant answered:

> *“It depends on whether something specific happened. If a new choice was made about a new pump or… Then I might think back to the last check-up, but if it was just a check-up like the one or two times ago, then I think it’s just more general than I'm thinking.”* [ID 10]

As a result, they described that their answers were often based on a more general impression of their clinic consultations.

Feasibility

In the COSMIN framework, feasibility is defined as the ease of application and the availability of the measurement instrument. It is not considered a measurement property and is therefore not assessed using statistical methods; instead, it depends on the specific context of use. In this study, the response rate is used as an indicator of feasibility. Statistical analysis of 447 questionnaires from the short questionnaire showed that for participants aged between ≥11 to 15 years, the proportion of missing responses on the PRO “I talked to the health care staff about the questions or concerns I had” was over 30%, almost 50% higher than for participants aged between >15 and 18 years. This may be interpreted as a sign of difficulty answering the question, especially among the youngest participants.

Internal Consistency

Internal consistency is defined as the degree of interrelatedness and is assessed using Cronbach α and the interitem correlation, and the mean interitem correlations were calculated as the average of the Pearson correlation coefficients between all item pairs. In both groups, α was well above the recommended threshold of 0.70, with no substantial differences observed between them (Table 2). For both groups, the mean interitem correlation was just below 0.5, which indicates adequate homogeneity among the items without suggesting substantial redundancy.

Construct Validity

Construct validity refers to the degree to which scores align with theoretically derived hypotheses, including expected internal relationships, correlations with other instruments, and differences between relevant groups, under the assumption that the instrument validly measures the intended construct. Construct validity was assessed by testing a set of predefined hypotheses. These hypotheses were based on established properties of patient involvement, namely that higher levels of perceived patient involvement are positively associated with greater overall satisfaction and better self-rated health [39]. As expected, the actual Kendall τ-b correlations were strong for overall satisfaction in both age groups. For the WHO-5 Well-Being Index, the picture was different; the correlation was small for the youngest age group and insignificant. For the older group (aged >15 - 18 y), the correlation was only in the expected direction but small with significance at the .05 level (Table 3).

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Table . Expected and actual Kendall τ-b correlations with patient involvement.

Correlation	Age group (y)					
	≥11 - 15		>15 - 18		All	
	Overall satisfaction	WHO-5[a] Well-Being	Overall satisfaction	WHO-5 Well-Being	Overall satisfaction	WHO-5 Well-Being
Expected correlations	+++[b]	+++	+++	+++	+++	+++
Actual correlations	0.457	0.067	0.52	0.122	0.425	0.091
P value actual correlation	<.001	.32	<.001	.05	<.001	.04

[a]WHO: World Health Organization–5.

[b]Strong correlation.

Discussion

The PRO questions were originally designed to measure the degree of patient involvement in adult clinical interventions and to provide feedback to health care professionals on the quality of care. To our knowledge, this is the first study to validate PRO questions about patient involvement in adolescents with diabetes. Overall, the PRO questions proved valid for measuring patient involvement in adolescents with diabetes, as participants indicated that the PRO questions were easy to understand, relevant, and comprehensive. Some questions appeared harder for participants younger than 15 years to interpret, as indicated by a higher number of missing responses among these participants. If they did reply, there were no indications that their answers were less valid. Therefore, we conclude that although developed for assessing patient involvement in adults, the 5 PRO questions are also suitable, especially for adolescents older than 15 years. Younger adolescents had a larger number of missing responses, which could be due to problems with interpretation as well as developments in social and self-awareness [8]. However, certain adjustments and specifications regarding the target group, usage, and preparation could be considered to enhance the ability to measure adolescent patient involvement, emphasizing age and context.

We found that some participants had problems understanding specific item words, particularly the words “appropriate” and “experiences.” Other studies exploring the understanding of words among children and adolescents aged between 6 and 17 years have shown that these difficulties are related to age. It is incredibly challenging for those aged younger than 12 years [40,41]. Still, these studies also emphasize that some items may be too vague or ambiguous to be clearly understood. This may be the case with the words “appropriate” and “experiences.” Reviewing the items to discuss related synonyms and retesting them would be relevant. Another alternative would be to include instructions for the PRO questions before use. In our study, some participants relied on their parents to explain the words, leading to a more comprehensive understanding.

We found that the participants did not use the whole scale. The answers were concentrated on the positive end of the scale. Optimally, one would want the answers to be distributed symmetrically around the middle of the scale without a skew in any direction. On the surface, this suggests that patients have positive experiences with their involvement, but it may also reflect social desirability bias among patients. The biggest problem is that the distribution of responses is skewed toward the positive end of the scale. The skewed distribution reduces the question’s ability to discriminate and increases the risk of ceiling effects. This effect may limit responsiveness and the ability to detect improvements in longitudinal applications. Skewed distributions are a common problem in PRO questions, also known as person-reported experience measures [42].

This study measured the degree of involvement ahead of a consultation and as part of clinical practice. The participants described it as difficult to remember and evaluate the last consultation. Additionally, it could be challenging to honestly evaluate the health care professionals they were about to talk to. Still, the participants and the PP partners found it important to be asked these questions, as they stressed the importance of being involved—for example, being talked to rather than having the health care professional primarily address their parents. Other studies on diabetes care for adolescents describe similar results [43]. Hence, it is essential to have tools like these questions to measure patient involvement, support dialogue, and assess user involvement in clinical practice. The PP partners suggested that patient involvement questions could be handed out after the consultation, allowing adolescents to evaluate the consultation alone or with their parents. Testing different evaluations of user involvement in a clinical setting would be relevant to investigate further.

The PRO questions evaluated 5 dimensions covering adolescents’ involvement in care [4,21]. A scoping review of PRO questionnaires used to measure the experience of adolescents aged 11 to 18 years with type 1 diabetes and their involvement in treatment shows that it was common for other PRO questionnaires to include several dimensions of user involvement [44]. Still, none of the questionnaires focused solely on measuring user involvement while including other aspects of diabetes care. Access to validated instruments that focus exclusively on user involvement and encompass all aspects of user involvement, for example, exchanging information or involvement in decision-making, may contribute to a more stringent and focused evaluation of user involvement. Furthermore, as in other studies using the 5 PRO questions to investigate patients’ experience of user involvement, patients seem to report a relatively high score between “To a high

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degree" and "To a very high degree" [45,46]. One may argue that to represent a good score, the patient's response should be either "To a high degree" or "To a very high degree."

Using the PRO questions within a clinical environment, rather than their intended use in research or quality improvement, could potentially influence participants' responses and introduce a risk of social desirability bias. This bias occurs when patients answer sensitive questions and choose what they believe is more socially desirable. In research and quality improvement, questionnaires can be completed after the consultation, and respondents are always anonymous. Hence, the participants in our study might have expressed a high degree of involvement because they knew that their health care professional would view their answers. The risk of this bias logically depends on 2 factors: first, whether the respondents consider the answer they want to give to be socially undesirable, and second, how much trust they have in their health care professional. This means we cannot rule out the possibility that the results of this study are context-dependent. In a different context, if questions were asked after the consultation or if there was lower trust between patient and clinician, the results might differ.

Structural analysis is understood as the degree to which the scores of a health-related PRO instrument adequately reflect the dimensionality of the construct being measured. It is often calculated using confirmatory factor analysis or exploratory factor analysis. Because this study contains only the 5 items measuring patient involvement, the ability to perform a factor analysis is limited. The omitted structural analysis means that this study cannot conclude whether the construct is 1D or how well it differentiates from other related aspects. This limitation highlights the need for future studies with a more comprehensive item pool to allow robust structural analyses and a more thorough examination of the construct's dimensionality.

An analysis of responsiveness measures whether the constructed measure responds to a change in the underlying problem [25]. In this study, we do not have sufficient data to perform this analysis, so we cannot conclude how responsive the construction measure is.

In this study, PP partners in research were part of the analytical process, and 2 PP partners were included. This meant the data analysis incorporated a lay perspective and strengthened the analysis. The PP partners also articulated that a focus on user involvement in clinical practice is valuable, and they expressed how the clinic could use the PRO questions in clinical practice. Only 2 PP partners still participated in the analytical process. Increasing the number of PP partners and their involvement in other parts of the research process might have led to, for example, other lay perspectives or optimized the recruitment of participants. In future studies, we recommend more comprehensive involvement of PP partners [37].

In our study, the interview guide for the semistructured interviews focused on the entire short questionnaire. Hence, the focus was not entirely on the PRO questions, as the interviews covered all the questions in the short questionnaire. The quality of data concerning the semistructured interviews and the understanding of the 5 PRO questions could have been more in-depth if the 20 interviews had focused solely on the 5 PRO questions. Considering this, we conducted a second round of interviews with 5 participants. These interviews strengthened the validity of the study as they confirmed the findings from the first interviews [33,47].

The English translation of the Danish PRO questions has been guided by the protocol and guidelines from the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) [48]. Although this makes the PRO measures usable in English-speaking countries, additional testing among adolescents in English-speaking countries would strengthen their validity regarding age, language, and culture. Here, cross-cultural validity, as described in the COSMIN checklist, is important to consider [24]. One of the items to address is whether the right people were involved in the translation process. Hence, it might strengthen the translation to include adolescents as part of the process. Furthermore, another aspect to consider is the cultural context of the health care system. Denmark is a high-income country, and its health care services are funded by an extensive welfare system, making them heavily or entirely subsidized. Furthermore, user involvement in care has been a focus for many years as an important factor in improving clinical outcomes [49]. This might affect clinical encounters and collaboration between adolescents and health care professionals and should also be considered when assessing generalizability beyond the Danish context. In clinical practice and research, we need tools to evaluate children's and adolescents' perspectives on user involvement in their care. One way to measure patient involvement is through PRO questions. This study has shown that the 5 PRO questions are valid for measuring adolescent involvement in their care, as the participants indicated that the PRO question items were easy to understand, relevant, and comprehensive. Still, when using the PRO questions, it is important to consider adolescents' age, as the study shows that the PRO questions are most robust for those aged 15 years or older.

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Authors' Contributions

ALJ, RBJ, and CBA were primarily responsible for design and data collection. ALJ and JTH performed the analysis and wrote the first draft of the manuscript. All authors critically took the final analysis and critical discussion of the result and approved the final version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
First and second interview guide.
[DOCX File, 32 KB - jopm_v18i1e86580_app1.docx]

Multimedia Appendix 2
Patient and public partners' involvement in the analytical stage of the research.
[DOCX File, 28 KB - jopm_v18i1e86580_app2.docx]

Checklist 1
COSMIN checklist.
[DOCX File, 804 KB - jopm_v18i1e86580_app3.docx]

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Abbreviations

COSMIN: Consensus-Based Standards for the Selection of Health Measurement Instruments
HbA_{1c}: hemoglobin A_{1c}
ISPOR: International Society for Pharmacoeconomics and Outcomes Research
PP: patient and public
PRO: patient-reported outcome
WHO-5: World Health Organization–5

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Integrated Knowledge Translation for Social Innovations: Case Study on Knowledge Translation Innovation Incubator

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Abstract

Background: The Knowledge Translation Innovation Incubator (KTII) initiative, launched by the Knowledge Translation program of the CHILD-BRIGHT Strategy for Patient-Oriented Research Network, provided funding support for researchers and partners to experiment with various approaches and strategies to support the development of innovative knowledge translation (KT) research in the context of neurodevelopmental disabilities.

Objective: We aimed to describe the process and contexts of innovation development in integrated knowledge translation (iKT) practices in patient-oriented research.

Methods: We applied an iKT practice to conduct the collective case study of 7 KTII-funded projects. We interviewed 10 researchers, 4 research trainees, 2 clinicians, 2 parentpartners, 2 patient-partners (1 adult and 1 youth), 1 community partner, 1 KT specialist, 1 designer, and 1 research program manager at the middle and the end of the project period. We conducted qualitative content analysis using the Consolidated Framework for Implementation Research to identify and assess patterns of determinants of (1) drivers of innovation, (2) facilitators and barriers to innovation development, and (3) enablers for sustainability of KT products.

Results: Innovative KT was majorly driven by the identified know-do gap to meet the needs of people with lived experience. Outer setting constructs, such as funding and partnerships and connections, were not only drivers but also facilitators to innovation development. iKT practices presented in this case study were fostered by researchers' approach to participatory design, involving iterations of listening to emerging ideas and feedback of patient-partners and other partners, and researchers' continuous reflections on their roles in knowledge creation. Despite the challenges in building consensus and the limited time of the fluid process, researchers' strong passion for engagement and value placed on lived experience led to flexible engagement and open communication to create KT products. Intangible outcomes included further relationships at individual and organizational levels, capacity building of young people, and a collective voice to influence communities. Sustainment of the KT products requires not only accessibility and adaptability of the product itself but also mechanisms at inner settings, such as training, continued interest of patient-partners and the community, and institutional partnerships to support the further uptake of the product.

Conclusions: This study illustrates the critical roles of researchers in addressing power dynamics and making the research partners' tacit knowledge visible for successful innovative KT. The research landscape should also change in terms of funding and timeline in order to foster researchers' mental models in designing thinking and actions on collaborative research engagement.

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KEYWORDS

integrated knowledge translation; innovation; patient-oriented research; disability; case study; research engagement

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Introduction

Research on concepts, theories, and frameworks for knowledge translation (KT) and implementation has rapidly evolved in the past two decades [1]. The Canadian Institutes of Health Research (CIHR) defines KT as "a dynamic and iterative process that includes the synthesis, dissemination, exchange, and ethically sound application of knowledge to improve health, provide more effective health services and products, and strengthen the healthcare system" [2]. One element of KT science focuses on identifying, testing, and developing the best methods to meaningfully engage partners in research and to convey the findings and outcomes of scientific research to those that are interested in or affected by the research. It aims to implement findings and effective evidence-based interventions into health care, policy, and other areas of practice or clinical settings. In Canada, KT is strongly encouraged in the research process since the adoption of the Knowledge to Action Framework in 2006 [3], mainstreamed by the CIHR [4].

The CIHR's Strategy for Patient-Oriented Research (SPOR) initiative was created to emphasize the engagement with diverse partners in KT and the integration of "patients" as partners in the research process. To this purpose, "integrated knowledge translation" (iKT) has been put forth as a useful model for collaborative research. It is expected that engagement with patient-partners can improve study development and increase uptake of evidence. Despite the recent development in strategies to engage a variety of partners in the research process, challenges still remain: a misfit between the type of problem and the approach taken to address it and a lack of validated methods for research partner engagement in terms of how to measure outcomes of engagement and how to quantify and qualify what meaningful engagement is and what the best methods to conduct studies using this approach are [5,6]. The development of new strategies that address these challenges and evolve with the field of iKT is timely.

The CHILD-BRIGHT Network is a pan-Canadian network that aims to improve life outcomes for children with brain-based developmental disabilities and their families. This network was funded by the Canadian Institutes of Health Research SPOR program, and therefore patient-partners (youth with disabilities and parents or caregivers of children with disabilities) are actively engaged as partners in all research projects and the activities of the network as a whole. The KT program of the network launched the KT Innovation Incubator initiative with the purpose of conceptualizing a vision for iKT, providing funding support for researchers and partners to experiment with various approaches and strategies to propose innovation and support the development of innovative KT research in the context of neurodevelopmental disabilities.

The current research challenge contends that many research engagement approaches are poorly specified and unvalidated [6]. In addition, children and youth with disabilities and their family members are not fully involved in the implementation of health research [7,8]. In this context, it would be beneficial to consider innovations in the process of conducting iKT practices. Innovation is here defined as a product, action, service, or relationship that has the potential to enhance health outcomes [9]. Innovative KT involves multifaceted innovativeness in developing and implementing tools that help the wide dissemination and uptake of new knowledge, engaging with diverse research partners. One example is the translation of evidence-based recommendations in clinical guidelines into educational tools and accessible resources to different target audiences by engaging with key opinion leaders, as well as the creation of a training program [10]. Seven Knowledge Translation Innovation Incubator (KTII) awarded teams had their own visions, approaches, strategies, and relationships for research engagement with diverse partners to bridge the gap between knowledge and practice in a particular context. In this context, this study aimed to describe the process and contexts of innovation development in iKT practices in patient-oriented research.

Methods

Research on Research

This study is best understood as research-on-research: a collective case study examining the processes and contexts of innovation within iKT practice happening in the context of 7 KTII projects [11]. We applied a case study, which is "an empirical enquiry that investigates a contemporary phenomenon in depth and within its real-life context, especially when the boundaries between phenomenon and context are not clearly evident" [12]. We describe both the phenomena and the context to gain an in-depth understanding of how innovation happens in patient-oriented research, specifically in the area of neurodevelopmental disability. A collective case study can help us understand the differences and the similarities between the cases (ie, projects) and generate a broader understanding of a particular topic [11-13]. Our constructivist approach aimed to capture the perspectives of different participants and focus on how their different perspectives and meanings illuminate the context and process of innovation development in iKT practices [13]. The comparison between different partners in one case (eg, researcher vs nonresearcher partners) as well as between different cases (ie, projects) was made when mapping the codes on the Consolidated Framework for Implementation Research (CFIR) framework and reviewing the particular contextual information. While qualitative content analysis was used to support thematic synthesis, the primary aim was not theory development or phenomenological inquiry but structured reflection on the research process.

KT Innovation Incubator Initiative

The KT program launched the KTII initiative with the purpose of conceptualizing a vision for iKT, providing funding support for researchers and partners to experiment with various approaches and strategies to propose innovation and support the development of innovative KT research in the context of neurodevelopmental disabilities. The objective of this initiative was to study how innovation involving "the process of making changes to something established by introducing something new" [14] can be adopted into KT strategies in the context of a patient-oriented research network.

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Seven Canadian KT projects were selected to receive funding (CAD $12,000, approximately US $9300 at the conversion rate of US $1 = CAD $1.29 in 2018) from this KTII initiative from 2018 to 2021 in order to promote and facilitate innovative KT products in childhood disability (Table 1). In 2018, the inaugural team, the Child-Sized KT project, proposed to co-design an online family portal that uses child and family partner stories about the value of research engagement. In 2019, the Making Sense of Connectedness project was awarded to work with neurodiverse youth to co-develop initiatives to promote sensory-friendly spaces in Montreal through a web-based hub. The Ready 2 Work team proposed to create an online platform to help young people with autism spectrum disorder successfully enter the workforce. In 2020, the WeeWheel project team aimed to develop and adapt the Wheelchair Skills Training Program educational resources for children through the creation of a training workbook, instructional posters, and a storybook. Another awardee, the Perspectives of Mental Health project, proposed to develop strategies and materials that could facilitate dialogues between youth and health care providers. In 2021, the Let's Go to the Library! team focused on the voices of young people to design and develop storybooks on different sexuality topics for preteens. Lastly, the CommuniKIDS team proposed to develop a freely accessible bilingual trial results communication tool in collaboration with youth and families impacted by different forms of child disability.

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Table . Overview of the 7 KTII[a] projects.

Project title	Innovation incubation goal	PWLE[b]	Family or caregivers	Others	KT[c] approach	Methods	KT products
Child-Sized KT	Develop an interactive online platform for children and families to learn about health research	✓ (children)	✓	Health care providers and writers	Knowledge to Action Framework model	Qualitative interviews and meetings	Family stories and online family portal
WeeWheel	Develop and adapt Wheelchair Skills Training Program education resources for children to address the evidence-practice gap	✓ (children)		Health care providers, decision-makers, and knowledge users	Knowledge to Action Framework model	Focus groups and interviews	A storybook, instructional posters, and a training workbook
Ready 2 Work	Develop and pilot an online vocational/employment readiness platform for people with autism spectrum disorders, families, and vocational program professionals	✓	✓	Advocates and professionals from vocational and employment organizations	Need to Knowledge Model and iKT practice	Focus group, testing, feedback, and piloting	Websites
Making Sense of Connectedness	Give neurodiverse children and youth and their families an opportunity to build an online hub of sensory environments in Montreal to engage the public about the impact of these sensory spaces	✓ (youth)	✓	Community partners (decision-makers from research institutes), students, and designers	iKT practice	Meetings	Pamphlets, videos, bags, and T-shirts
Perspectives of Mental Health	Create digital stories of youth with neurodevelopmental disabilities that can facilitate more dialogue between youth and health care providers in mental health discussions	✓ (youth)	✓	Community partners	Co-KT Framework	Workshops	9 digital stories
Let's Go to the Library	Create a free book to support nonjudgmental conversations with preteens with disabilities on sexuality and disability	✓ (youth)	✓	Health care providers, educators, graphic designers, multimedia consultants, website developers, professional writers, and actors	iKT practice	Online meetings and the use of information-sharing platforms	Books (downloadable PDF or narrated version)

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Project title	Innovation incubation goal	PWLE[b]	Family or caregivers	Others	KT[c] approach	Methods	KT products
CommuniKIDS	Develop a freely accessible trial results template in collaboration with youth and family advisors	✓ (youth)	✓	Health care providers or trialists, research ethics board (REB) committee members, and graphic designers	iKT practice	Virtual workshops	Trial results template, tip sheet for template users, and websites

[a]KTII: Knowledge Translation Innovation Incubator.

[b]PWLE: people with lived experience.

[c]KT: knowledge translation.

Use of Integrated Knowledge Translation in Our Case Study

We also used iKT, a model of collaborative research, to conduct the collective case study of 7 KTII-funded project teams [15]. The KTII funding applications were reviewed by the KT Program review panel, which included a number of researchers, research trainees, and nonresearchers (parents of children with disabilities, youth with disabilities, clinicians, and community partners). Each project was assigned to a dyad of peer reviewers constituted by 1 researcher and 1 nonresearcher, according to the research topic proposed (eg, KT projects directed at families were reviewed by a parent or researcher dyad). All members of the panel participated in the development of the application assessment forms and received equal training to rate applications. While the evaluation grid was used to standardize the rating of applications, each dyad had discussions to clarify their viewpoints and rationale for the rating results to provide the shared review results based on both the researcher and patient or parent-partner perspectives.

Our case study team—consisting of researchers, a project coordinator, parent-partners, and trainees—shared different research tasks throughout the case study series, including cochairing the review panel and addressing questions of panel members. Our parent-partner, who was part of the review panel, contributed to conceptualizing, designing, analyzing, and writing the case study as an integral part of the research team. While the researcher, who co-led the KT program with the parent-partner, guided the data collection and analysis process, both complimented each other's expertise—the researcher's expertise on the methodology and the patient-partner's expertise based on lived experience, along with her curiosity about the topic—and the collegiality enabled shared decision-making during the regular coleads meetings.

Ethical Considerations

Institutional ethical approval was provided by the Institutional Review Board at McGill University Health Centre-Research Institute (2019-4745). Written informed consent by participants was obtained prior to interviews. Participants did not receive compensation. The persons with lived and living experience who are coauthors were compensated following the CHILD-BRIGHT patient-partner compensation guidelines [16].

Participants and Data Collection

Participants were members of the KTII-funded projects' teams. The funding criteria included the inclusion of at least one nonresearcher as coprincipal investigator (including financial compensation for this person and other nonresearcher partners in the study budget description), the submission of a midterm and end-of-grant report that focused on reporting on the KT innovation and iKT methods, and the applicant's acceptance to participate in the KTII case study.

The studies' principal investigators and other partners who were members of the research team (not study subjects or participants) participated in two semistructured interviews. The interview guide was developed in partnership with the KT committee members for general input and in detail with the parent-partner, trainee, and researchers who accepted to participate in the specific project subcommittee. Interviews were conducted by a project coordinator at 2 points: midproject and end of the project. The interview at the midproject point focused on the definition of innovation, drivers of innovation, facilitators, barriers, and challenges of innovation development, innovation development process, and engagement with partners. The interview at the end of the project focused on the innovation development process, tangible and intangible outcomes, and sustainability of the developed KT innovation product (Multimedia Appendix 1). The interview recordings were verbatim transcribed for coding.

Data Analysis

Each KTII project is considered as a case in our analysis. We conducted qualitative content analysis [17,18]. First, a list of codes was cocreated based on the interview questions (eg, driver of innovation, engagement with partners, and enabler for sustainability) with the guidance of the senior researcher. After training on qualitative analysis by the research associate involved in the project with guidance from the senior researcher, parent-partners were paired up with a research trainee for analysis. They met on a regular basis, first with the entire research subcommittee, then with their dyads (parent partner-trainee). During the first meeting done via Zoom, all participants opened one Microsoft Word file (online) while the researcher shared her screen. One person volunteered to read the transcript, and the researcher led the prompts toward deductive coding. For example, she would prompt: "What do you think this is about? Does it speak to any of the items we

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already have here such as innovation, engagement, sustainability, or is there something else that this participant is communicating? If so, what is it?" The initial codes were done in this fashion, using color codes and comments on the online Microsoft Word document. In parallel, a living document (online shared) of code definitions was created, where written comments prompted discussion for clarification and establishment of the common understanding (referred henceforth as "Journal"). This was done for a series of meetings until the first interview transcript was entirely coded, with breaks to clarification and for any process or content questions from all involved. Then the dyads met to code the same interview transcript and met with the entire group once a month to review what they had coded, including notes, questions, and reflections. While reviewing the results of their partners' coding and discussing the findings, new codes were added, and the creation date and rationale were added to the journal.

After the iterative process of both deductive and inductive coding, a research trainee reviewed all coded texts and consolidated coding results in NVivo 12 (Lumivero). The preliminary findings were shared with the team members to receive feedback. As the coding process continued, the trainee iteratively reviewed and organized the code list by referring to the updated CFIR [19,20]. The initial data analysis plan did not consider the use of an implementation framework. However, we adopted CFIR during the data analysis as we needed a standardized structure for building on findings across multiple cases, while comprehensively distinguishing a wide spectrum of contextual determinants ranging from external context to individual characteristics [21]. CFIR provides a guiding framework to identify and assess a range of contextual factors of innovation development and implementation in 5 major domains: intervention characteristics, outer setting, inner setting, characteristics of the individuals involved, and the process of implementation. Determinant frameworks applied in CFIR helped us identify and assess patterns of determinants of (1) drivers of innovation, (2) facilitators and barriers to innovation development, and (3) enablers for sustainability of KT products across the intervention development process among different cases [20].

Engagement of parent-partners as well as research trainees shifted during the entire project period due to a shift in roles, personal conditions, and commitments. Although scheduling a meeting specific to the case study became difficult due to everyone's limited availability, we used regular meetings for the KT program coleads or committee members and email communication within the case study team to report on the progress of the interviews and to discuss the preliminary results of the analysis to ask specific questions and establish confirmability. In addition to the interview transcripts, midterm and final reports submitted by each KTII project were reviewed for data triangulation to gain a more comprehensive understanding of the project context when interpreting findings from interviews [22]. The midterm reports included information about achievements, engagement strategies, innovative KT approaches, and challenges faced by the project team. The final reports included future recommendations. The information validated what had been shared during the interviews, while adding other contextual information (eg, impact of COVID-19 and organizational change) which was not necessarily mentioned during the interviews. The research trainee who reviewed the reports took notes on new information about the process and context of the project. We used strategies to enhance analytic credibility—such as coding dyads, peer debriefing, and triangulation with project reports—but did not apply a full trustworthiness framework, as our aim was not to generate generalizable qualitative findings but to support learning about applied iKT practices.

Reflexivity

We position our research within social constructivist paradigms, and our stances on reflexivity deeply reflect this paradigm. Social constructivism posits that knowledge is created and applied through individuals' active interactions and learning in a particular social context [23]. SPOR's endorsement of the active partnership of research partners, including parent or patient-partners, researchers, health professionals, and decision-makers, shaped our attitude toward the way we as a team created new knowledge based on the shared value of collaboration and colearning. While team members' educational background and research experience varied, the spirit of colearning and the value of positioning parent-partners as equal research partners created each member's openness to different perspectives and points of view. The senior researcher learned about a different way of conducting qualitative analysis by partnering with a parent-partner in all steps of the data creation and analysis. This prompted reflections about qualitative methods and true partnered research, which had previously been done mainly on KT processes (eg, dissemination and feedback on outputs), not systematically through the creation of questions, analysis, and manuscript production. The parent-partner, who was the colead of the KT program, appreciated the expert knowledge from a senior researcher who guided the qualitative data analysis. The process gave the parent-partner confidence to contribute. Participating in the KTII case study allowed the research associate to bridge methodological rigor with meaningful partner engagement, ensuring that partners felt confident and supported in the qualitative analysis. The research associate role fostered richer, more nuanced interpretations and strengthened the integration of diverse perspectives in the final results. The project coordinator valued the collaborative nature of the iKT process, which created an adaptive learning environment where research team members not only learned about the different aspects of the research study (eg, qualitative analysis) but also appreciated how meaningful engagement of partners brings about relevant perspectives and enriches the process. The research trainees also appreciated parent-partners' critical insights into iKT practices, their strong curiosity, and active engagement through bringing questions during coding and analysis. It was also a learning process to reflect on the role of researchers and rethink what makes KT innovative beyond the existing common research practices.

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Results

Synthesis

Participants included 10 researchers, 4 research trainees, 2 clinicians, 2 parentpartners, 2 patient-partners (1 adult and 1 youth), 1 community partner, 1 KT specialist, 1 designer, and 1 research program manager who were members of the KTII-funded projects' research teams.

Many participants described outcomes, as well as the approach and process of engagement with research partners in their KT project, as innovative. Innovative KT was majorly driven by the identified know-do gap to meet the needs of people with lived experience. Outer setting constructs, such as funding and partnerships and connections, were not only drivers but also facilitators to innovation development. iKT practices presented in this case study were characterized by researchers' listening to ideas of patient-partners and other various partners with specific expertise and their continuous reflections on their role in knowledge creation. Despite the challenges in building consensus and limited time, researchers' strong passion for engagement and value placed on lived experience allowed flexibility of engagement and open communication to create KT products. Intangible outcomes included further relationships at individual and organizational levels, capacity building of young people, and a collective voice to influence communities. Sustainment of the KT products requires not only accessibility and adaptability of the product itself but also mechanisms at inner settings, such as training, continued interest of patient-partners and the community, and institutional partnerships to support the further uptake of the product.

Drivers of Innovation

Interview participants commonly conceptualized innovations as creativity in thinking and actions under a vision for creating something new for improvement and problem-solving by thinking outside of the box and pushing boundaries. A critical driving factor for innovation development was a construct of the CFIR Inner Setting domain, tension for change, or the degree to which research partners perceive the current situation as intolerable or needing change (Multimedia Appendix 2). Multiple researchers reported that they had identified the evidence-practice gaps to adapt programs and services that are informed by people with lived experience.

In one case, the identified gap was a lack of knowledge uptake since the "wheelchair skills training program isn't adapted to the pediatric client and the clientele or the pediatric population" [Clinician, Project 4]. Similarly, a researcher in another case (Project 7) stated, "it seemed surprising that nothing like this (communication tool) was available to trialists who wanted to share trial results back to families...and the kids."

The identified unmet needs driving innovation in 4 cases can be described through a human rights lens or broader issues of injustice toward youth with disabilities (Projects 2, 3, 6, and 7). A project lead researcher (Project 6) stated that "it is a fundamental human right to be able to explore [your] sexuality and be a sexual person in whatever way that looks like for [you]" by referring to young people with disabilities who "don't have those opportunities to express their sexuality, to figure out their identity." A parent co-lead in Project 2 also stated, "I think what brought us into here...there are voice to be heard," by quoting her son, who described the sensory environment where autistic people do not feel welcomed and people's misunderstanding or ignorance as unfair and injustices. Similarly, a researcher in Project 7 explained why tailoring trial results communication tool to youth was needed because youth themselves "have that autonomy and the right to get the results back from their own trials as well."

Among the CFIR outer setting factors, funding and partnership and connections were common drivers for innovations. In Project 1, a researcher reported that a series of conversations among different research groups who already had good relationships with each other organically led to a partnership development to create a digital technology innovation. At the inner setting level, institutional strategy to adapt the Wheelchair Skills Program as a relative priority to the pediatric population was an additional innovation driver (Project 4).

In the individual domains, the project lead's motivation was an often-cited driver of innovation. Researchers in all cases expressed their motivations, passion, and interest in knowledge cocreation with patient-partners during the interview. They also shared their strong belief that lived experience is a valuable source of knowledge that provides a potential solution to the identified complex problem:

> *I feel like these individuals have some really unique strengths that employers could be utilizing, but we're having a hard time seeing past that. So, trying to find a platform that not only builds on their current skillset so that they can be seen, but also a platform that may possibly reach employers at some point, be able to see the abilities of this population, and the benefits that they can actually bring to their businesses.* [Researcher, Project 3]

Process of Innovation Development

Teaming, Assessing Needs and Context, and Planning

Most teams applying to this competition had a previously established relationship through ongoing clinical and research activities (eg, research meetings, conferences, and public events). These connections gradually expanded to include other partners, such as family partners, advocates, and designers, to build transdisciplinary teams and pull a project application together. By applying the iKT practice, research partners were involved from the beginning of the project.

At the inner setting, while the needs, priorities, and preferences of patient-partners were broadly identified at the beginning of the project, objectives were not necessarily clear. A researcher (Project 1) stated, "We falsely assumed we knew exactly what we were trying to do, despite having vagueness to what we're trying to do." The objectives for the project evolved to gradually address unmet needs through a concomitant process of reviewing the existing research evidence and listening to the voices of research partners.

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> *We were listening to our groups. So even if we came up with certain ideas of what we wanted to present, this is like our participatory group here that, you know, our own stakeholders are coming in and saying what they think is important to them. And even like, be it outside consults or our team. And then that helped guide us to where we were going.* [Colead researcher, Project 2]

In the process, many researchers reflected on a shift in thinking of who obtains the most valuable knowledge.

> *The way I was trained in research was that "We're the experts. We go to them, they tell us how to do it," but I've found the opposite is true because if we start with them and say, "Okay, these are the things we're interested in. This is what the problem is from a research angle. How do we go about this?"* [Lead researcher, Project 5]

Similarly, a designer and a researcher in Project 2 stated, "the innovation is to flip how we think about expertise, that [young people] are ahead of the game, that they already know these things that would benefit lots of other aspects and people in society."

Tailoring

Once objectives became clear, projects adopted a series of different strategies, such as focus groups, interviews, and regular meetings with project partners, to design innovative products and strategies based on the initial wish list (ie, unmet needs and desires presented by project partners) and available evidence-based resources. After the brainstorming phase, researchers used different strategies to create something useful by integrating what was shared and considering feasibility. In all cases, teams designed a prototype of a KT product or a draft of a KT plan and continued refinement through iterative consultations, member checks, and integrating feedback.

> *What really helped was...just listening to everybody's opinions and trying to understand so that...what that does, it allows all the members of the project to add on one another or ask more questions, and so when you ask more questions, it makes the process more exhaustive. So like we truly understand everybody, as opposed to just that small group in the middle that thinks they know what they're talking about, but might not actually understand all of it.* [Youth, Project 5]

Participants expressed the complexity of tailoring the initial design of a KT product to adapt to the needs of patient-partners as a nonlinear process involved a great degree of uncertainty. The capacity to deal with uncertainty and adapt to change was integral inner setting characteristics of many projects.

> *Never in the iKT process do you see one linear phase of getting to, you know, here's your research question, here's the materials, the tools, and then they're up there the everyone starts using. That's not the way it goes. It's always this circle of, okay, here's what we have, we evaluate, here's what needs to be refined, we bring that back, and it's always that process of evaluation and follow-up and refining.* [Researcher, Project 4]

During the adaptation of KT products to the partners' needs, research teams showed the changes made due to the feedback received from research partners. A patient-engagement leader (Project 7) shared:

> *That was very well received. I mean, people wanna see that. They don't wanna give up on their time to not have an impact. So, for our youth and family stakeholders, I would say that through a combination of evaluating, you know, them, asking them, but also us making sure that we're accountable to them all the time, I think that's how we know the contribution is making an impact.* [Patient engagement leader, Project 7]

At the same time, outer setting characteristics such as funding and project management posed challenges. Reflecting on the fluidity of KT innovation with partners, a researcher of Project 3 found it a challenge when researchers had to make sure they respected the voices of their research partners while also meeting the expectations of the granting agency or partnership.

In addition, while multiple ideas in the development of projects were highly appreciated, building a consensus with a heterogeneous team was a challenge, as stated in two cases. Key challenges highlighted are related to creating a harmonious balance: (1) between research evidence and innovative elements underpinned by lived experience (Project 6) and (2) between individual preferences and an idea agreed upon by the majority of the team (Project 1). At the same time, a researcher in Project 1 reflected,

> *I think getting consensus in what we're trying to build, what exactly we're trying to build was [...] probably the biggest challenge. Then so to this question is what's the biggest successes that [...]. Once we got to that point, things felt very well, which is how it typically [goes] but not always. Sometimes once you start to get along somewhere [during] the iteration, people [start] saying, "Let's do this, let's do this," this sometimes can move [forward] whereas in this one in particular, we got to a point where we drive a process to get to that consensus and now it's around execution. We had good stakeholder, good feedback and people are engaged. Some of the patient-partners in particular were very helpful.*

Even though uncertainty characterized the experienced process of innovation development, it was also considered as an inevitable path leading to discovery, contributing to the adaptation of the intervention being proposed.

> *You go down a road and you don't know what you're gonna find on that road. So, it was kind of like, "Let's just do this, and let's just see what the result is." So I think that part was really exciting, too.* [Patient engagement leader, Project 7]

Even though things did not necessarily go as initially planned, researchers in the case study commonly highlighted that lived experience guided them during the iterative feedback process.

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> *...youth had come together and...and kind of brought in their...their experience, and what was the best way for them to relay that information that their lived experienced, you know, to the...turn it into a tool that could be useful to others.* [Researcher, Project 2]

Despite the time-consuming nature of the process, it was also a valuable learning experience for many researchers. A researcher in Project 1 stated, "everyone has stuff to learn. We have things to learn about how to communicate better with our family partners." In Project 3, a researcher explained that a multiple-stage approach was adopted so that people with specific expert knowledge can lead the stage. For instance, "computer tech person will be taking the lead and we [researchers] will be learning from him. So, I think that's really kind of helpful" [Researcher, Project 3].

Engaging

Participants stated that innovation was not only reflected in the KT products created but also in their participatory design process. In many projects, flexibility was a key for active participation of research partners. In three cases (Projects 2, 3, and 5), multiple modes of communication were available so that participants could express their ideas and emotions in a way they would like to. Speaking a lay language was also necessary for researchers' engagement with patient partners so that everyone on the team remained on the same page. In all cases, researchers also made sure that voices of partners were heard throughout the entire engagement process.

> *I think that [a parentpartner] said she felt included. We went back and forth in terms of trying to make a decision about something and making sure everyone had input, but she would say, "Well, I defer to you on that because you have the background and quality at research," but then we'd say, "Well, as a parent, is this going to resonate with you? Or, what do you think is more important? How should we group these things?"* [Researcher, Project 1]

Particularly in cases involving children and young people, several approaches were taken to address inherent adult-youth power differentials. For instance, in Project 7, young people attended meetings led by another youth facilitator, separate from adult research partners.

> *For the youth meetings, we just have the one person, she's a young woman, you know, she's got a rare disease herself and, you know, and she facilitates those meetings and the rest of us turn our cameras off, and we're just in the background. We don't intervene at all. So, it's a different kind of approach, too. And that's just a decision that we made.* [Patient engagement leader]

In another project, when young people and their parents attended meetings together, a youth interviewee shared that "it's more like the parents are backing up what the youth say as opposed to the parents say it for the youth and then the youth just go on with it" [Project 5]. In Project 4, a researcher reported that a video created with a young patient-partner helped reach out to other young participants for recruitment.

Furthermore, reciprocity in research engagement in the form of adequate compensation such as honorarium, opportunities for skills development, and friendship building was also highlighted in 4 cases. In one case (Project 4), a researcher reported that financial compensation encouraged children to participate, while making them feel that they were given an important responsibility based on their knowledge and expertise in wheelchairs. A researcher in Project 2 shared,

> *Participant 1: Bringing this awareness out into the public, especially the young public, I think it was very good. Very positive effect. They responded wonderfully to it, they were excited I think to see it.*
>
> *Interviewer: So you have motivated youth.*
>
> *Participant 1: And vice versa, I now get to design a course around youth mental health for the spring. I won't design it without having a component where those youth have an opportunity to come in and teach the students. So, it equally influences us, maybe that's the whole...maybe that's also a part of the innovation, right? It is not a one-way research model. It changes everybody who comes into contact with it in a way, I think.*

An often-cited engagement challenge was keeping the team connected. Despite challenges in scheduling meetings, having regular meetings was reported to be helpful in three cases (Projects 3, 6, and 7). In Project 5, where clinicians' availability was limited, researchers used their routine meetings to present the KT product, which captivated the interest and also made them feel that the tools really met the need that was named by them in previous studies." In another project (Project 5), a researcher tried to be flexible by telling research partners, "if you can't make it, come when you can so that everyone who wants to participate can still participate."

Facilitators for and Barriers to Innovation Development

At the outer setting level, technology was identified as one of the facilitators for innovation development in three cases as it can enhance connections and engagement (Projects 1, 3, and 5) (Multimedia Appendix 3). In Project 5, a youth partner stated that the digital platform "becomes easier to communicate" and "easier to show other people what we are doing" since "most youth are automatically accustomed to most digital things [...] more reliant upon social media and the kind of network."

At the inner setting level, multiple relational constructs are reported to have facilitated the innovation development: (1) relational connections, which were built on the previous working relationships in many cases; (2) a culture that values lived experiences and appreciates patient-partners not only as users but also as knowledge creators; (3) transdisciplinary work that fostered collaborations with people from different organizations and disciplines; and (4) open communication that respects diverse viewpoints. The importance of good relations on the team was highlighted, as one researcher (Project 1) described their team as a "group of people who are super flexible, adaptive, [and] rigidity and boundaries weren't going to work."

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In all cases, multidisciplinary composition of the team brought in a range of expertise and experiences, including (1) researchers, clinicians, community partners, and parent-partners and patient-partners (youth and adults with neurodevelopmental disabilities, children using wheelchairs, and families) and (2) people with specific expertise in fields such as computer programming, data informatics, behavior analysis, and knowledge brokering. Many researchers reflected on the importance of lived experiences and specific expertise and skills, such as communication designing, website designing, and story writing, as important components contributing to the KT innovation.

At the individual level, researchers' characteristics (perseverance, openness, passion, and being well organized) fostered patient-partner centered culture. In parallel, researchers often discussed that project team members' strong interest and willingness to make contributions kept the research team motivated to move forward. As one parent-partner (Project 1) stated,

> *It's a really strong team and they really have a heart for it. I think it'll just keep growing. Patient-family engagement is just the root of us so much that potential that has to be put in place. I think that's what they're trying to do very hard.*

Three cases (Projects 1, 2, and 7) also highlighted the capability of a knowledge translator and facilitator.

> *Our ability as a team to translate the youth knowledge was almost simultaneous with [designer] because she was quickly generating. She [...] will come and then she would pick up and then she would help start already the translation...When these youths would see that back again, to see their ideas in this kind of very...this format that's so official, you know, that it kind of solidified their own and ideas. I think it was really engaging. It was immediate. I think that really helped them to feel like they were part of something that was moving forward as a group.* [Researcher, Project 2]

Many researchers identified timeframe and availability of funds as barriers to innovation development at the outer setting level (Multimedia Appendix 4). A researcher (Project 7) pointed out, "[it is] double edge sword of innovation, right? It's innovative because it hasn't been done before, but then that also means that you haven't got anything to learn from before, so it is taking so much more time and other resources to work through this." Similarly, as one researcher (Project 2) described it as "reverse order of things," researchers stressed that the iKT practice cannot be done properly in a conventional research timeline that expects finishing the study and publications within a certain amount of time.

> *The time I ask [patient-partners] versus the time they give me a response, it could be a few days. It could be a week. Versus if I make that decision on my own, it's a lot faster, right? So, again, there's value and merit to that, but the time delay piece, again, in a world so obsessed with being so hyper-productive all the time can lose some of the value of what we're doing.* [Researcher, Project 5]

Therefore, the funder's flexibility to allow noncost extension was highly appreciated, as a researcher (Project 6) stated, "We have had to extend a couple of times and flexibility has been critical for us to produce this high-quality product."

Furthermore, 6 project teams were developing innovations during the COVID-19 pandemic (critical incidents at outer settings), which brought unprecedented barriers to innovation development and required creative, flexible thinking and acting on top of the planned innovation process:

> *COVID happened and COVID just really floored us. I mean, really, really floored us 'cause I think we were making really great strides up until then and then everything changed.* [Parent-partner, Project 2]

The pandemic gravely delayed the ethics approval process and changed the mode of participation from in-person to online. During this unprecedented event, research teams (Project 4) had to be creative to conduct interviews with a child:

> *Interviewee: What we did to overcome interviewing children online, because of the pandemic, we used a happy face system, um, where if they liked something or thought it was okay or didn't like it, they could do a green happy face, a yellow kind of straight face or a red sad face, or orange sad face. I think it was red.*
>
> *Interviewer: Yeah, yeah, yeah, yeah angry face or something like that, yeah.*
>
> *Interviewee: Exactly, and yeah, it worked okay. But the kids wanted to be doing other things. They didn't really wanna be sitting on a screen flashing and sad faces.*

Similarly, many interview participants found adaptation due to public health restrictions was a learning opportunity. A researcher (Project 5) described that it was the time to rethink the way they usually conducted research and be creative to make it inclusive. By switching from in-person format to online meetings, improved accessibility for participation was reported in two cases (Projects 3 and 5). It became unnecessary for young people to go to a meeting venue, which in turn opened up possibilities for participation for people in different geographic locations, as well as nonverbal youth participants who were able to engage in discussion by typing their ideas (Project 5).

In addition, limited funding was another barrier at the outer setting. One student (Project 3) described that "we tend to come with these kinds of pie in the sky ideas" when trying to develop something innovative. At the same time, the use of certain technology and hiring people for the development of programs, as well as for administration and coordination, is costly (Projects 1 and 3). In order to manage limited time and budget, some research teams tried to be realistic by selecting areas that everyone had agreed upon (Projects 1 and 2).

Outcome

In addition to the tangible KT products, many research teams reported additional outcomes had come out of their innovation development process, which they did not expect to see. Several

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cases (Projects 6 and 7) named new partnerships (outer settings) for further collaboration opportunities.

> *Given that the organization that I'm representing here, [institution's name], has now worked with this particular group, I can see us working together on other projects moving into the future too. So while we delivered on the original intended outputs, I think we've kind of seeded things to maybe do other things together as a group.* [Researcher, Project 7]

Such connections were being made outside of research settings in two cases. In Project 2, researchers were excited to see the community members starting to reach out to invite youth groups for consultations. Youth's friendships were organically fostered in Project 5.

The project teams involving youth research partners highlighted opportunities for capacity building and empowerment (Projects 2, 5, and 7).

> *Some of the youth have said, you know, like "I showed this to some of my friends who have mental health challenges and have a neurodevelopmental disorder and they never thought that a kid with autism can do this", right? So again, it's almost breaking stereotypes for some kids as well that they're not broken or damaged, like they've been told before, but that they have kind of potential and are worthwhile.* [Researcher, Project 5]

In addition, another case stressed the collective voice of youth as the outcome that has the most potential for impact on the community (Project 2).

> *Researcher: You know, having like your pamphlets and so on. You're not just someone who sounds like, "Oh, I'm advocating for myself or I'm complaining." That's how people sometimes see you. But coming together as a collective and having it branded and having it, you know, sort of bringing in that credibility, you know, it brings in more gravitas. You have, you know, people's ear. And so I thought that was quite significant.*

Sustainability of Developed Innovation

The identified enablers of sustainability of the innovation products that each research team developed are multifaceted (Multimedia Appendix 5). In the innovation domains, accessibility and adaptability of the product to different populations were identified as a key enabler for the sustainable implementation of the innovation. Whereas a strategy to make materials available online through their own website or their partner organizations' website was put in place in many cases, one research project (Project 4) also pointed out the need to print resources in both a print and a digital version to share with families as well as clinicians.

Furthermore, innovation was seen in the ways that teams granted credibility to their KT products. In one case (Project 6), they obtained an ISBN as a strategy to increase the sustainable use of their book. They explained: "it helps [a library at our hospitals] to catalog our book and for us, it helps get the book out, so it is sort of both adding credibility but also helping other people get it out more." Another crucial enabler was funding to update and maintain the developed product relevant to the users and/or expand the users to different target groups (outer settings).

In the inner setting domains, in Project 4, whose target users include clinicians, researchers were aware of the need for training for implementation. Therefore, continuing education on the innovation (pediatric wheelchair skills training) was a work infrastructure in inner settings that was required to make a longer use of the developed KT innovation.

Some research teams found relational connections with existing and newly developed partnerships with other research teams as an enabler to innovation and help sustain the developed innovation products. For instance, a researcher (Project 7) stated, "even though the project team is formally disbanded, there is a commitment from [the name of an institute] as a partner organization to continue to update the website, and to continue to potentially make changes to the results template if we're hearing enough feedback from people that that should be done." Similarly, another project team (Project 6) believed that close relationships with the communications and public engagement department, as well as a very large network of partners, can help disseminate their KT product and guarantee better knowledge uptake and use.

Many project teams also found that continued interest of patient-partners and the community, which were part of the innovation development process, can help sustainable use of the developed product.

> *I'm looking forward to those benefits that I think will come as we build a community of people who are involved and actively participating on the [web]site because again, I'm the researcher and [...] I see my role as facilitating the process but it's meant to live as a result of the community who benefits from it.* [Researcher, Project 3]

The team of Project 2 discussed that sustainability is not just the product but also relationships to create changes in the community:

> *I do and that, you know, usually, we think of sustainability, like as an environmental or the longevity of a product, but it's essentially grounded in our relationships, right? And if people are empowered...I think you were both saying that P3 and P2 in different ways, like to...that they just know that they can create these changes. I mean, I think that's what we're trying to give people more than any actual product in a way.* [Researcher]

On the other hand, local attitudes in outer settings can be a potential barrier to the sustainable use of the KT product. The members of Project 3, who developed an online platform that provides resources and tools to people with autism in order to support their employment, noted that "we need to start challenging employers' perceptions of individuals with autism" by seeing them facing the structural barriers to employment. Furthermore, they also found that maintaining relational

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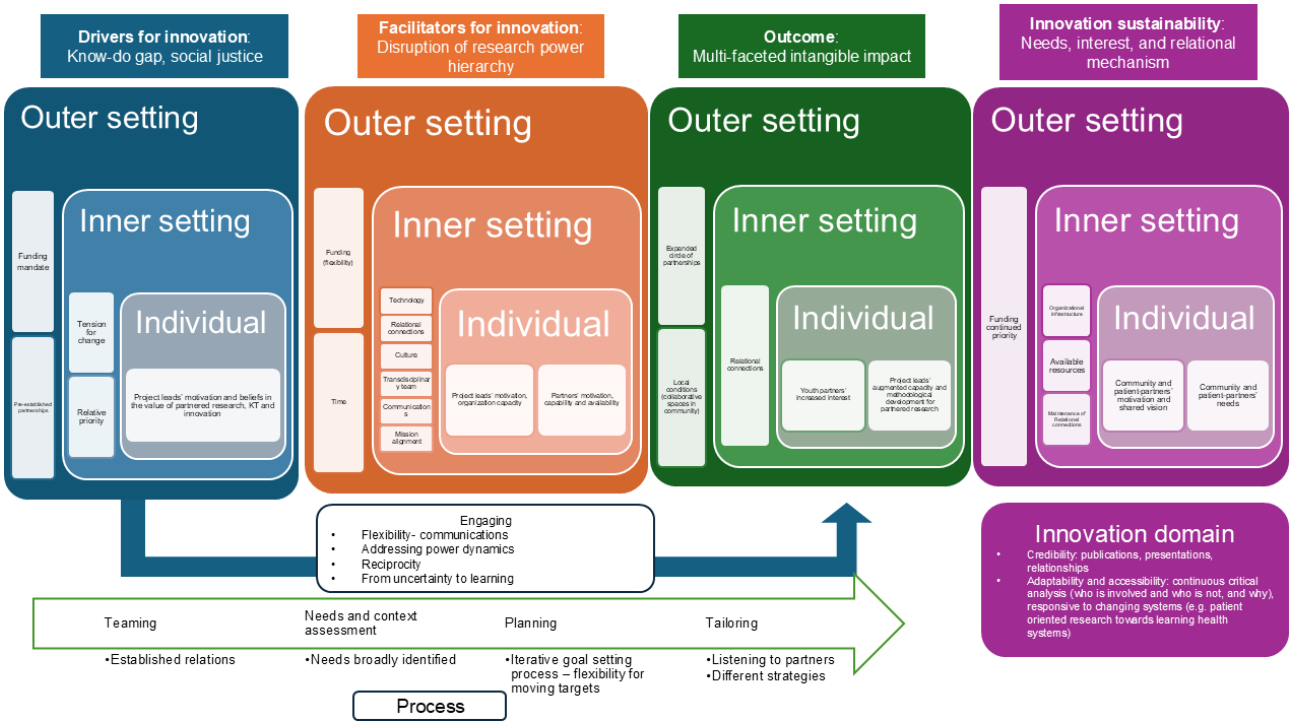
connections and networks that are aimed to be created by the developed platform can be a barrier to sustainable use, as people's needs can shift while the employment situation is always changing.

Discussion

Interconnected Contextual Factors

A range of contextual factors in different domains of the CFIR framework (outer settings, inner settings, and individual characteristics) are interconnected to shape the unique process of innovation development in each case (Figure 1).

Figure 1. Overall findings with CFIR constructs. CFIR: Consolidated Framework for Implementation Research.



Driver for Innovation: Closing the Know-Do Gap

In addition to resources such as funding and existing partnerships, identification of a clear know-do gap was a major driver for innovation development [24,25]. In four cases (Projects 2, 3, 6, and 7), a social justice lens focusing on the human rights of young people with disabilities was a driver for innovation development. Although little attention has been paid to social justice and equity in iKT discourses [24-26], these cases demonstrate that social justice can be a critical starting point for KT efforts to advance health equity.

Another critical driver for innovation development was researchers' attitude toward knowledge cocreation [27]. While the know-do gap was historically conceptualized as a problem of knowledge transfer (for instance, inadequate efforts to translate academic knowledge into practice), an iKT model considers the know-do gap as a problem of knowledge production [25]. In all cases, interviews reflected researchers' beliefs and philosophies in research partnership with patient-partners, which were also identified as facilitators for innovation development, and not only knowledge users.

Participatory Design in the Innovation Development Process

All research teams applied a participatory design approach where "participants are not only research subjects but also contributors to the design of a service of other outcome that will affect them" from the beginning of the project [28]. The collaborative process led to the creation of spaces where different types of knowledge were valued and shared, and solutions to address pressing real-world challenges were collectively created [29-33]. However, the existing hierarchies of value in knowledge systems are constructed against a background of social and institutional relations and cultural context [24,31,34]. Therefore, patient-partners' voices can be often neglected due to power imbalances or methodological structures for generating "valid" knowledge [35,36]. The issues of power imbalance encountered in the cases of this study were attenuated by a funding and reporting structure that valued and, in a certain way, regulated a collaborative and more equal structure [30].

This study highlighted the critical roles of researchers in making the research partners' tacit knowledge visible and turning the KT process into "collective making" [30]. The researchers' openness and listening to diverse views, respectful and accessible communication, and provision of multiple methods of participation facilitated relational connections and the team culture that recognizes people with lived experience as valuable knowledge partners [37]. Researchers also made intentional efforts to address the existing power difference by having a youth or a peer facilitator [35].

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For some researchers in this case study, building consensus was not easy due to tensions of leveraging lived experience [38,39]. Nonetheless, they made the cocreation process accountable, transparent, and authentic by showing the changes made based on their input and acknowledging their contributions [30].

The space of "collective making" was gradually built by generating research partners' interest in the process, as well as having knowledge translators, facilitators, and specialists, such as IT specialists as knowledge brokers.

The traditional knowledge-to-action approach tends to hold linear assumptions that knowledge comes first, and it underlies effective action and practices [40]. By contrast, in this study, uncertainty was an inevitable part of the process yielding innovations, requiring researchers' openness to changes and funders' flexibility.

Outcomes

In addition to the tangible KT products, all cases have reported different types of other intangible outcomes, including expanded research relationships that can be leveraged for knowledge mobilization and further research opportunities, as the knowledge cocreation process became a "relational design" [41]. Considering the transformational aspect of the iKT practice leading to innovation sustainment, we posit that capacity building and empowerment through research engagement and raising awareness through community engagement should be considered as the iKT's primary goal for effective knowledge uptake and sustainment of knowledge application [37,41].

Keeping the Innovation Sustainable

While accessibility and availability are commonly identified as the key to sustainable use and implementation of the innovative product, a variety of funding should be available since human and financial resources are necessary to keep the knowledge updated and accessible. The innovation sustainment often requires changes in local conditions and attitude (outer settings) to create a favorable socioeconomic environment to address inequality and injustices that people with lived experience are facing in their daily lives and in the health system. Therefore, including a strategy to bring a positive change in the local conditions and attitudes through community engagement is important during the creation of KT products [42].

Implications

While several recommendations for forming and maintaining research partnerships are already drawn and presented somewhere else [43], this case study using the CFIR highlights that iKT practices require additional time, effort, and resources for a long-term engagement with research partners [44]. To support the relationship building, iterative participatory design process, and sustainable uptake and use of the product, we recommend flexibility and diversity of funding [5]. We also suggest that funding, reporting, and regulatory structures are put in place to allow for projects to develop in a context of uncertainty, but having the collaborations and partnerships at the center of the requirements.

In parallel, uncritical emphasis on participation without a shift in power dynamics may pose a risk of turning iKT into a new label for tokenistic research relationships [45]. In this case study, researchers were reflective of whose voice is missing, and their characteristics mediated to foster a positive team culture that values lived experiences as expert knowledge. This finding reiterates the importance of a shift in researchers' mental models, as defined as "particular set of conceptual knowledge, expectations, and causal beliefs," in KT [46]. While academics are not traditionally trained or rewarded for their interpersonal skills, their design thinking, "a problem-solving approach that emphasizes empathy, collaboration, and iterative prototyping to develop innovative and human-centered solutions," should be better valued in academia [32,44,47,48].

Limitations

This study has limitations. Even though a total of 24 participants were interviewed from the KTII-awarded projects, the participation of patient-partners was limited. Researchers often felt that they had asked enough of their partners, and participating in one additional interview could be onerous. This is an important consideration for mandates for partner engagement in research. More first-hand accounts of patient-partners as co-knowledge creators, particularly children and young people, as well as information about group-level demographics of interview participants, might have provided a novel and in-depth understanding of effective engagement approaches and processes for innovation development. Case studies including intersectionalities, such as Indigenous research partnerships, would also be beneficial to learn how a transcultural lens can be applied to decolonize iKT practices and to define what we consider innovation and how we respond to needs in different contexts and populations. In addition, all KTII-awarded teams had established research relationships at the time of grant application. Therefore, even though inclusion and equality underlie participatory design [28], critical examination of structural participation barriers related to diversity, inclusion, and representation was limited. Lastly, the collected data did not necessarily include the long-term impact of innovations after the knowledge dissemination activities were concluded. Future studies should also measure the long-term knowledge uptake and its impact on social and health conditions and the sustainability of research partnerships with diverse teams of partners.

Conclusions

This case study showed multidimensional aspects of innovative KT in patient-oriented research, particularly (1) a clear know-do gap is an opportunity for innovations, (2) innovation is a process as well as an approach of creating new knowledge from lived experience and other expertise of various research partners, (3) innovation disrupts the traditional knowledge hierarchy and power imbalance in research, (4) innovation requires flexibility in timeframe and funding, (5) a challenge can be an opportunity for another innovation, and (6) innovation can bring not only tangible but also intangible outcomes at individual, organizational, and community levels. For successful innovative KT, the research landscape should also change in terms of funding and timeline in order to foster researchers' mental models in designing thinking and actions on collaborative research engagement.

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Acknowledgments

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Data Availability

The data that support the findings of this study are available to those who meet the criteria to access confidential data on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

Authors' Contributions

SY led data analysis and manuscript writing. AZ was involved in participant recruitment, interviewing, qualitative coding, and coordination of the study. KR, RC, and ZB were involved in the reviewing panel and qualitative coding. CP was involved in conceptualization, study design, qualitative coding, and analysis. KS was involved with conceptualization, study design, and supervision. All authors provided critical feedback and helped shape the research, analysis, and manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Interview guide questions.
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Multimedia Appendix 2
Drivers for innovations.
[DOCX File, 16 KB - jopm_v18i1e77581_app2.docx]

Multimedia Appendix 3
Facilitators for innovations.
[DOCX File, 17 KB - jopm_v18i1e77581_app3.docx]

Multimedia Appendix 4
Barriers to and challenges with innovation development.
[DOCX File, 15 KB - jopm_v18i1e77581_app4.docx]

Multimedia Appendix 5
Enablers to sustainable use of the knowledge translation product.
[DOCX File, 17 KB - jopm_v18i1e77581_app5.docx]

Checklist 1
GRIPP2 (Guidance for Reporting Involvement of Patients and the Public, second version) checklist.
[DOCX File, 18 KB - jopm_v18i1e77581_app6.docx]

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Abbreviations

CFIR: Consolidated Framework for Implementation Research
CIHR: Canadian Institutes of Health Research
iKT: integrated knowledge translation
KT: knowledge translation
KTII: Knowledge Translation Innovation Incubator
SPOR: Strategy for Patient-Oriented Research

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Patient Preparation in Walk-in Clinics Through the Implementation of a Consultation Preparation Sheet: Qualitative Study

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Abstract

Background: Effective communication is essential for high-quality care, yet in walk-in clinics, patients often have limited time to prepare, and physicians face challenges in understanding patients' needs due to lack of prior contact. To address this, a consultation preparation sheet (CPS) was developed to help patients articulate their symptoms, concerns, and expectations.

Objective: This study aimed to explore the implementation and perceived usefulness of a CPS designed to support patient preparation during walk-in clinic consultations.

Methods: We conducted a qualitative exploratory study using semistructured interviews and focus groups, with data collection informed by the RE-AIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance) framework and the PACE (prepare, ask, check, and express) method. The CPS was implemented over 9 months (January-October 2019) in a university-affiliated walk-in clinic in Quebec, Canada. During this period, 3115 patients received the CPS in the waiting room. Of the 23 patients who expressed interest in further participation, 12 were recruited for interviews. Additional participants included 2 physicians, 2 administrative staff, 2 nursing assistants, and 1 clinic manager. In total, 6 interviews and 5 focus groups were conducted. Data were transcribed verbatim and thematically analyzed, with AI-assisted review used as a supplementary check on data coverage.

Results: Patients generally found the CPS helpful for organizing their thoughts, reducing stress, and avoiding omissions during consultations. It was considered particularly useful for patients with multiple concerns or communication difficulties. However, physicians rarely referred to the CPS, often preferring direct verbal exchanges. This lack of acknowledgment sometimes frustrated patients and diminished their perception of its usefulness. Organizational challenges—including inconsistent distribution, lack of explanation, and an unclear workflow—further hindered implementation. Participants suggested clearer communication about the CPS's original purpose, earlier access through electronic formats, and brief clinician acknowledgment when patients chose to share their priorities.

Conclusions: The CPS shows promise as an optional patient-preparation tool for walk-in consultations. Earlier access and a clear explanation may support its use without requiring formal clinician review; brief acknowledgment may suffice when patients choose to share their priorities. Future studies should assess improved practice implementation strategies and digital adaptations.

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KEYWORDS

patient participation; physician-patient relations; primary health care; patient engagement; communication tools; qualitative research; implementation science; patient-centered care

Introduction

Background

Physician-patient communication is central to disease management, relying on mutual collaboration, in which physicians provide medical expertise and patients share their experience of the illness [1,2]. Effective collaboration requires dialogue to identify health issues and their impact on the patient's life [3]. Beyond biomedical aspects, patient-centered communication enhances information retention, treatment

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adherence, stress management, and trust in the health care system [4-10].

Effective clinical communication depends in part on patients' ability to contribute actively to the consultation, particularly by providing information to physicians for accurate diagnosis and treatment [11]. Cegala [12] defines participation through 4 dimensions: seeking information, stating preferences or opinions, providing information, and expressing concerns. This approach helps physicians address patients' ideas, fears, and expectations. However, barriers such as wait times, consultation duration, health literacy, language, and trust levels affect participation [2,12-15].

Studies indicate that methods and tools supporting patient preparation improve question-asking and information retention without extending consultations [2,7,12,16-18]. These strategies take various forms. For instance, Cegala et al [19] developed the PACE (prepare, ask, check, and express) method to help patients organize their concerns during consultations. Other tools, like DocVisitGuide and question prompt lists, help guide the patient before, during, and after consultations [20,21]. However, these resources require prior training, which can be both costly and time-consuming, whereas online tools tend to offer more accessible alternatives [22-25]. In this context, *Discutons Santé*, a PACE-based website, was developed to enhance chronic disease management [22,25,26]. Users have reported increased engagement, reduced stress, and improved consultation readiness [25].

In addition to previously reported barriers to the use of web-based tools, such as limited digital literacy and internet access for some users [27], walk-in consultations pose challenges for *Discutons Santé* adoption. In Quebec and Canada, walk-in clinics provide quick access to primary care, especially for those without family physicians [28-31], reducing emergency department pressure [32]. However, this type of consultation may limit patient preparation time and weaken physician-patient relationships. The physician's lack of knowledge of the patient's history, as well as the absence of an established and ongoing trusting relationship between physician and patient, can weaken the quality of communication about the illness and needs [28,30,31].

To address these limitations, the consultation preparation sheet (CPS) was introduced in 2018, inspired by the *Discutons Santé* website and adapted for walk-in clinic patients. While there is no research, to our knowledge, on optimizing walk-in consultation exchanges, this study examines CPS implementation in a Quebec walk-in clinic and its perceived impact on consultation quality.

Study Objectives

Our objectives were to explore (1) participants' perceptions of barriers and facilitators to the implementation of CPS, (2) participants' perceptions of the characteristics, impact, and usefulness of CPS when consulting in walk-in clinics, and (3) participants' interests in the future use of the CPS, and suggestions for improving its implementation.

Methods

Study Design

This study is part of a broader mixed methods research design. The present paper reports the qualitative component, following COREQ (Consolidated Criteria for Reporting Qualitative Research) principles [33], with the completed COREQ checklist provided in Checklist 1.

Study Setting

The CPS was implemented over 9 months (January 6-October 4, 2019) in a walk-in clinic of an academic family medicine clinic affiliated with the Université de Montréal. In this clinic, family medicine residents see many patients and are supervised by attending physicians. This clinic, serving approximately 15,000 registered patients as of March 2019, was already familiar with and promoted the use of the *Discutons Santé* website [25].

Codevelopment and Pretesting of the CPS

Available in French and English (Multimedia Appendix 1), the CPS was codeveloped with patients and physicians and then pretested with 25 patients consulting at the hospital where the study is set (13 from the walk-in clinic and 12 from the emergency room of the hospital near the walk-in clinic) and 15 physicians from the same hospital (7 working in the walk-in clinic and 8 in the emergency room) to assess and refine its relevance, format, and content. Administrative staff contributed to its implementation evaluation but not to its initial design.

The CPS comprises 10 multiple-choice and 6 open-ended questions. It was designed for approximately a 6th grade reading level to facilitate completion in the waiting room, including patients with more limited literacy skills.

The CPS covers both the biomedical and experiential dimensions of semiurgent consultations: (1) reason for consultation, (2) patient concerns, (3) expectations from the consultation, and (4) discomfort level and impact on daily activities.

Implementation Process

This pragmatic implementation project was first defined collaboratively by the project coordinator, the clinic manager, and a nursing assistant. No formal training was developed by the project team for clinicians (physicians, family medicine residents, and nurses); however, they were informed that the CPS would be offered to patients. The responsibility for introducing the tool to all clinicians was left to the clinic manager, who had flexibility in how this was carried out. In practice, the tool was typically introduced during regular weekly team meetings. Upon arrival at the clinic and confirming their presence with the administrative staff at reception, patients were invited to complete the CPS in the waiting room before seeing the physician. Administrative staff were responsible for distributing the CPS (an example script for explaining the CPS to patients was provided). Patients were encouraged to share the CPS with their physician if they wished, while physicians were encouraged (but not mandated) to review its content when presented by patients.

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Participants and Recruitment Process

Sample Size and Recruitment

Given the exploratory nature of this qualitative study, no a priori sample size was given in advance. Recruitment followed a pragmatic approach: all eligible participants who expressed interest and could be scheduled within the study time frame were invited to take part. The final sample was therefore shaped by participant willingness, availability, and the time constraints of the implementation project, rather than by a predefined numerical target. The aim was not statistical representation, but to obtain sufficiently rich accounts from the different participant groups involved in the implementation of the CPS.

Patients

Of the 4297 patients invited to participate, 3115 (72.5%) received the CPS in the waiting room prior to their consultation. Between August and October 2019, an optional appreciation questionnaire was also offered. Its purpose was to gather patients' impressions of the CPS and to allow them to indicate their interest in joining a focus group or participating in a semistructured interview.

Eligibility criteria included having previously completed the CPS, being 18 years of age or older, and being able to read and speak either French or English. Two hundred patients received the appreciation questionnaire. Of the 23 who expressed interest in participating further, 12 were ultimately recruited for interviews, including 8 men and 4 women. The reduced number was due to some patients later declining, being unreachable, or too much time having passed since their initial expression of interest.

Health Care Professionals and Administrative Staff

Physicians, nurses, administrative staff, and a manager were invited to take part in a focus group or a semistructured interview at the end of the project to share their experiences, with eligibility requiring that participants work at the clinic during the CPS implementation and attend to patients in walk-in consultations during the project. Physicians and nurses were approached through the administrative manager and via email by the research team, while administrative staff were approached through the administrative manager. The clinic manager was approached in person. The research team was not provided with information on the number of eligible staff who did not participate or the reasons for nonparticipation; no information on participant withdrawals was available. Participants included 2 family physicians (a woman with 11 y and a man with 3 y of clinical experience), 2 female nurses employed at the clinic for over 10 years, 2 female administrative staff members with more than 15 years of experience at the clinic, and a male clinic manager aged between 40 and 50 years who had occupied this position for 5 years.

Ethical Considerations

The study was approved by the Scientific and Ethics Committee of the Laval Health and Social Services Center (study: 2018 - 2019/01-03-E).

Before interviews and focus groups, all participants provided written consent, and every effort was made to protect participants' confidentiality. Only the interview data are presented here.

Participants received a snack during focus groups but no financial compensation.

Data Collection

Interviews and Focus Groups

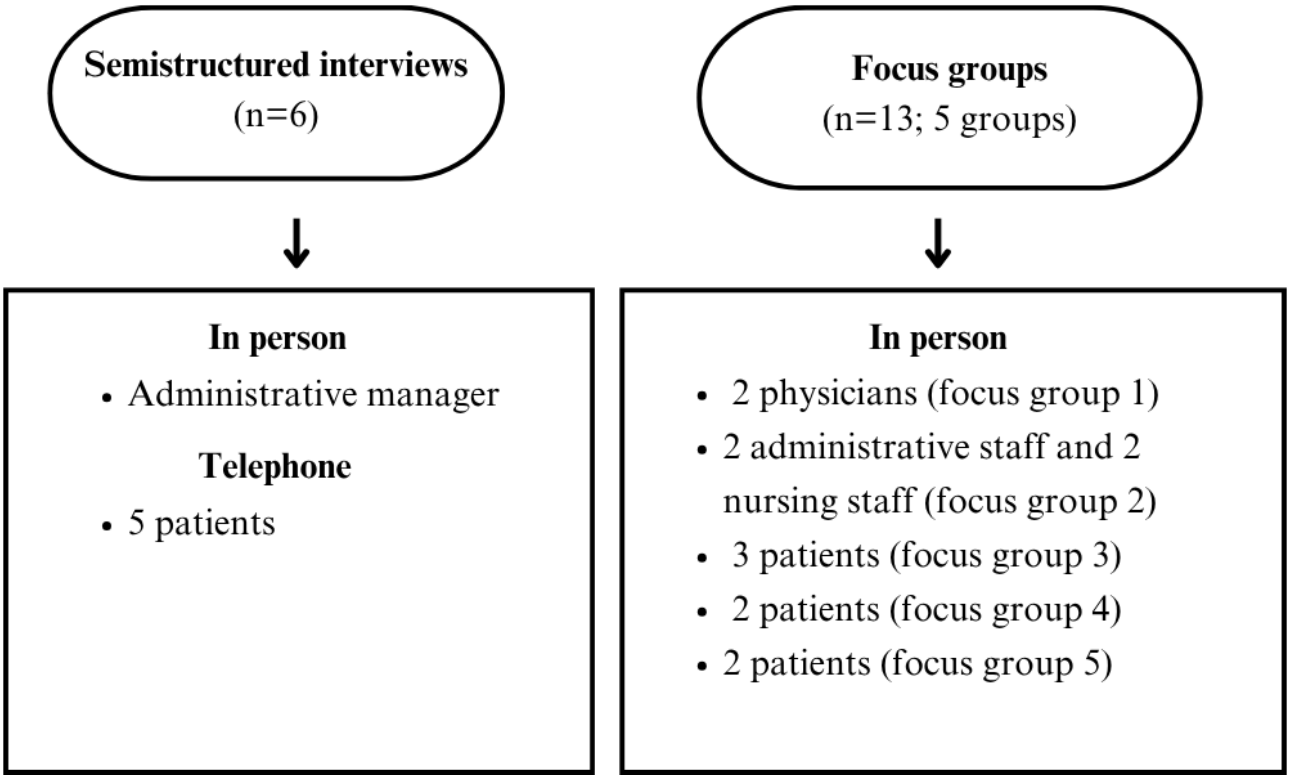
Interviews and focus groups were conducted by MEL, female, who was a research associate at the time of the study and held a PhD. She had more than 15 years of experience and training in qualitative interviewing. No relationship had been established with participants before recruitment. Participants were informed of the interviewer's role and the purpose of the study and were reminded before each interview that the discussion would focus on their experience with the CPS.

Between October 2019 and January 2020, interviews and focus groups were scheduled based on participant availability. We held sessions with health care professionals (nurses and physicians), the manager, and administrative staff in a private clinic room, ensuring confidentiality. We conducted patient focus groups in the same setting, while those unable to attend participated in individual telephone interviews. No one other than the participants and the researcher conducting the interview or focus group was present during the sessions.

In total, we conducted 6 semistructured interviews (1 in-person interview with the administrative manager and 5 telephone interviews with patients) and 5 in-person focus groups. These included physicians (focus group 1), administrative and nursing staff (focus group 2), and patients (focus groups 3 to 5). These were distributed as described in Figure 1. Sessions lasted approximately 30 to 60 minutes, for a total of 6 hours of audio-recorded material. All sessions were recorded and transcribed verbatim; no formal field notes were taken during or after the interviews or focus groups. No repeat interviews or follow-up interviews were conducted. Transcripts were not returned to participants for comment or correction, and participants were not asked to review or validate the study findings.

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Figure 1. Participant distribution by role and method.



Interview Guides

Patient and physician interview guides (Multimedia Appendix 2) largely followed the PACE approach [19]. Patient discussions explored prior knowledge of the *Discutons Santé* website, first impressions of the CPS, its use in consultation (consideration of the CPS by the physician, verification of information, description of symptoms, expression of concerns and questions to ask the physician, possible effects on stress reduction, an active role in the consultation, and structure of the encounter), interest in the future use of the CPS, and improvement suggestions. Physician interviews examined CPS walk-in clinic implementation, perceived usefulness, consultation and workflow impact, communication quality, interest in the future use of the CPS, and improvement suggestions.

For the manager, administrative, and nursing staff, interview guides largely followed the RE-AIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance) framework, as described by Glasgow et al [34], which evaluates the impact of health interventions and their implementation into care. The discussions covered implementation challenges, perceptions of the CPS, workload impact, and improvement suggestions.

These frameworks served as sensitizing frameworks to guide data collection rather than to structure the analytic process or the presentation of results.

Analysis

Thematic Analysis

To analyze participants' experiences and perceptions regarding the CPS, a thematic analysis was conducted, following the steps described by Braun and Clarke [35,36] and listed below. This method allowed themes to be developed iteratively from both the study questions and the interview data. The following steps were followed: (1) the main analyst repeatedly listened to interviews and transcribed them during data familiarization. (2) The main analyst generated codes by matching verbatim responses to interview questions (predefined codes) and supplementing them with new codes coming from emerging topics spontaneously introduced by participants. (3) The main analyst searched for themes by grouping responses according to the type of participant (patients, clinicians, staff, or managers). (4) The main analyst reviewed and iteratively refined the themes, and the supervisor validated them. (5) Defining themes involved both the main analyst and the supervisor agreeing on the final themes.

The analysis did not rely on a formal coding tree developed in advance. Instead, it followed an iterative process of thematic construction based on the interview material. After each interview or focus group was transcribed and reviewed, its content was examined in relation to the study questions and to the themes already identified in the preceding material. When a participant introduced elements that had not yet been represented in the analysis, these were added to the evolving thematic structure. When material corresponded to themes already identified, it was used to enrich, nuance, or contrast those themes. In this way, the analytic process consisted of progressively building thematic presentations that brought together convergent, divergent, and complementary perspectives across interviews and participant groups. This process continued throughout the full corpus.

Thematic sufficiency was considered to have been reached when successive interviews no longer contributed substantively new thematic elements but rather added variation, illustration, or nuance to existing themes. One researcher, the main analyst

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(JB), performed the primary coding of the full dataset. No dedicated qualitative data-analysis software was used.

Supplementary AI-Assisted Data Coverage Check

In addition to regular discussions between the main analyst and the supervisor, ChatGPT-4o (OpenAI) was used as a limited supplementary tool for a language-based data coverage check during the analytic process, in line with recent studies exploring the potential contributions of this tool in qualitative and thematic analysis [37-39]. Specifically, it generated a separate categorization of excerpts to help identify potential blind spots, overlaps, omissions, or alternative ways of grouping the data. The AI output was not treated as an independent coder, and no interrater agreement was calculated or used as a marker of rigor. Instead, the research team compared the AI-generated output with the developing thematic structure and critically assessed whether any suggested distinctions or groupings were conceptually relevant and supported by the data. All interpretive decisions remained the responsibility of the research team. The AI-assisted review, therefore, served as a supplementary analytic sense-check intended to strengthen data coverage, not as a reflexivity or validation procedure. Importantly, ChatGPT was not used to generate theoretical interpretations.

We adjusted ChatGPT parameters to ensure participant confidentiality and made sure that no personally identifiable information was entered into the platform. We conducted the verification according to the following process: (1) Verbatim compilation involved compiling all responses, with the type of participant (patient, physician, manager, administrative staff, or nursing staff) identified for each statement. (2) The AI-assisted data coverage check involved ChatGPT generating an independent language-based categorization of the anonymized excerpts. (3) The comparison involved the research team comparing this output with the developing thematic structure. (4) The discrepancy review found high convergence for explicit content. Differences from implicit inferences were examined, discussed, and resolved by consensus between the main analyst and the supervisor. The necessary adjustments were made.

Research Team Positionality

This study was conducted by a multidisciplinary research team with expertise in health communication, primary care, and qualitative research. Some members of the team had previously been involved in the development and implementation of the *Discutons Santé* platform, from which the CPS was derived. This prior involvement provided in-depth knowledge of the intervention and its intended use, but it may also have shaped expectations regarding its relevance, feasibility, and uptake in clinical practice. To address this, particular attention was paid during data collection and analysis to participants' critical, ambivalent, or negative perspectives on the CPS in order to avoid privileging confirmatory interpretations.

In addition, 3 members of the research team, including the main analyst (JB) and the patient partner (CD), had not been involved in the implementation of the project, which contributed to a more external and critical perspective on the data, while the involvement of a patient partner also ensured the integration of the patient voice in the interpretation of the findings. Interpretive decisions were discussed iteratively between the main analyst and the supervisor, and emerging themes were reviewed by all authors in light of both supportive and disconfirming cases.

Results

Summary

This research highlights key points regarding CPS implementation and use. Table 1 summarizes findings from the interviews. The themes are presented in greater detail in the section below, with illustrative quotes from participants.

Table . Summary of key themes across participants.

Themes	Patients	Physicians	Manager and administrative/nursing staff
Implementation of CPS[a]	Lack of explanation; often not shared with physicians	Low familiarity with the tool; lack of explanation	Increased administrative workload; unclear transmission process; unoptimized flow
Use in consultation	Rarely used	Rarely used; preference for verbal communication	Not systematically provided to physicians
Perception of benefits	Helps structure ideas; reduces stress	Useful for disorganized patients or with multiple issues; supports prioritization	Clarifies expectations
Barriers encountered	Ignored by physicians	Lack of time; limited implementation	Internal communication and organizational issues; low physician interest
Suggestions for improvement	Early access to CPS; electronic version	Early access to CPS; need for training and systematic implementation	Improve internal communication; need for more structured support

[a]CPS: consultation preparation sheet.

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Implementation of CPS in the Clinic

Workload

Administrative staff experienced an increased workload with CPS, especially when managing multiple forms. However, health care professionals (nurses and physicians) reported no significant impact on their workflow, stating that CPS implementation neither disrupted their activities nor changed their work approach.

Distribution and Circulation of the CPS

Interviews revealed internal organizational issues, particularly between health care professionals and administrative staff regarding managing the distribution and circulation of the CPS. Patients said the way they submitted their CPSs varied: 4 gave them to a nurse, 2 to a physician, and physicians interviewed sometimes found them on their desk. The limited time in the waiting room has been identified as a barrier by the manager, administrative, and nursing staff, making it difficult to distribute and fully complete the CPS before patients are called into the exam room. Consequently, some patients filled it out partially during consultations with a nurse.

> *Sometimes they [patients] are with us, and the nurse already calls the patient before we finish giving the form […] some completed it while waiting after seeing the nurse.* [Administrative staff 2]

Lack of communication and explanation about the CPS caused confusion among patients and physicians. While the manager said some physicians were interested in the tool, others seemed unaware of its existence and did not integrate it into their clinical routine. The 2 interviewed physicians noted that family medicine residents often asked questions about the CPS, indicating limited familiarity with the implementation of the tool. According to administrative and nursing staff, some physicians' lack of interest affected follow-up efforts regarding the reception of CPS by physicians.

> *And I've even had residents go, "What am I supposed to do with this?"—you know, they'd come back with the form like, "What do I do with this?" And I'd be like, "Well, it's to see, you know, why the patient's here, whether we're going to meet their expectations—it helps guide the purpose of the consultation.* [Physician 2]

Regarding the involvement of physicians, the manager mentioned a significant barrier: the clinic, which is affiliated with a regional hospital, was, at the time of the CPS implementation, undergoing its periodic 5-year accreditation by Accreditation Canada, so CPS was not seen as a priority.

According to the administrative and nursing staff, some patients also complained about having to complete the CPS during return visits. This task was demotivating for them when patients did not understand the purpose of the tool.

> *Me, I think that once the form is gone, it's really…our role is to hand it in, yeah, to check it, and bring it…to pass it on to the resident physician, but at that point, it's up to them. And I've said it to them often. I went to see [manager] and I said, look, we're being told they won't read it and that they don't even look at it.*
>
> *[Nurse]*
>
> *That's not very motivating.* [Administrative staff 1]

Overall, the manager and staff stressed the need for better project oversight and internal communication. As an implementation facilitator, clinician acknowledgment of the CPS was consistently described as important to successful implementation, with suggestions to leverage existing committees and to conduct regular surveys to assess team understanding.

Characteristics of the CPS (Format and Content)

Despite organizational and communication limitations affecting the implementation of CPS in the clinic, as stated in the previous section, the CPS format and content received overall positive feedback from the manager, administrative, and nursing staff. Among the 12 patients interviewed, 8 were unfamiliar with the *Discutons Santé* website before the study. When asked about their reactions to the CPS, 5 expressed a positive response, while 3 reported confusion or avoidance, which they attributed to a lack of explanation regarding the CPS purpose.

> *I was very pleasantly surprised. I've been going to the family medicine clinic for several years, and I discovered the form at the end of the summer. So it was my first experience with it, and my first impression was really, really positive.* [Patient 2]

Patients and physicians found the CPS simple and quick to complete. 4 patients deemed the symptom-related questions relevant, while opinions were mixed regarding questions about concerns (1 found them useful vs 3 unnecessary), discomfort (3 useful vs 2 unnecessary), and consultation expectations (4 useful vs 4 unnecessary). One argument against the questions about concerns and expectations was that it seemed self-evident: people naturally worry when seeking care, and they expect to understand their condition and receive solutions.

> *But of course [in response to the question about expectations], you want to be relieved, you want to know what you have. It seems logical to me—it's automatic. If you're going to consult, it's because you want to understand what's going on.* [Patient 3]

However, 1 patient cited format challenges, including literacy barriers and language selection.

> *Like I was saying earlier, there might be an issue for people who are illiterate — you might need to find another way if you want to implement that document.* [Patient 6]

Physicians found the CPS questions relevant in the walk-in context, particularly those regarding repeated consultations for the same issue.

Perceived Impact and Usefulness of CPS in Consultation

CPS Benefits

Participants—including patients, physicians, managers, and staff—acknowledged that the CPS could help patients better

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prepare for consultation. In particular, it would allow them to structure their thoughts and avoid forgetting important points to discuss. Five patients found it useful for organizing their concerns and communicating effectively.

> *I would say that I was better equipped thanks to the CPS. When you're better equipped, you feel more at ease, you communicate more easily with your doctor, so in that sense, it was beneficial.* [Patient 2]

Some patients reported positive effects, including stress management and the ability to better identify their needs and level of discomfort. However, 4 patients did not find the CPS beneficial, citing reasons such as the physician's disregard for it, a consultation for a baby where the CPS was deemed inappropriate, or health issues considered too simple or obvious.

Beyond individual experiences, the majority of patients (n=8) recognized broader advantages: avoiding omissions (n=6) and taking a more active role in consultations (n=5). Two patients highlighted increased patient responsibility:

> *There is certainly an awareness of the responsibility we have as patients. That is, we realize…it's not true that the doctor can know everything. They could run a full set of tests while we remain completely silent, but they need to talk to us because our lived experience is essential to properly complete the consultation. So, I think it fosters a sense of responsibility in that regard […].* [Patient 11]

Half of the patients interviewed (6/12) recognized that preparation is crucial for effective consultations, and 2 generally considered themselves to be well prepared. Three mentioned that they saw CPS as particularly useful for children, older adults, or those with communication or memory difficulties.

Physicians, unfamiliar with patients before consultations, found it difficult to assess the CPS's impact but acknowledged its role in addressing concerns and managing expectations. They also noted that some patients relied on the CPS to make sure they didn't forget anything. Finally, they acknowledged that the CPS could be useful for structuring discussions during consultations, particularly with patients who have multiple issues or a disorganized presentation in the context of walk-in clinics:

> *[…] In consultations, as we were saying, walk-ins are often focused on a single issue. Sometimes, a patient comes in with what we call a 'grocery list'—five, six, seven, or even eight problems. Being able to prioritize them a little, to see what is most urgent or not, already gives the patient a useful exercise […]. So, I think it's beneficial in a walk-in setting […].* [Physician 1]

According to the manager, while physicians were divided on the CPS's value, those who used it noted time-saving benefits. Administrative and nursing staff emphasized its role in clarifying patient expectations and facilitating collaboration on health issues, especially during first-time visits.

Barriers to CPS Use During the Consultation

Despite its advantages, among the 12 patients interviewed, 8 did not show the CPS to their physician, citing reasons such as perceived physician disinterest (n=1), discomfort with the physician (n=1), or the belief that their issues were self-evident (n=2). Only 1 patient actively presented and discussed the CPS during the consultation. Although most patients did not bring it up themselves, many were disappointed that the CPS was not acknowledged. Eleven patients observed that their physicians did not refer to it at all or did so only rarely during consultations. This lack of consideration led to varied reactions: 5 patients expressed surprise, disappointment, or frustration, while 3 felt that completing the CPS had been redundant or unnecessary.

> *The doctor has to get that to use this, they need to read it, they need to be interested in reading it, definitely. If this doesn't get read, then there's no point to the whole thing.* [Patient 1]

Physicians confirmed infrequent use of the CPS and expressed preferring direct verbal interactions with the patient. All participants stressed that physician engagement was important to avoid patient frustration. Three patients found completing the CPS beneficial regardless of physician use, but 5 questioned its relevance if not acknowledged. Two stated that neglecting the CPS negatively impacted the physician-patient relationship.

> *The most important thing is the physician, because it is the contact between the physician and the patient. I think both of them should get to know each other better. […] It wasn't my family doctor, I understand that, but I expected him to read […].* [Patient 9]

Future Use of the CPS and Suggestions for Improving Its Implementation in Clinical Routines

Most participants supported the future use of the CPS. Seven patients expressed their intention to continue using it, particularly when consulting unfamiliar physicians, addressing new health concerns, or during infrequent visits. In contrast, 3 participants found the CPS less relevant for routine appointments with their regular physicians.

Participants proposed several ways to enhance its implementation into clinical routines. A key suggestion shared among participants was the need for clearer communication—to ensure that all stakeholders understand the CPS's purpose, benefits, and link to the *Discutons Santé* website. Patients also expressed a preference for accessing and completing the CPS before their clinic visit, allowing physicians to review it in advance and be better prepared for the consultation.

> *In most cases, I would say I would like to have a sheet before leaving in the morning […] to make a summary of what I'm going to talk to them about, the issues I have, and everything.* [Patient 5]
>
> *So, having the CPS before going to the clinic?* [Interviewer]
>
> *Mmmhm. [And] for the doctor to have time to review it.* [Patient 5]

Electronic access was widely suggested, including via mobile apps, appointment confirmation links, or interactive waiting-room kiosks. Physicians proposed centralized digital platforms or physical drop-off points near their desks to improve accessibility. They recommended providing the CPS directly

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to physicians rather than to family medicine residents, in order to encourage greater involvement from physicians.

Enhancing Adoption and Promotion

Participants' Suggestions for CPS Implementation

The participants' suggestions can be grouped into 3 main categories: better explanation of the CPS, better adoption of CPS usage by clinicians and administrative staff, and promotional tools to use. These initiatives could not only improve the implementation of the CPS but also maximize its impact on the quality of consultations and the overall patient experience.

Explanation of the CPS and Its Usefulness

Adding a brief explanatory text to the CPS, distributing an informational sheet during consultations, or integrating it into clinic onboarding kits were recommended. Strengthening its connection with *Discutons Santé* was also suggested.

Clinician and Staff Involvement

The importance of involving clinicians and administrative staff to encourage patient use of the CPS was recognized by both patients and the manager. The manager noted that support from respected physicians could significantly impact its adoption, while patient testimonials about how the CPS improved their consultations could also persuade others to use it.

Promotional Tools

Patients recommended posters, social media, and phone wait-time messages to increase the visibility of the CPS and the *Discutons Santé* website. The manager suggested PowerPoint presentations, and volunteers in waiting rooms could introduce patients to the CPS and *Discutons Santé* without burdening staff.

Discussion

Evaluation of the Achievement of Objectives

Interviews and focus groups reveal that most patients found the CPS helpful in structuring their thoughts and preparing for walk-in consultations. These findings align with previous studies on preparation tools, such as question prompt lists [18,20,21]. However, even when patients perceived a personal benefit, many waited for clinicians to acknowledge or legitimize its use during the encounter.

This pattern reflects prior findings showing that patient preparation often depends on clinician encouragement [20,21]. It also echoes participatory medicine theories emphasizing that patients' participation is shaped by implicit role expectations and by physicians' legitimization of participatory practices, with patients often expecting clinicians to initiate or validate the use of such tools [40]. Although the CPS was designed primarily for patient use, these findings suggest that this purpose needs to be clearly communicated when introducing the tool.

Physicians preferred direct verbal interaction and were often unaware of the CPS. In high-flow walk-in clinics, clinicians face competing priorities and limited time [31]. These findings support an approach that does not require clinicians to formally review or manage the sheet; brief acknowledgment may nevertheless help legitimize patients' preparation [20,21].

Earlier or electronic access may facilitate patient preparation, but digitalization alone would not address the relational and professional norms identified here. Patients may still hesitate to introduce the CPS when its optional purpose is unclear or because of deference to medical authority, while clinicians' nonuse may reflect established routines. Thus, nonuse should not be understood solely as an implementation failure, but also as a practice embedded in the social organization of care.

Finally, although the CPS aims to enhance patient participation, interviews offer little exploration of this. The theories of Cegala et al [11,12,19] emphasize addressing the psychosocial dimensions of illness for appropriate treatment, but not all interviewed patients recognized the relevance of such questions. For example, several did not understand the usefulness of discussing their concerns, even though it seemed logical to them to be worried when seeking care. This may stem from insufficient explanation of the CPS's purpose. Thus, despite the literature on its benefits, patients may not feel the need to share their concerns during consultations, assuming these are implicit. This may also reflect the idea that they do not see themselves as active partners with valid experiential knowledge.

Problems With the Implementation of CPS

One of the main challenges identified in our study is the lack of information and support surrounding the implementation of the CPS, despite efforts being made to explain it by the research team. The implementation problems appear to reflect a mismatch between the research team's assumptions and the clinic's actual readiness. Previous experience with the *Discutons Santé* website may have led the team to overestimate familiarity with the CPS, while no standardized workflow was established for explaining, circulating, or acknowledging the tool. Implementation also coincided with the clinic's accreditation period, which may have reduced attention to a new initiative.

Patients retained the choice to present the CPS, but the clinic had no clear process for explaining this option or responding when they did so. A predictable, brief acknowledgment when patients chose to share it could support its use without creating a mandatory review task. Participants also recommended providing the CPS in advance, consistent with prior studies [21]. Clinics could, therefore, standardize how the CPS is offered and explained while adapting the process to local realities.

The implementation challenges observed in our study reflect barriers identified in the literature. Lau et al [41] highlighted that factors such as institutional policies, organizational culture, and available resources play a crucial role in the adoption of innovations in primary care. These elements are particularly relevant in high-flow primary care clinical settings where pressure on resources and time can hinder the implementation of new tools aimed at improving patient preparation and engagement.

The findings can be interpreted through the complementary lenses of PACE and RE-AIM, which informed the design of the study. From a PACE perspective, the CPS appears to facilitate the "Prepare" component most directly and, to some

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extent, supports patients in asking, checking, and expressing themselves more clearly during the encounter. However, the findings also suggest that preparation alone does not guarantee active use of the tool during the consultation. When physicians did not acknowledge the CPS, many patients did not feel legitimized to mobilize it, which limited its contribution to a more reciprocal form of participation.

From a RE-AIM perspective, the study highlights that the main challenge was not only the perceived usefulness of the tool, but also its implementation into routine practice. Reach was substantial in that many patients received the CPS, but the findings suggest that receipt did not necessarily translate into meaningful uptake, especially when the purpose of the tool was not clearly explained or when time constraints limited its completion. Effectiveness, as perceived by participants, was mainly related to improved preparation, reduced stress, and better organization of concerns, but these benefits were diminished when the tool was not recognized during the consultation. Based on the data collected, adoption remained unclear due to lack of specific questions related to this part of the framework in the interview guide. Implementation was hindered by unclear circulation procedures, inconsistent explanation, and weak integration into the clinic workflow. Finally, participants' suggestions regarding earlier access, clearer communication, and digital formats point to conditions that may support future maintenance, but only if clinician acknowledgment and organizational support are also strengthened. Taken together, these 2 frameworks help to show that the CPS may support patient preparation at the interactional level, while its sustained value depends on stronger uptake at the organizational and clinical levels.

Research Limitations

This study has limitations. First, the 3-to-5-month gap between CPS use and interviews may have affected participants' recall accuracy. Thus, future research should implement strategies to better consider the on-site use of participants and prioritize real-time data collection. Second, only 2 physicians were interviewed, making it difficult to assume that their perceptions are shared by most physicians in the walk-in clinic. Limited physician access during implementation also likely influenced physician engagement. The AI-assisted comparison was used only as a supplementary data coverage check and not for interpretive sense-making.

Lastly, as the researchers conducted the study in a university clinic with a unique structure, results may not apply to other settings. Family medicine residents, who see many patients, were not interviewed. Additionally, the interviewed physicians supervised residents remotely, requiring careful interpretation of their insights.

Actionable Lessons for Other Walk-in Clinics

Our findings suggest practical lessons for walk-in clinics and other high-flow primary care settings seeking to implement patient-preparation tools such as the CPS: (1) at the organizational level, clinics should establish a clear process for offering the CPS as an optional patient-preparation tool and making it available before the visit. It need not be automatically transmitted to clinicians or formally reviewed by them. (2) At the relational level, the CPS should help patients identify and prioritize what they want to discuss. When patients choose to use it, a brief acknowledgment (eg, "Thank you for completing the CPS") may legitimize their preparation without adding a formal task for clinicians.

Conclusions

This study suggests that the CPS may be most feasible when used primarily to support patient preparation in walk-in clinics. It can help patients identify and prioritize what they want to discuss without requiring clinicians to formally review or manage the sheet. When patients choose to share their priorities, brief clinician acknowledgment may help bring them into the conversation.

Clear explanations, earlier access, and feasible clinic processes may support implementation. The CPS was codeveloped with patients and physicians, while administrative staff contributed to implementation evaluation. Future refinements could be coproduced through joint review by patients, physicians, and administrative staff, integrating both content and implementation perspectives. The explanatory summary and electronic access, now under evaluation, will be reported in future studies.

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Data Availability

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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Authors' Contributions

Conceptualization: MTL
Funding acquisition: MTL
Investigation: MEL
Methodology: CR, MHG
Project administration: MEL, MTL
Supervision: MTL
Validation: CR (colead)
Writing – original draft: JB (lead)
Writing – review & editing: JB (lead), CR (colead), MHG, MEL, VT (supporting), CD (supporting), MTL

Conflicts of Interest

CR is the spouse of MTL and is part of the research team submitting this article. He has received a salary (10 h/wk) for his work as one of the project coordinators. This relationship has been declared to the ethics department of the CHUM (Centre hospitalier de l'Université de Montréal) Research Center, MTL's university department, and the funding agencies, which have recognized his unique competency for this project and have approved his participation. The other authors declare no conflicts of interest.

Multimedia Appendix 1
Consultation preparation sheet, English version.
[PDF File, 223 KB - jopm_v18i1e83489_app1.PDF]

Multimedia Appendix 2
Interview guides.
[PDF File, 535 KB - jopm_v18i1e83489_app2.pdf]

Checklist 1
COREQ checklist.
[PDF File, 338 KB - jopm_v18i1e83489_app3.pdf]

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Abbreviations

COREQ: Consolidated Criteria for Reporting Qualitative Research
CPS: consultation preparation sheet
PACE: prepare, ask, check, and express
RE-AIM: Reach, Effectiveness, Adoption, Implementation, and Maintenance

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Using Participatory Methods to Create Informational Videos for Inclusive Brain Stimulation Research Recruitment: Action Research Study and Pilot Randomized Controlled Trial

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Abstract

Background: Black and Hispanic/Latino communities experience disproportionate chronic pain and are underrepresented in pain research. Transcutaneous auricular vagus nerve stimulation (taVNS) and transcranial magnetic stimulation (TMS) are promising tools for pain management. Therefore, it is critical to ensure that research using these tools engages all communities to make research findings more generalizable and reach all who may benefit. Lack of diversity in the research workforce itself is a key barrier to improving Black and Hispanic/Latino representation in pain research, and video-enhanced recruitment and consenting may be useful tools to better engage Black and Hispanic/Latino communities.

Objective: The primary goal of this project was to use participatory methods to develop informational videos for inclusive brain stimulation research recruitment.

Methods: Using community participatory research principles in an iterative process, key stakeholders were engaged in 2 consecutive studies to create and then test informational videos on taVNS and TMS. The key stakeholders included neuromodulation researchers as well as Black English-speaking, Hispanic/Latino Spanish-speaking, and Haitian Creole-speaking people with chronic pain. The first study involved iterative feedback from stakeholders through focus groups and interviews to develop test videos, which were then refined based on community member input. The second study was a pilot randomized controlled trial used to assess the impact of these videos on participant expectations for pain relief with taVNS.

Results: Twenty-five community members with chronic pain provided input into the development of the videos, which received overwhelmingly positive feedback. Twenty-eight people with chronic neuropathy were enrolled in the randomized controlled trial, with 24 completing the study. There was no significant difference in expectancy scores between participants who viewed the videos and those who received traditional brochures (median values of 8.2 for both groups; 95% CIs for the means of 7.2 - 8.7 and 6.4 - 8.7, P=.8).

Conclusions: These findings suggest that while the videos may improve engagement, they do not unduly influence expectations, potentially making them valuable tools for improving research participation in noninvasive brain stimulation research. These videos will be freely available to help researchers engage people from diverse communities.

Trial Registration: ClinicalTrials.gov NCT05896202; https://clinicaltrials.gov/study/NCT05896202

(J Particip Med 2026;18:e79311) doi:10.2196/79311

KEYWORDS

action research; recruitment; consenting; transcutaneous auricular vagus nerves stimulation; transcranial magnetic stimulation; video enhanced recruitment; community engagement

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Introduction

Black and Hispanic/Latino communities are disproportionately affected by chronic pain, with greater prevalence and worse outcomes than non-Hispanic White communities, yet these same communities are underrepresented in pain research [1-9]. Transcutaneous auricular vagus nerve stimulation (taVNS) and transcranial magnetic stimulation (TMS) are forms of noninvasive brain stimulation (NIBS) with great promise for improving pain management. In fact, there is rapidly growing interest in taVNS and TMS, as demonstrated by the >300 clinical trials currently investigating these interventions for pain (listed on ClinicalTrials.gov). However, underrepresentation of Black and Hispanic/Latino communities is particularly problematic in NIBS research due to a number of factors, including lack of diversity in the research workforce, incompatibility between the technologies and certain hair types and styles, and reluctance of Black and Hispanic/Latino populations to participate in clinical trials [10]. This reluctance is often rooted in a well-founded medical mistrust stemming from historical unethical research practices, such as the Tuskegee Syphilis Study, as well as ongoing experiences with systemic bias and a lack of cultural humility within the contemporary health care system [10,11].

It is critical that research on taVNS and TMS includes perspectives of people from these communities to ensure that the research reaches all of those who may benefit and to make research findings more generalizable. Achieving greater diversity in the NIBS research workforce is an important long-term goal for improving this problem. In the present, however, meaningful short-term efforts can be undertaken to improve the inclusion of participants representative of the overall population within NIBS research studies.

A commonly cited barrier to recruiting minoritized people for research is medical mistrust [11]. The best-known approach for overcoming this barrier is community-engaged research [12], and large centers with a history of community-engaged research have been found to offer better opportunities for Black and Hispanic/Latino groups to participate in research [12]. Unfortunately, community-engaged research methods can be challenging to employ, particularly for smaller institutions with limited resources.

Video-enhanced recruitment and consenting can be used to better engage Black and Hispanic/Latino communities, bridging the potential racial discordance between researchers and Black and Hispanic/Latino participants. Recent studies consistently indicate that video enhancement improves participant satisfaction [13,14] and improves understanding and retention of the information provided [15-17]. This is not surprising, as it is widely recognized that many learners experience more effective communication in visual formats such as video. In one of the largest studies on the topic, Fanaroff et al [18] compared the enrollment performance of text-only sites with sites using video enhancement in a multicenter study that included 7904 patients across the United States. Compared with text-only sites, the video enhancement sites enrolled more Black patients. Indeed, a systematic review concluded that "video interventions are well-received by (Black and Hispanic/Latino) survivors and may improve (Black and Hispanic/Latino) representation in clinical trials, yet they are underused." [13]

Video is increasingly used for getting information in today's world [19,20]. Information provided in video format is often perceived as more credible [21,22], and, when developed from an inclusive perspective, may help to engender better recruitment and retention rates [13,18]. Such videos may be used for informing communities, recruiting participants, and enhancing the consenting process. However, the development of informational videos must be done with care and with the participation of the communities themselves to avoid missteps that could cause further alienation. Additionally, patient expectations are known to influence pain outcomes [23-26], and it may be important to assess the influence that these videos may have on patient expectations. The primary goals were to (1) involve Black English-speaking, Hispanic/Latino Spanish-speaking, and Haitian Creole-speaking communities to develop informational videos on taVNS and TMS and (2) make these videos publicly available to provide informational materials for the field at large. Collectively, these goals were focused on providing a practical application to establish infrastructure, resources, and community relationships for a research agenda focused on equitable and inclusive research on NIBS for pain management, and the specific research questions (ie, video influence on expectations) were secondary.

Methods

Study Design

A "technical-scientific and positivist" [27] model of action research, with the intention of linking research to action, was used for this project. Action research is defined by a focus on generating solutions to practical problems (ie, poor recruitment of Black and Hispanic/Latino persons in NIBS research), and it is characterized by the use of participatory strategies [28]. The technical-scientific and positivist model of action research assumes that the investigators have greater initial research scope than the community participants; thus, in this project, the research questions and theoretical framework were set independently and a priori of interaction with community members, and the community participants acted as "on-the-ground feedback." [27] By researching and developing culturally sensitive videos, the intention was to provide the research team, and the field, with data and tools to enhance racial and ethnic diversity in NIBS research.

This project consisted of 2 studies. First, an iterative process was used to engage key stakeholders for input and feedback in the video development process (video production study, IRB No. 20230210). Then, the videos were tested in a feasibility pilot randomized controlled trial (Pilot RCT; ClinicalTrials.gov identifier NCT05896202). The pilot RCT was designed specifically to test the videos developed in the first study, and here we focus on the findings pertinent to the videos. Outcomes pertaining to research questions on feasibility, symptom response, and change in physiological measures with taVNS are published elsewhere [29].

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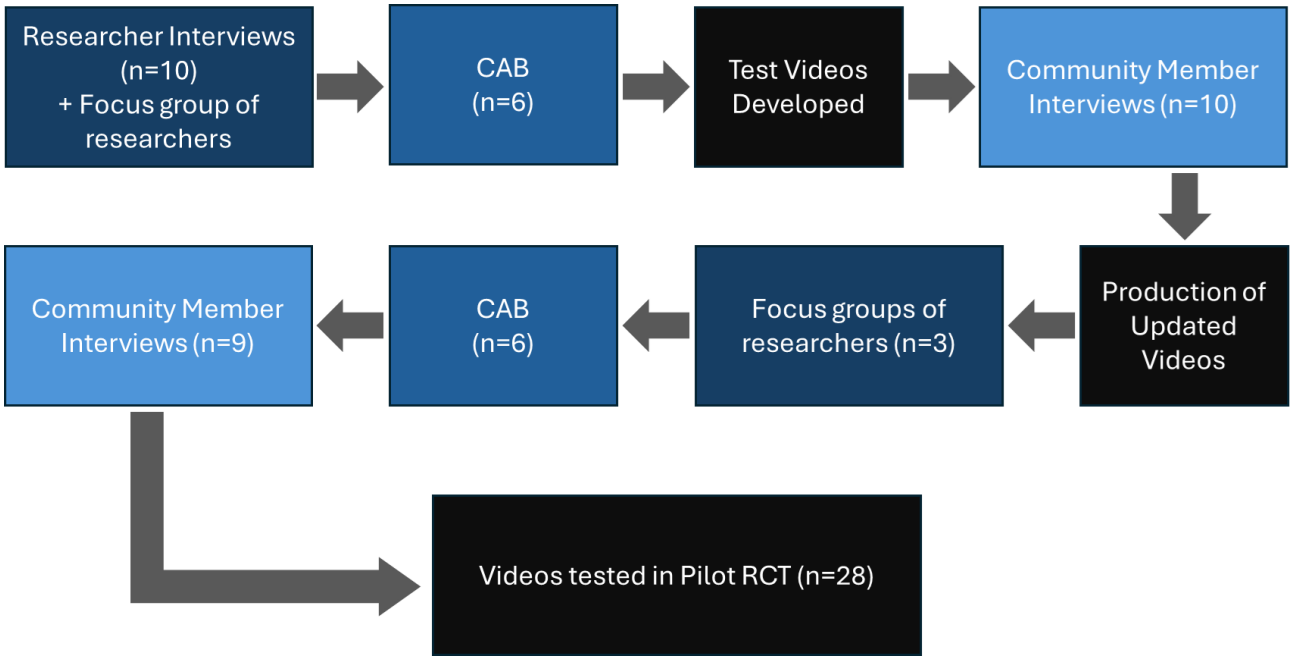
Ethical Considerations

For both studies, approval was granted by the University of Miami Institutional Review Board (20230210 and 20230154), and informed consent was obtained from all participants. Participants in the video production study were compensated US $100 for their participation in the interviews. Participants in the pilot RCT received a compensation of US $250 upon completion of all study activities. We deidentified all data, removed potentially identifying information from transcripts and quotations, and stored files on password-protected systems accessible only to the research team.

Patient and Public Involvement in the Research

Two representatives from each ethnic/racial group of interest (ie, Black English-speaking, Hispanic/Latino Spanish-speaking, and Haitian Creole-speaking) were recruited for the community advisory board (CAB), with a total of 6 CAB members. CAB members reported strongly identifying with their respective communities and reported that English, Spanish, or Haitian-Creole was their primary language. CAB members provided feedback on the research plan, recruitment strategy, test and final videos, and the interim summary findings and interpretations. Four of the CAB members also had chronic pain. Additionally, 2 rounds of interviews were used to engage 19 people with chronic pain from the target communities to provide feedback on the videos (Figures 1 and 2).

Figure 1. Participant involvement across studies. CAB: community advisory board; RCT; randomized controlled trial.

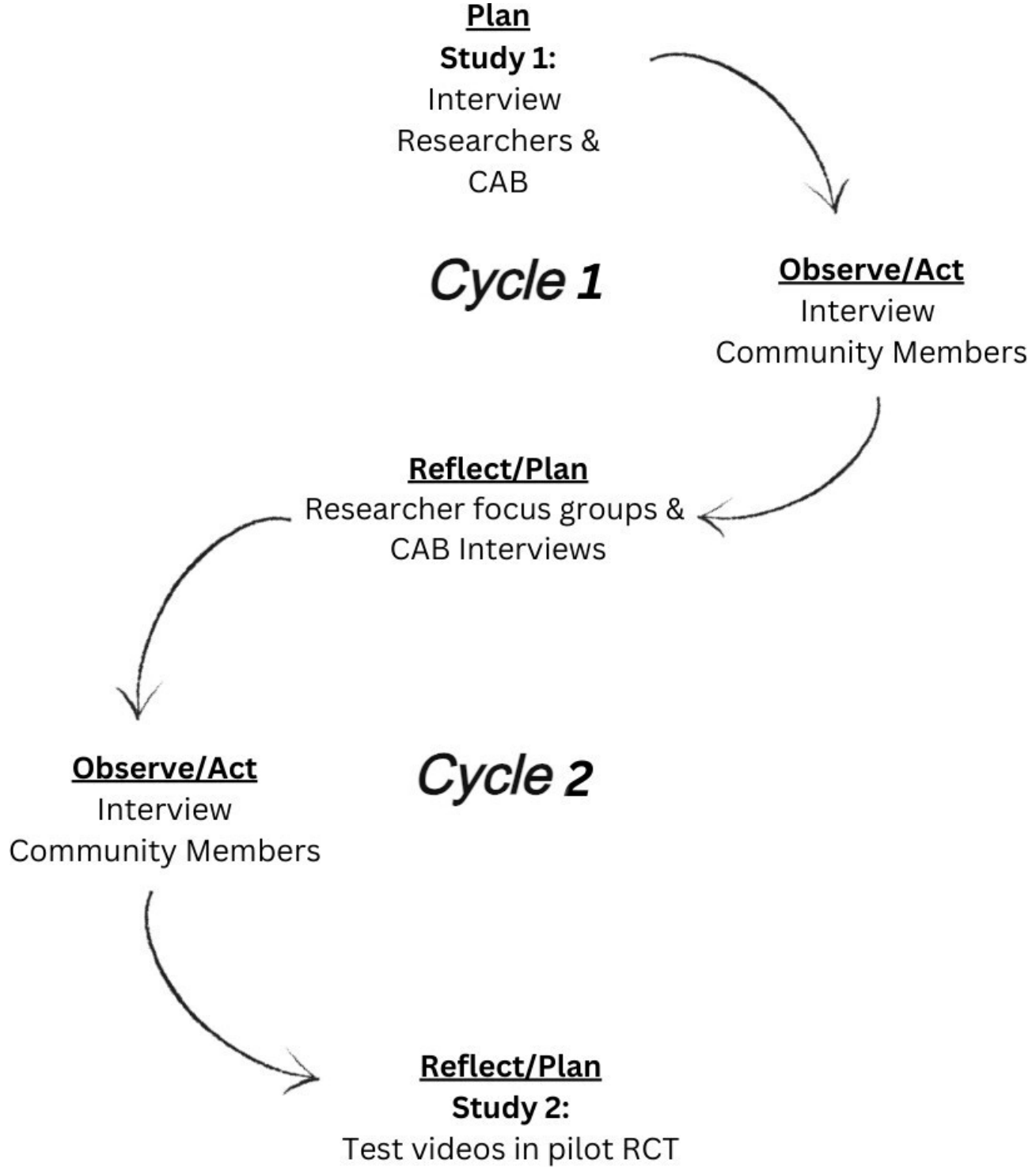


Video Production Study

A generic qualitative research design, from an interpretivist paradigm, was employed for this project. This design was chosen because it does not claim allegiance to a single established methodology [30] and thus allowed the researchers to adapt their methods to fit the specific needs of the study as the project unfolded [31]. The interpretivist paradigm emphasizes the subjective nature of reality and acknowledges that individuals create meaning through their experiences and interactions [32,33]. Key stakeholders, including neuromodulation researchers, recruiters, and racial/ethnic Black and Hispanic/Latino community members with chronic pain, were engaged in an iterative process throughout video development (Figures 1 and 2). To get input from neuromodulation practitioners, researchers from the National Center of Neuromodulation for Rehabilitation (NC-NM4R) were first engaged via one-on-one interviews and 2 focus groups. Input from a small focus group of researchers at the Berenson-Allen Center for Noninvasive Brain Stimulation was also obtained during the second round of the feedback process. For Black and Hispanic/Latino community member input, individuals with chronic pain from the representative communities were recruited locally in the Miami-Dade County area through health fairs, flyers in clinics, and snowball sampling to purposefully identify potential participants. Participation was in-person or remote via Zoom, determined by preference.

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Figure 2. Action research cycle. CAB: community advisory board; RCT: randomized controlled trial.



Neuromodulation Researchers

As the first step in the project, 60-minute informal, semistructured one-on-one interviews were conducted with 10 researchers from the NC-NM4R, and a large 90-minute focus group of NC-NM4R researchers and recruiters was conducted by the principal investigator (MW), who did not have prior relationships with the interviewees. The interviews and focus group were used to generate ideas for the video content and the desired mood or feel of the video to make sure that the views of those conducting NIBS research were represented in the end product. The format was deliberately informal (ie, no audio recordings) and semistructured to better facilitate idea generation, open feedback, and to encourage diverse perspectives. A sample mood reel was presented to stimulate ideas and feedback, consisting of a 60-second video with sample footage of investigator-participant interactions, animations of neurophysiological effects, and on-screen text. The following questions were used to guide the discussion:

- What are your challenges with recruiting and retaining Black and Hispanic/Latino participants for your research?

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- How could videos best be used to help improve the recruitment and retention of Black and Hispanic/Latino participants?
- What content do you think should be in a video [to enhance recruitment and retention of Black and Hispanic/Latino individuals in this type of research]?
- Describe how you envision a short animation would be used to best describe the underlying mechanisms.
- Here is a sample framework for the videos. What are your thoughts?

Using the feedback from researchers, test videos were developed, and these test videos were presented to NC-NM4R researchers via 2 additional informal and unstructured small focus groups for feedback. Feedback was also received from a small focus group of researchers at the Berenson-Allen Center for Noninvasive Brain Stimulation. Field notes were made during and after the interviews and focus groups.

Community Member Participants

CAB members agreed to meet twice from June 2023 to May 2024. All other community member participants were recruited for a single-session interview and were required to meet the following criteria: (1) be at least 18 years old, (2) have persistent pain of any etiology (eg, back pain, diabetic neuropathy [DN], knee arthritis) for >3 months, and (3) self-identify as one of the target communities and reported that their primary language was English for those in the Black English-speaking group, Spanish for those in the Hispanic/Latino group, or Haitian Creole for those in the Haitian Creole-speaking group. Interviews and focus groups were conducted with racial/ethnic–concordant investigators in the preferred language for each participant. Specifically, all Black English-speaking participants were paired with a Black English-speaking investigator, Spanish-speaking participants were paired with a native Spanish-speaking investigator, and Haitian Creole-speaking participants were paired with a native Haitian Creole-speaking investigator. The interviews and focus groups were audio recorded and transcribed, and non-English recordings were translated into English by a certified professional translation service (GMR Transcription) for analysis. The first round of semistructured interviews was used to gain feedback on the taVNS test videos. Then focus groups of only the CAB members were conducted to provide member checking on interpretation of the interview findings.

In addition to interview or focus group participation, all community member participants completed the questionnaires (in their preferred language) described below.

Video Production Study Measures

Pain Assessment

A structured interview was conducted to determine the participants' pain characteristics. In addition to questions regarding pain intensity, location, and chronicity, participants were asked to state whether their pain was improving, worsening, not changing, or waxing and waning (pain status).

Adapted Group-Based Medical Mistrust Scale (MMS)

Medical mistrust has been widely reported as a key barrier to participation of Black and Hispanic/Latino persons in clinical trials [34]. The Group-Based Medical Mistrust Scale (MMS) was originally developed and has been widely used to assess medical mistrust in Black and Hispanic/Latino people who contact the health care system [35]. The original group-based MMS was adapted to measure mistrust in health researchers (MMS), and the adapted version has also been shown to have strong psychometrics [36]. Thus, the MMS was used in this study to assess community member participants' degree of mistrust in medical research. The MMS is a 6-item questionnaire assessing a person's beliefs that their race/ethnic group is prone to mistreatment in medical research. Each item is scored on a 5-point Likert scale ranging from strongly disagree (1) to strongly agree (5). MMS scores are reported as a total of the 6 items, with the last item reverse scored and potential scores ranging from 6 to 30, and higher scores indicate greater mistrust in medical research.

Credibility/Expectancy Questionnaire Version II (CEQ)

Participants' feelings of uncertainty pertaining to the credibility and expectancy of researchers and the interventions being studied have also been reported as a barrier to Black and Hispanic/Latino participation in clinical trials. However, the influence of credibility and expectancy on NIBS outcomes has not been established. Thus, the Credibility/Expectancy Questionnaire Version II (CEQ) [37] was used to explore credibility and expectancy for pain relief with taVNS. The CEQ is a validated tool for assessing participants' perceptions on the credibility of therapeutic tools and their expectations for symptom improvement. The questionnaire consists of 6 questions, scored on a Likert scale ranging from 1=Not at all useful to 9=Very useful (with 5 representing "Somewhat useful"). Participants are instructed that the first set of questions pertains to what they *think*, and the second set of questions pertains to what they really and truly *feel*. Examples of the CEQ items include, "At this point, how successful do you think that taVNS will be in reducing your pain?" and "At this point, how successful do you feel that taVNS will be in reducing your pain?" The mean of the 6 items is reported as the CEQ scores, with higher scores indicating greater perceived credibility of taVNS and expectancy for pain relief with taVNS.

Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences (PRAPARE)

Social determinants of health are known to influence health care utilization and outcomes. The Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences (PRAPARE) [38] is a nationally standardized and widely used, screening tool for assessing an individual's social drivers of health. It consists of 21 items covering the domains of personal characteristics, family and home, money and resources, social and emotional health, and institutional or environmental vulnerability (ie, recent time spent in jail/prison, refugee status, and spousal abuse). In this study, the PRAPARE was used to gather important contextual information on the participants in this study, but it was not scored.

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The MMS and PRAPARE were administered at the beginning of each session, and the CEQ was administered after participants viewed the videos and provided feedback.

Pilot RCT

The pilot study was a single-blinded, sham-controlled feasibility trial designed to (1) examine the influence of the newly developed videos on participant expectations for pain relief with taVNS and (2) explore the feasibility and intended effects of taVNS in Black and Hispanic/Latino people with chemotherapy-induced peripheral neuropathy (CIPN) or DN. A target sample size of 24 was chosen for this study because it was estimated that this would provide the needed power to reach saturation with qualitative analysis and to assess feasibility outcomes [39,40]. Twenty-eight were recruited in all to account for attrition. As noted before, the feasibility and physiological findings are published elsewhere [29], and here the findings pertaining to the influence of videos on participant expectations for pain relief are reported.

The pilot RCT included only Black and Hispanic/Latino patients with CIPN or DN, and block randomization by race/ethnicity was used to ensure that there was equal representation of these groups across the intervention and control groups. Due to financial constraints, we were unable to accommodate the Haitian Creole speakers in the pilot RCT. Participants were recruited from the University of Miami medical health care system from January to May 2024. Potential participants were identified by medical record and then their respective providers (ie, oncologist or endocrinologist) informed them about the pilot study during clinical visits. Inclusion criteria included anyone with glove or stocking distribution paresthesia or dysesthesia that developed after receiving neurotoxic chemotherapies or with a diagnosis of DN and who self-identified as Black or Hispanic/Latino. Exclusion criteria included (1) any unstable medical condition or medical contraindication to moderate physical exertion (eg, unstable angina or cardiac arrhythmia), (2) pregnancy, (3) presence of cognitive impairment or language barrier that impairs full autonomy in the consent process or in the ability to participate in detailed interviews, (4) implants in the head or neck, cochlear implants, or pacemakers, (5) head or neck metastases or recent ear trauma, and (6) history of seizures.

Participants were randomly assigned to video or control groups, and all participants completed 3 visits. Visit 1 consisted of approximately 90 minutes of education on taVNS, including review of brochures and consent forms (both groups) and 3 short video segments on taVNS for the intervention group. The videos contained the same content as the brochures and consent forms, so all participants received the same information but in different formats. Further, all participants had ample opportunity to ask questions and discuss the content with the investigators. Racial and ethnic differences between participant and investigators/providers are also known to influence expectations and pain outcomes [41,42]; thus, a Black investigator provided all educational sessions for Black participants, and a Hispanic/Latino investigator provided all education sessions for Hispanic/Latino participants and in their preferred language (English or Spanish). Both investigators provided the same information to participants. For visits 2 and 3, participants received trials of active or sham taVNS, and those results are described elsewhere.

Pilot RCT Measures: The Expectations for Complementary and Alternative Medicine Treatments (EXPECT)

At the end of the educational session, participants provided feedback on the educational materials and completed the Expectations for Complementary and Alternative Medicine Treatments (EXPECT) [43] questionnaire. The EXPECT is a 4-item questionnaire that assesses expectations for pain improvement. Each of the 4 items is scored on an 11-point scale, with 0 being no change and 10 representing complete relief. Sample items from the EXPECT include “How much change do you hope for in your back pain? and “How much change do you realistically expect in your back pain?”

Quantitative Analysis

For both studies, descriptive statistics were assessed for demographic data and questionnaire findings. This included sample means, medians, and SDs for each continuous variable and frequencies and percentages for categorical variables. Group comparisons were conducted using Kruskal-Wallis and chi-square tests, and correlations were assessed using Spearman ρ. Statistical analyses were conducted using SPSS (version 29; IBM Corp.), and figures were rendered using GraphPad Prism (version 10.4.0; Graphpad Software).

Qualitative Analysis

Rapid qualitative analysis is widely used for implementation projects, such as this, when the goal is to create change in response to the findings rather than to generate new theories. Rapid qualitative analysis was systematically applied in this study according to established protocols [44]. The interview guide was used to create structured templates and matrix displays to facilitate data condensation, synthesis, and theme development. Templates were developed collaboratively by the team (MW, CM, CG) and pilot tested to ensure consistency, usability, and relevance. Once consistency was demonstrated, MW completed summaries of transcripts from sessions with Black English-speaking participants, both GG and CM completed summaries of transcripts for Spanish-speaking participants, and CM completed summaries of transcripts for Haitian Creole-speaking participants. The summaries were aggregated by MW and CM to populate the matrices that enabled systematic comparison between participants.

All 3 team members who were engaged in the qualitative analysis were physical therapists and pain scientists, with an interest in health equity and with extensive experience working with the target populations in clinical settings. As mentioned earlier, all recordings were transcribed in English, and the racial and ethnic backgrounds of the team members who analyzed the transcripts were Black Caribbean (MW, male), White American (CM, female), and Latino Mexican (GG, male). MW had experience with qualitative and mixed-methods research through involvement in several funded projects, and he received formal mentorship in qualitative research from recognized experts as part of the pilot funding programs that supported this project.

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CM had completed formal coursework and training in qualitative research as part of attaining her master's degree in public health. This was GG's first exposure to qualitative research, and he received training in interviewing and qualitative research principles prior to initiating data collection processes.

Results

A. Development of Test Videos

A.1 Neuromodulation Researchers' Initial Input for Video Content

A variety of perspectives were gained from the informal interviews and focus group with NC-NM4R researchers. Most felt that the best use of the videos would be for recruitment purposes, while some felt that they would best help with enhancing the consent process, and a few felt that the best use of videos would be to direct them to the researchers, enhancing their cultural sensitivity. Recruitment was commonly viewed as the biggest barrier. Thus, the decision was made to design the videos to be primarily informational, to assist with recruitment efforts.

Opinions also differed on the optimal length and content for the videos, with some advocating for very brief videos (<1 min) to capture attention and generate interest with recruits, and others advocating for more lengthy videos (over 5 min) to provide detailed information on the research procedures as well as the risks and regulations involved. As a result, we decided to start with the taVNS content and create test versions for full-length videos (~6 min in length) as well as segmented versions, in which the full-length videos were divided into 3 separate video segments organized around the following content areas: (1) introduction and how taVNS works, (2) risks and regulations, and (3) what to expect when you participate in taVNS research (Table 1). In the introduction segment, information on the potential indications for taVNS was provided, and an animation of the proposed mechanisms of taVNS was presented. In the risks and regulations segment, the potential side effects were outlined, and the process of research oversight was described. In the final segment, entitled *what to expect*, the process of prepping and applying taVNS was demonstrated. Block allocation was used, with alternating assignment within each racial/ethnic group (ie, the first participant received the full-length version, and the second participant received the segmented version for the Black English-speaking group), to get feedback on the full length and segmented versions of the videos.

Table . Overview of test video segments.

Video segment	Content summary	Key imagery
1. Introduction and how it works	• Potential effects include decreased pain, improved mood, and enhanced brain function. • Based on technology that has been safely used for over 60 years. • Description of the vagus nerve anatomy and physiological effects.	[
2. Risks and regulations	• Additional research is needed to gain FDA[a] approval for the noninvasive form of taVNS[b]. • Studies are done with strict oversight to ensure that they are being done safely and ethically. • There are no guarantees that it will help you. • It has been shown to be very safe thus far with low rates of side effects.	
3. What to expect	• You will set up in a comfortable position, and they will clean around the ear to apply electrodes. • In some studies, the stimulation is so mild that you don't feel anything at all, and in other studies, the stimulation may be set to an intensity that you feel as a strong tingling sensation. • Heart rate monitoring is often used with taVNS to assess the effects.	

[a]FDA: Food and Drug Administration.

[b]taVNS: transcutaneous auricular vagus nerve stimulation.

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A.2 Community Member Participants: Round 1

Sixteen community members, including both CAB and community participants with chronic pain, provided feedback on the test videos produced in their respective languages (5 Black English-speaking, 6 Spanish-speaking, and 5 Haitian Creole-speaking). The group mean (SD) age was 51.6 (16.2) years, and 12 of the participants were female (12/16, 75%). The 14 participants with chronic pain had moderate pain on average, with mean (SD) scores on a scale of 0 to 10 for current, best, and worst pain intensity within the last week of 4.9 (3.2), 3 (2.7), and 6.9 (3.4), respectively. There were no significant differences between racial and ethnic groups in other demographic characteristics, pain characteristics, or social risk factors (Table 2). The group was diverse in social risk factors, with 3 of the participants not having any health insurance, 3 with Medicaid coverage, 5 with Medicare, and 5 with private insurance. Four participants reported that within the last year, they or a family member they live with were unable to get medicine when it was needed. There was also diversity in medical mistrust, with a group mean (SD) score on the MMS of 17.8 (6.6), a median of 18.5, and scores ranging from 6 to 26.

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Table . Participant characteristics.

Primary language	Sex	Age (y)	Diagnosis	Current pain	Best pain	Worst pain	Pain status
Round 1							
English	Female	76	Knee pain	6	2	8	Not changing
English	Female	66	Lumbar degenerative joint disease	3	3	10	Getting worse
English	Male	52	Postherpetic neuralgia	2	1	6	Getting better
English	Female	59	Spinal Stenosis	8	9	2	Getting worse
English	Female	68	Arthritis	0	0	7	Coming and going
English	Female	79	Arthritis	7	3	10	Not changing
Spanish	Male	36	__[a]	—	—	—	—
Spanish	Female	46	Lumbar herniated disc	10	8	10	Getting worse
Spanish	Female	31	Migraine	9	2	8	Getting worse
Spanish	Female	38	Scoliosis	6	3	10	Coming and going
Spanish	Male	42	Back pain	7	3	10	Coming and going
Haitian Creole	Female	29	—	—	—	—	—
Haitian Creole	Female	59	Lumbar radiculopathy	4	2	7	Coming and going
Haitian Creole	Female	58	Abdominal pain	4	1	8	Not changing
Haitian Creole	Male	30	Angina	6	5	8	Coming and going
Haitian Creole	Female	56	Arthritis	6	4	6	Coming and going
Round 2							
Spanish	Female	62	Lateral epicondylitis	4	3	9	Coming and going
English	Female	72	Osteoarthritis, Congenital spinal stenosis	10	1	10	Getting worse
Spanish	Female	46	Low back pain	5	3	8	Not changing
Haitian Creole	Female	52	Foot pain	4	—	—	Not changing
English	Female	37	Plantar fasciitis	5	3	10	Getting worse
Haitian Creole	Male	74	Headaches	0	0	0	Coming and going
Haitian Creole	Female	65	Knee pain	5	3	8	Getting worse
English	Female	37	Ankylosing spondylitis	7	5	10	Coming and going
Spanish	Female	49	Shoulder pain	6	5	8	Not changing

[a]Not available.

The interviews identified several potentially important differences across racial and ethnic groups for participants' current pain management strategy. All Black English-speaking participants used medication as their primary pain management strategy, and none had ever tried electrical stimulation. Conversely, 4 of the 5 (80%) Spanish-speaking participants used medication for pain management when needed, 2 of the 5 (40%) had tried electrical stimulation, and all reported

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cognitive/emotional or active coping strategies (ie, distraction, "learning to live with it," breathing, going to the gym) as primary forms of pain management. Three of the 5 (60%) Haitian Creole speakers reported using medication for pain when needed, and all reported using alternative or "natural" treatments (ie, tea, massage, oil) as their primary pain management approach.

A.3 Community Member Participant Feedback on Test Videos

Participants watched the videos in their primary language and provided feedback in their primary language (ie, American English, Caribbean Spanish [since these videos were intended to be used in Miami-Dade County], and Haitian Creole). Overall, the videos were well received by participants, and details on their feedback and the decision log can be found in Supplement 1 in Multimedia Appendix 1. Key themes identified across all groups were that they most appreciated the animation and education on "how it works," they found the video to be "clear," and there was concern about taVNS not being Food and Drug Administration (FDA) approved. The general appreciation for the videos' educational value is best articulated by the following participant comment:

> *This is a positive all the way across the board, because I can tell you it by being a black female and dealing with different doctors. Most of them tell you, they don't talk to you. They don't allow time for you to ask questions, or just like you had a video to show.* [P-E3]

In addition to frequent and repeated use of the term "clear," the feeling that the video was comprehensible was supported by comments such as "good pace," "educational," "enough info and easy to understand." The concern about taVNS not being FDA approved was commonly expressed by participants across racial/ethnic groups.

The mean (SD) participant CEQ score was 7.2 (1.2) (median 7.2), with scores ranging from 5 to 9, indicating that all participants rated the credibility and expectancy as moderate to high. There were no differences between racial and ethnic groups in CEQ scores (P=.57), and CEQ scores were not significantly correlated with MMS scores (r=.06, P=.83). Participant feedback was similar for both the full-length and segmented versions of the videos. One participant thought that the full-length version was too long to digest in a single viewing; additionally, the segmented versions seemed to encourage more participant interaction with the investigators between segments, and this enhanced engagement may facilitate rapport building and recruitment efforts.

B. Development of Final taVNS and TMS Videos

B.1 taVNS Video Edits in Response to Feedback

The original plan was to reshoot the videos in response to participant feedback. However, feedback was overwhelmingly positive, and thus the videos received only minor editing alterations. For example, due to the enhanced engagement of the shorter videos, we decided to only make segmented versions for the final taVNS and TMS video production. In addition, to allay participants' concerns about FDA approval, we added the following to the narration of the taVNS Risks and Regulations video segment:

> *An invasive form of vagus nerve stimulation is FDA approved to treat epilepsy, depression, and stroke. Additional medical research is needed to gain FDA approval for the noninvasive form of TAVNS with these conditions and for other conditions like chronic pain.*

B.2. TMS Video Development

Financial constraints were a major limiting factor, and we were only able to develop videos on TMS in English and Spanish due to the high costs associated with video production, conducting interviews and focus groups on Haitian Creole, and for translation and transcription services. We applied lessons that were learned from the test video development for taVNS (ie, preference for segmented versions and concerns about FDA approval), and the TMS content was divided into 4 short video segments entitled (1) introduction (how TMS works), (2) TMS for research, (3) TMS as a treatment, and (4) risks and regulations.

The final videos are available for public use, and the web addresses for the taVNS and TMS videos can be found in Multimedia Appendix 2.

B.3. Final Video Feedback: Round 2

To get feedback on the final videos, 3 new community members from each racial and ethnic group were interviewed (Table 2). Since there was no additional budget for translation services, feedback was sought from bilingual Spanish and Haitian Creole speakers for the final round of interviews, and they watched the videos in their primary language but provided feedback in English. The bilingual Haitian Creole speakers provided feedback on the final taVNS videos in Haitian Creole and TMS video in English since Haitian Creole versions of the TMS videos were not produced. Participants in the second round of interviews had lower levels of mistrust than those in the first round, with mean (SD) MMS scores of 11.2 (3.2) (median 12, range 6 - 15)

Overall, the videos for both taVNS and TMS videos were well received, and details of their feedback and preferences can be found in Supplement 1 in Multimedia Appendix 1. For the taVNS videos, the mean (SD) participant CEQ score was 7.7 (1.1) (median 7.9), with scores ranging from 5.7 to 9, indicating that again all participants rated the credibility and expectancy as moderate to high. Once again, participants appreciated the clarity of the videos, calling them "clear," "concise," and "transparent." In addition, word choice and translation were important to the Spanish-speaking group. Specifically, they commented that although the translations used for the words "safety" and "seizure" were accurate, the literal translation was more alarming in Spanish.

After providing feedback on the videos for both taVNS and TMS, participants were asked if they were more interested in trying one of these interventions than the other. Key themes regarding treatment and learning preferences across groups were

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that they preferred the treatment option of TaVNS compared to TMS. All participants expressed greater interest in taVNS, and many indicated that there was a lack of clarity for how TMS would help with pain. For example, participants stated:

> *The first one you literally stated it could be effective with the chronic pain conditions. Especially, for me, the inflammation. Whereas the second one, it was more so for the smoking or the obsessive-compulsive disorder.* [P-E7]

> *…Because the TMS helps with convulsions, depression, and things like that I didn't feel it's something that can help me with my chronic joint issue, with what I have.* [P-S8]

This is also supported by the greater detail provided by participants in their descriptions of what they learned from the taVNS videos compared to the TMS videos. Many participants were able to discuss specific details on the theorized mechanisms for pain reduction via the vagus nerve with taVNS, but they could only vaguely discuss connections between brain stimulation and pain reduction with TMS.

Brochures of the same video content were also produced, and participants were asked to provide feedback on their preference for learning about taVNS and TMS from the videos or brochures. Surprisingly, there were varied preferences. All 3 Spanish-speaking participants preferred learning from the video because you can see the procedure and participants undergoing the procedure, stating "you see more of what will happen to you" [P-S6], and "you see that the patient is calm…" [P-S7]. However, 2 of the 3 Haitian Creole-speaking participants preferred the brochures over the videos. When providing reasons for their preference of the brochure over the video, the 2 participants discussed the importance of being able to take their time to read and research the information to discuss with their physician to make a decision about their care. For example:

> *I like the reading part. The video will be limited to me because even if it's on TV or if you watch the video. But if I got it on my hand, I can read it, I can read it again, and then I can get that with me, and sit down somewhere, do more research…I keep the paper on my hand and I write it down. I notice word, which is something about what I don't understand, I can go verify what's the meaning of that…* [P-C4]

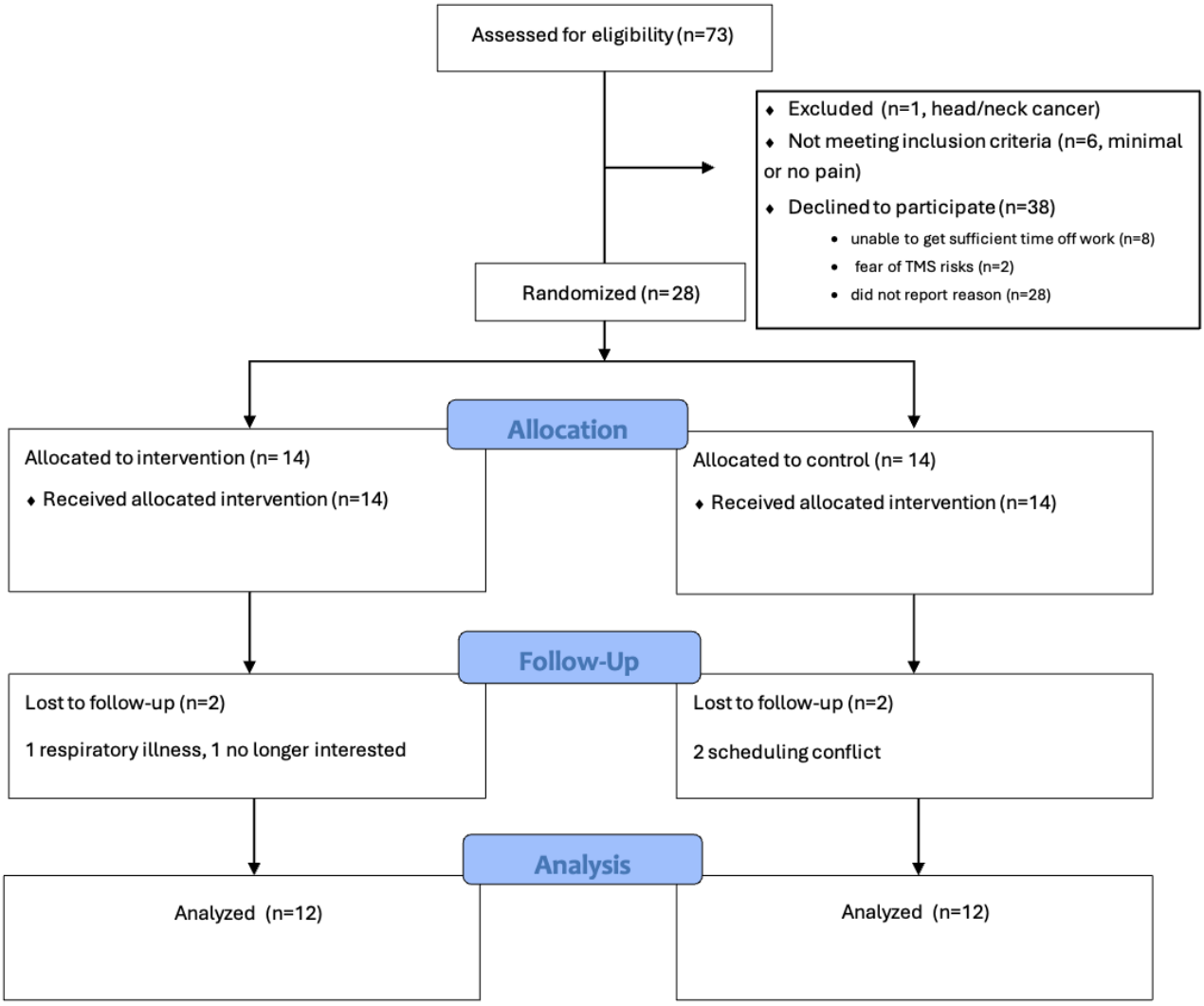
> *You grab one, you read it, that's how you are going to know the medication, that's how when I go to the doctor's I tell my doctor that I read the brochure outside and I see this medication is good for this certain thing.* [P-C3]

C. Testing of the taVNS Videos in a Pilot RCT

Twenty-eight people with peripheral neuropathy were recruited (Figure 3; Checklist 1), of whom 14 received the taVNS videos in their preferred language (video group), and 14 received education via brochures only (control group). There were no differences between groups in participant demographics (ie, race/ethnicity, sex) or medical condition (CIPN vs DN). The mean (SD) age of the participants was 58.2 (11.3) years; 20/28 (71%) were female, and 14/28 (50%) identified as Black and 14/28 (50%) identified as Hispanic/Latino. Additionally, 17/28 (61%) had CIPN, and 19/28 (68%) were using prescription medication to manage neuropathic symptoms, with gabapentin the most used medication (17/28, 61%). On average, participants had high symptom burden with mean scores ranging from 6.1 to 8 on a scale of 0 to 10 for each of the following symptoms: pain, numbness, tingling, burning, and shooting or electric shocks.

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Figure 3. CONSORT (Consolidated Standards of Reporting Trials) diagram. TMS: transcranial magnetic stimulation.



After receiving education on taVNS, there was no meaningful difference in the median EXPECT scores between the video and control groups, with respective mean values of 8 and 7.5 (median values of 8.2 for both groups, and 95% CIs for the means of 7.2 - 8.7 and 6.4 - 8.7, *P*=.8). However, the video-exposed group had less variability in EXPECT scores, with an SD of 1.3 compared with 2 for the control group (Figure 4). Similarly, there were no differences between groups after completing the trial, with mean (SD) EXPECT scores at visit 3 of 8.1 (0.9) and 8.2 (1.9) for the video and control groups (median values of 8.1 and 9 and 95% CIs for the means of 7.6 - 8.7 and 6.9 - 9.4; *P*=.6). Further, there was no significant change between visit 1 and visit 3 EXPECT scores (mean difference −0.2, *P*=.28).

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Figure 4. Group differences in EXPECT scores. EXPECT: Expectations for Complementary and Alternative Medicine Treatments; taVNS: transcutaneous auricular vagus nerve stimulation.

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Discussion

Principal Findings

In these 2 studies, community participatory research principles were used to develop and test culturally sensitive informational videos on taVNS and TMS. These videos were designed specifically to enhance the recruiting and consenting processes for taVNS and TMS research with Black English-speaking, Hispanic/Latino Spanish-speaking, and Haitian Creole-speaking people by providing the information in an easily digestible format, with input from the target communities, and with representation of these communities within the videos. The final video products were well received and generated interest in these modalities among the participants. We anticipated that the videos would increase expectancy for pain relief with taVNS, but there were no differences in EXPECT scores between those who viewed the videos and those who learned about taVNS from brochures only. Although unanticipated, this finding likely increases the potential value of these videos for use in research. An undue increase in expectations could be a potential confounding factor in studies, and these results suggest that these videos are neutral and do not generate unrealistic or misleading expectations for pain relief with taVNS.

A strength of this study was the range of medical mistrust observed in the sample, with scores from the lowest possible to the highest possible on the MMS. In a racially and ethnically diverse sample of 615 American adults and adolescents, the mean MMS score was 13.3 [36], which is lower than the mean score of 15.8 found in this sample. Much has been made of medical mistrust as a key barrier to recruitment and retention of Black and Hispanic/Latino groups in research; however, in this study, high medical mistrust did not result in low perceived credibility, expectancy, or interest in participating in taVNS research. Feelings of uncertainty are known to contribute to Black and Hispanic/Latino patients' reluctance to participate in research, and poor-quality information can contribute to participants' uncertainty [45]. Research on Media Richness Theory has shown that richer media are viewed as more credible, and that a video-with-audio medium will be perceived as higher in credibility than a picture-with-text medium [21,22]. Therefore, it is plausible that the high CEQ scores and expressed interest in taVNS research observed in this study were a result of the videos mitigating feelings of uncertainty. However, additional research is needed to confirm this.

It was interesting that all community participants in round 2 of video production study expressed greater interest in taVNS than TMS, and they demonstrated greater understanding of the proposed mechanisms for pain relief with taVNS compared to TMS. Therefore, in this sample of chronic pain patients, understanding treatment mechanisms appeared to be an important factor in treatment preference across cultural/language groups. There were also group differences in their preference for learning material format, with only members of the Haitian Creole-speaking group expressing a preference for brochures over video. It is well known that Haitian immigrants have complex language and cultural barriers that limit access to health care services [46-48]. Haitian participants in this study differed from the Black English-speaking and Hispanic/Latino Spanish-speaking participants in that they preferred brochures over videos for learning about NIBS, and this highlights the importance of using nuanced approaches to optimize community engagement in research. We plan to build on these lessons in the future by providing future potential Creole-speaking participants with brochures in both Haitian Creole and in English, so that they will have tools to discuss the studies with their families and providers.

Limitations

Although these studies achieved their aims, there are key limitations worth noting. The qualitative analyses were done on translated transcripts of the Spanish and Haitian Creole audio recordings rather than transcripts in the native languages. Additionally, no Haitian Creole speakers were involved with analyzing the transcripts. It is possible that salient points were missed or misinterpreted during translation, but this risk was mitigated by member checking during CAB meetings. It is also important to note that while many of the participants were originally from different countries or different parts of the United States, all but one were current residents of the Miami-Dade County area. Thus, the findings in this study may not be reflective of all other communities, and researchers should consider the nuances of their respective communities and possibly test the videos before implementing them.

Due to budgetary constraints and the high costs associated with translation services, we were unable to produce Haitian Creole versions of the TMS videos. Outside of costs associated with video production and personnel for conducting the interviews, over US $17,000 was spent on translation and transcription services across both studies, with more funds dedicated to Haitian Creole translation than either English or Spanish, despite not including Haitian Creole speakers in the pilot RCT. For example, the rates that were received for transcribing the audio recordings of the interviews varied greatly depending on the language, with the per recorded minute rate at US $1.50 for English-to-English, US $5.50 for Spanish-to-English, and US $20 per audio minute for Haitian Creole-to-English. This 13-fold increase in transcription costs for Haitian Creole audio is a significant barrier to including this underserved population in health research opportunities. Further, compared to the English and Spanish recordings, the transcription service used was more likely to deem the audio quality of the Haitian Creole interviews as "difficult," which added US $0.50 per minute to the cost. Based on a review of transcription service websites, language is one of the greatest factors in determining cost, with less common languages costing more. Artificial intelligence (AI) tools have the potential to transform this disparity by providing access to cost-effective transcription. However, currently, human transcription is more accurate than AI, and existing AI services do not cover less common languages like Haitian Creole [49].

Our goal was to use participatory research principles in this research, and we implemented this by using the CAB and seeking input from community members. Ideally, we would have used a more mutually collaborative model, in which community members have input throughout the research process, including conceptualization, data collection, and dissemination

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of the findings. However, these studies were the first steps in developing infrastructure for a research agenda focused on the use of NIBS for equitable pain management; thus, we did not have strong existing relationships with community partners, and most of our participants were not experienced with research involvement. Additionally, community participants expressed difficulty generating unguided input due to the novelty of taVNS. As a result, we chose to use a technical-scientific and positivist [27] in which community members were only used as a sounding board for feedback.

Recommendations for Future Research and Programming

Based on the findings of this action research study, the following recommendations are proposed for future research and recruitment initiatives.

Prioritize Mechanism-Based Education

Recruitment materials should clearly explain the neurophysiological mechanisms of the intervention (eg, how taVNS affects the vagus nerve), as participants reported that understanding "how it works" significantly enhanced treatment credibility and interest.

Implement Nuanced Cultural Tailoring

Researchers should avoid a monolithic approach to minority recruitment. For instance, while video was preferred by Black English-speaking and Hispanic/Latin Spanish-speaking participants, Haitian Creole speakers in this study preferred traditional brochures, highlighting the need for community-specific formats.

Mitigate Uncertainty Through Rich Media

Using high-quality video content can help mitigate feelings of uncertainty and medical mistrust by providing transparent, accessible information that is perceived as more credible than text-only materials.

Transition Toward Collaborative Models

Future programming should move from "technical-scientific" feedback models toward deeply collaborative partnerships that involve community members in the early conceptualization and design of research protocol.

Conclusions

Together, these 2 studies describe the process of engaging stakeholders to develop and test culturally sensitive informational videos on taVNS and TMS. The iterative process used to develop the videos in this project resulted in enhanced community awareness, engagement, and interest in our research agenda. Our hope is that the videos produced in this project will provide NIBS researchers with culturally sensitive and useful tools to engage Black and Hispanic/Latino communities in their research.

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Data Availability

The data used in the manuscript are available upon reasonable request to the corresponding author.

Authors' Contributions

Conceptualization: MLW, LMM, MMT, FJP, EWN
Data curation: MLW, CM, GG
Formal analysis: MLW, CM, GG
Funding acquisition: MLW, LMM, MMT, FJP, EWN
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Project administration: MLW
Resources: MLW, LMM
Supervision: MLW, LMM, EWN
Validation: MLW, CM
Visualization: MLW, CM, MMT
Writing – original draft: MLW, CM, GG

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Writing – review & editing: MLW, LMM, CM, GG, MMT, FJP, EWN

Conflicts of Interest

None declared.

Multimedia Appendix 1
Qualitative data matrices.
[DOCX File, 44 KB - jopm_v18i1e79311_app1.docx]

Multimedia Appendix 2
Video links.
[DOCX File, 55 KB - jopm_v18i1e79311_app2.docx]

Checklist 1
CONSORT checklist.
[DOCX File, 37 KB - jopm_v18i1e79311_app3.docx]

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Abbreviations

AI: artificial intelligence
CAB: community advisory board
CEQ: credibility/expectancy questionnaire
CIPN: chemotherapy-induced peripheral neuropathy
DN: diabetic neuropathy
EXPECT: Expectations for Complementary and Alternative Medicine Treatments
FDA: Food and Drug Administration
MMS: Medical Mistrust Scale
NC-NM4R: National Center of Neuromodulation for Rehabilitation
NIBS: noninvasive brain stimulation
PRAPARE: Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences
RCT: randomized controlled trial
taVNS: transcutaneous auricular vagus nerve stimulation
TMS: transcranial magnetic stimulation

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Inside or Outside? A Qualitative Comparative Study of 2 Recovery Colleges in Sweden and Norway

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Abstract

Background: Recovery colleges (RCs) provide users of mental health services with self-management and coping skills, along with actions to promote social inclusion and reduce stigma. Research shows that recovery principles in mental health have the potential to improve services, but are poorly implemented. Better knowledge and understanding of RCs among mental health staff might help in addressing this challenge.

Objective: In order to shed light on that assumption, the study compares 2 RCs that differ in their formal relationship with the mental health service—1 "embedded" and 1 "freestanding." This comparative study aims to uncover whether there are differences in the perceived value of the RCs by participants, and in mental health staff views on the benefits and challenges related to RCs, and the potential for collaboration.

Methods: The design is an explanatory comparative case study. Thick descriptions of the cases were based on document analysis and stakeholder interviews, subjected to content analysis. A "strategic change management model" guided data collection and analysis. Empirical patterns demonstrating the character and interrelations of the context, content, process, and outcome were identified in the case descriptions, forming tentative explanations of benefits and challenges observed.

Results: RC participants reported some differences in experiences possible to relate to course content. Information on mental health services enabled a more efficient use of those resources. A focus on communication and coping strategies helped in building bonds and relationships and finding support in social networks. Both RCs supported empowerment and reduced the sense of stigma. Mental health professionals had a positive image of the RCs but were not well informed about their activities. Few saw the college as an activity that could complement their professional services but had interesting reflections on their workplaces in relation to recovery. Exposure to an RC could support a reorientation from "diagnosis-centered" to a more patient-centered care culture. Users offering peer support could be "go-betweens" and "bridge builders" to mental health services.

Conclusions: Mental health staff aware of RCs and having knowledge of their benefits will provide support and guide users to participate. Such positive experiences are more important as a promoter of collaboration with users and the interest to contribute to a recovery-oriented care culture than the organizational form of the RC and its formal link to mental health services.

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KEYWORDS

recovery; recovery college; mental health; self-management; patient-centeredness; person-centeredness; patient-staff collaboration; co-design; coproduction

Introduction

Background

Persons in need of psychiatric treatment and care have been front-runners in terms of self-management of disease and taking control over their lives despite disease, as well as organizing peer support. This started in the United States as a consumer movement in the 1970s [1] and coincided with the deinstitutionalization of psychiatric services. At the same time, longitudinal studies of patients with mental disorders changed the previously pessimistic view on severe psychiatric disorders, well in line with the personal experience of people that they were, despite a psychiatric diagnosis, able to lead meaningful and productive lives. Those studies also showed that the capacity of patients to recover fully or learn to manage their condition with strategies which were in many instances developed outside formal treatment settings [1,2]. During the last 30 years, an

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emergence of locally based services, therapeutic societies, and the development of social psychiatry have taken place, which has generated both new knowledge and new practices [3,4].

Perkins et al [5] contrast this patient-driven self-management activity from professional psychiatric care by referring to it as an "educational" rather than "therapeutic approach[es]." Instead of focusing on problems and dysfunctions, and limiting activities to therapies, the recovery movement supports people to identify and develop their talent and skills, explore their possibilities, and focus on achieving ambitions and goals. It has, consequently, also been defined as an "assets-based" approach, aiming at developing the "recovery capital" of patients, defined as "the array of social, psychological and cultural networks beyond professional inputs" [6]. It has subsequently been seen as complementary to specialist mental health services [7].

Recovery colleges (RCs) are examples of that educational approach. The first RC was established in Boston in the 1990s, initially named Recovery Learning Center. In Europe, the first RC was established in London in 2009, and today a total of 80 RCs are spread across Great Britain. Twenty other countries have followed suit [5]. An RC can best be characterized as an educational center based in the community with the overall aim to promote recovery among persons with mental health challenges by focusing on education and support [8,9]. These colleges organize, led by patient peers, courses in, inter alia, "Living with a mental disorder" and provide participants with skills and employment training, along with actions to promote social inclusion and reduce stigma. The courses are developed and co-designed, coproduced, and cofacilitated by both mental health professionals and persons with user experience.

Recovery is said to have its root in psychiatric rehabilitation, but its proponents tend to distance themselves from mainstream psychiatry [10]. On the other hand, initiatives such as UK RCs aim at moving beyond patient involvement to coproduction and the development of coproduced patient pathways. Importantly, Topor et al [11] emphasize that the lack of "recovery capital" among patients is associated with lack of trust in oneself, and that professionals are able to support if they gain acceptance as trustful agents by cocreating changes in those patients' lives. They also report that professionals were concerned with the fragmentation and societal shortcomings of their care organizations [11].

Recent research shows that RCs have overall positive outcomes from their activities. Several studies on students' experiences underscore that RCs provide a safe space and meaningful connections and give room for personal growth, empowerment, and hope [10,12-14]. Students using RCs seem to be, in general, representative of mental health service users, but some groups are underrepresented, such as men, older adults, ethnic minority groups, and those with developmental disorders [15,16]. RCs display consistent values and aims in supporting recovery but are diverse in their operations [8,17]. Furthermore, RCs differ widely in organizational structure and whether they are affiliated with a health trust or a local community. Research examining RC characteristics concerning their affiliation is sparse, but a recent study comprising 36 RCs across England found that those 2 RC types did not differ significantly on either clinical or any health service use outcomes [18].

The recovery movement within mental health is a prominent example of a patient-led activity that can improve the well-being of patients and, when carried out in cooperation with mental health services, contribute to their development into more patient- and person-centered organizations. Research shows that recovery principles in mental health have the potential to improve services, but that these principles are poorly implemented [19-21]. The challenge is to make the potential partnership come true by building trust, overcoming ideological barriers, and managing resistance to change among mental health professionals and their organizations.

These are organizational and leadership issues. However, the literature on RCs has until recently been scarce on organizational studies. The English RECOLLECT project, studying primarily RC effectiveness and cost-effectiveness, set out to identify organizational influences on fidelity and improvements in mental health outcomes and found that RCs basically fall into 2 categories: those located within National Health Service (NHS) Trusts with structured recovery planning and those outside the NHS that focused on social connection and community integration. No significant differences were found between those RC types in terms of perceived participant benefit [16]. Thaki et al [18] reported on how organizational factors facilitate or hinder the establishment and management of RCs. They identified the main organizational affiliation, roughly two-thirds of RCs being affiliated with a statutory health service (usually an NHS Trust) and one-third with a voluntary organization. Managers interviewed mentioned that the benefits of being affiliated with an NHS Trust were access to qualified professionals who can participate in coproducing RC workshops, higher professional staff awareness, and increased visibility to secondary service providers supporting service users, one example being employment agencies. Negative consequences were competition for resources within the NHS Trust, lack of support to the RC as higher priority is given to clinical services, and NHS bureaucratic rules restricting autonomy for RC operators. However, these insights were provided by an analysis of all interviews without identifying possible differences in experience between managers representing different organizational forms of RCs [18].

We address this gap in knowledge by analyzing and comparing 2 RCs in 2 different countries that differ in their formal relationship with the mental health service. One has a narrow focus and is embedded in a psychiatry organization engaging salaried staff with lived experience and the other is freestanding with voluntary workers and a wide range of activities. We chose those cases as we had since several years had access to the sites and had previously performed studies on the experience of participants. Despite the study on RCs aligned either to a mental health service or to the third sector [18], to our knowledge, no study involving an RC within psychiatry has been previously reported.

An educational program, called "the Patient School" and resembling an RC, is offered at the Region Stockholm (Sweden) Psychiatry Organisation by "user-influence coordinators" (UICs)

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and "staff with user experience" (SUEs) employed by the organization.

Sagatun Recovery (SR) (user-led center) in Hamar, Norway, is a freestanding facility organizing a range of recovery-supporting activities, locally, regionally, and nationally, with the overall aim to promote user involvement, empowerment, and recovery. Its "self-empowerment course (SEC)" is organized as an RC.

Purpose and Aims

The purpose of this study is to make a systematic comparison of the embedded versus the freestanding RC in terms of their perceived value and the views of mental health staff in those respective environments. Despite differences in content and organization these 2 RCs have the same overarching aim: to support recovery and coping by providing information and supporting self-management skills.

Both RCs have recently been evaluated by in-depth qualitative analyses. In Stockholm, course leaders, participants, and health care staff were interviewed individually with a focus on the perceived value of the course as well as promoters and barriers to implementation [22,23]. The value of Sagatun courses as perceived by participants was analyzed in focus group interviews, especially in relation to whether participants had an increased sense of independence and reduced dependence on public services, and whether the course had shown new ways of practicing user-provider collaboration [24]. In this study, we complement these findings with interviews with professional mental health staff in order to shed further light on how organizational factors, as well as their attitudes and practices, could further promote collaboration. The aim of this comparative study is to uncover whether there are differences between the embedded and freestanding RCs (1) in the perceived value of the RCs by participants, and (2) in psychiatry staff views on the benefits and challenges observed of the RCs and potential for collaboration.

Methods

Ethics Approval and Consent to Participate

Ethics approval was granted by the Regional Ethical Review Board of Stockholm (Dnr 2019 - 03849 decision date October 22, 2019, with amendments Dnr 2020 - 04604 decision date September 15, 2020, and DNr 2021 - 04724 decision date September 20, 2021) and by the Norwegian Centre for Research Data (NSD nr 332381 decision date May 15, 2023). All procedures followed were in accordance with the Declaration of Helsinki of 1975, as revised in 2000. Written informed consent was obtained from all informants of this study.

Design, Method Selection, and Analyses

The study design is an explanatory comparative case study. It uses the fact that the research group had access to 2 different user-led patient RCs, thus benefiting from increased variation in terms of contextual factors. The cases are from 2 countries, one being embedded in a mental health service and the other being a freestanding organization.

The case study research method is "an empirical inquiry that investigates a contemporary phenomenon within its real-life context; when the boundaries between phenomenon and context are not clearly evident; and in which multiple sources of evidence are used" [25]. The explanatory approach is used when the objective is to disclose causal links between real-life interventions and their outcomes, and experimental designs are not possible because of the complexity of events [25]. Those causal links will be demonstrated as empirical patterns, showing links between stakeholder actions, organizational and environmental conditions, and consequences observed.

Theoretical Framework

This study compares how 2 RCs have been established, organized and run, and has the ambition to uncover benefits and challenges and seek explanations for those. That resembles the application of new knowledge or technologies and the introduction of new policies or practices. Greenhalgh et al [26] reviewed the literature on innovation and change in service organizations. They concluded that real and persistent change is achieved through an intricate interaction between the external environment and its stability, the properties of the innovation (change), the implementation strategy, and the actual change processes. Attention should be paid to the motives and actions of the stakeholders involved and their interrelationships, as well as the internal environment characterized by its structure, resources, leadership, and internal communication. To manage this complexity, a framework to guide data collection, analysis, and interpretation is warranted. Whipp and Pettigrew [27] proposed in their "strategic change management model" that 4 dimensions of change are studied and analyzed in relation to one another and over time: the local environment (context), the planned intervention (the content of the change), the implementation (the process of change), and outcomes, both in relation to predefined objectives and unintended consequences. This framework captures the contributing factors highlighted by Greenhalgh et al [26] but is simpler and thus a more practical tool for guiding data collection and analysis.

Data Collection Methods

Individual and group interviews had been previously performed by the authors with RC participants as reported elsewhere [22-24]. Mental health staff were purposefully recruited to represent different services used by participants on both sites and interviewed individually or in groups (interview guides will be found in Multimedia Appendix 1). Documents consisting of advertisements, user information, course plans, and course material were studied. The data collection was guided by the Whipp and Pettigrew [27] framework in order to enable case descriptions with the following content:

1. Context: The mental health services for users in the cases, their professional staff and clinical practices, the relation between the service provider and the RCs, the funding of those, and policy and decision-making processes of relevance to the cases.
2. Content: The recovery-oriented activities described in detail.
3. Process: The ways in which those activities are performed, experienced by the users and their collaborating professionals, and the changes made in the clinical practices of the mental health services involved.

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4. Outcomes: The results of the RCs, as described by the users and mental service staff, as well as their views on the perceived benefits and problems.

Analysis

Interview data and documents were systematically examined by conventional content analysis [28]. Interviews were transcribed verbatim. The transcripts were subjected to conventional content analysis using an inductive approach. LA-A read the Stockholm transcripts and RJR read the Sagatun transcripts several times to reach immersion. They formulated independently meaning units with relevance to the study aims and covering all 4 dimensions of the theoretical framework. Those selected meaning units were then compared and discussed by LA-A and RJR and checked against the original transcripts. When consensus was reached the meaning units were labeled, grouped into categories (forming subthemes) and ultimately themes, separately for the 2 cases. Those were discussed by all authors, MB having detailed insights into the Stockholm case and HP into the Sagatun case. Consensus was reached on the appropriateness of the theme titles and related descriptions. As the views of the informants were used as an input to the characterization of the cases, dependent on other sources as well, member checking was not felt to be necessary.

Data from all sources, including the initial interviews with RC participants, were cross-checked and condensed into 2 thick case descriptions, structured according to the analytic framework [27]. Those are presented in full in Multimedia Appendices 2 and 3. Empirical patterns demonstrating the character and interrelations of the context, content, process, and outcome items were looked for and identified as tentative explanations to the benefits and challenges observed.

Study Context: The Cases

Patient Recovery–Guided Activities at the North Stockholm County Department of Psychiatry

The department is responsible for psychiatric services in the northwestern part of Stockholm County, Sweden. It organizes in-hospital as well as outpatient specialty services. The department has been a front-runner in promoting user involvement and user-driven activities in mental health in Stockholm. It has employed full-time UICs since 2007; presently, there are 2 such UICs.

UICs have promoted patients' rights and supported both in- and outpatients. Since 2016, service users (called "staff with user experience") have been employed to provide peer support to patients.

UICs and SUEs established an RC offered to outpatients, organized in outpatient clinics. This "Patient School" consists of a series of 5 workshops given over 5 weeks covering the following themes: Psychiatry—how does it work?, Recovery—what is helpful?, Other resources in the society, Relations and disclosure, and Personal tools. The aim is to support users in self-managing their care and lives with a focus on social factors. Users are encouraged to actively exchange personal experiences. The course leaders invite, to each workshop, health care personnel from the psychiatry organization or researchers to act as coleaders and substance matter experts. To date, 12 of these courses have been offered with over 70 participants.

SR, Norway

SR in mental health and substance abuse is a private foundation, organizing recovery-inspired user education and social activities. Although users self-refer to the center, there is a close collaboration between the mental health service and the center. Sagatun functions as a regional resource base for the Inland region of Norway and a hub for recovery, working on local, regional, and national levels. Sagatun's primary aim is to strengthen user involvement within the field of mental health and substance use, spreading information on a regional level and showing examples of good practice. The center is a low-threshold facility offering a meeting place and organizing social activities. On average, 50 persons visit the center regularly. "The Recovery Hub" is a collaborative project between the 6 regional user-led centers, including Sagatun, in Norway. These centers are meant to aid users' and carer's organizations, the educational sector, municipalities, and specialized mental health services in the adaptation of recovery principles. The Recovery Hub's main objective is to provide persons with mental health and substance use issues and their next of kin with possibilities of recovery, self-efficacy, and the experience of a dignified life.

Sagatun offers an "SEC," which resembles an RC. It comprises a course of 4 days; one 2-day workshop followed by a second workshop 14 days later. The themes are Empowerment, Communication, and User Involvement on an individual and systems level. Exercises are included that aim at strengthening self-confidence, spontaneous behavior, and the ability to set limits, as well as communicating those topics to others. Since the start in 2012, about 450 persons have attended the courses.

Results

Participant Views of the RCs

Stockholm "Patient School" (RC)

Sixteen participants of RC courses expressed in interviews that the following features of the RC were bringing value to themselves: the willingness of course leaders to share their own experiences, a sense of belonging and possibility to share with like-minded individuals, knowledge and practical skills acquired, and the opportunity to identify and experience new roles and behaviors. These experiences were empowering and enabled the transition from passive recipient of care to active partner, decreased feelings of stigma, and developed a sense that one's identity is not defined by the mental health issue. These insights were seen to have the potential to lead to a more efficient use of available health care services [22].

SR (Self-Empowerment Course)

The study on participants' views was a formal evaluation of the SEC that was launched in 2021 [24]. Six focus group interviews and 8 individual interviews were performed with former attendees during 2021 and 2022. Three overarching themes stood out as main findings of the study. Those were (1) From

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marginalization to independence: through increased knowledge and competence, the informants experienced becoming more self-sufficient and less dependent on the public services; (2) Knowledge of recovery: the informants saw a gap between their own needs and what the public services could offer, and that time was crucial to hold on to the recovery journey; and (3) Strengthening social networks: the course was acknowledged as an important arena for building bonds and relationships.

The Views of Professional Staff on RCs

Stockholm "Patient School" (RC)

Eleven health and allied professionals working in Stockholm Psychiatry units as well as in municipal social psychiatry services were asked about their views on the RC and its possible impact on their practice. Both informants with and with no personal experience of the RC were approached.

Two psychologists and 1 social worker had managerial roles in psychiatry units. Five nurses and 1 occupational therapist had clinical positions in psychiatry units, 1 as a manager. One educationalist and 2 social workers were consultants in municipal social psychiatry units (Table 1).

Table . Stockholm informants.

Informant	Profession or education	Role in organization
0061	Psychologist	Manager, geropsychiatry unit
0067	Specialized nurse	Manager, psychiatry clinic
0069	Educationalist	Housing support consultant, social psychiatry
0070	Specialized nurse	Employment support consultant, social psychiatry
0071	Social worker	Employment support consultant, social psychiatry
1591	Psychologist	Deputy manager and clinician, psychiatry clinic
3337	Specialized nurse	Manager, emergency psychiatry unit
3715	Occupational therapist	OT, affective disorder clinic
4101	Specialized nurse	Psychiatry ward
9142	Nurse	Nurse, mobile emergency psychiatry unit
9983	Social worker	Manager, affective disorder clinic

Interviewees were aware of activities organized by SUEs, and a few had participated in RC sessions. Those who knew the RC well highlighted its benefits to patients and recommended their patients to participate. An in-depth analysis of the interviews identified 3 overarching themes: "Shifting away from a diagnosis-oriented healthcare system," "Promoting co-care through education and peer-learning," and "Creating a sustainable implementation of the RC within the psychiatry organization." The first one relates to RC content, and the second and third themes relate to RC process. These staff views will be presented in detail in the section on the comparative analysis.

SR (Self-Empowerment Course)

This study examined what professionals working in different psychiatry units knew about the SEC. Individual interviews were conducted with 4 professionals working in either a Flexible Assertive Community Treatment team or a District Psychiatric Centre in April-June 2023. These informants were a nurse, special need nurse, or social worker. Three of the informants had higher education or a master's degree in mental health, addiction, cognitive therapy, or violence risk assessment. Common for all the informants was that they were engaged in clinical work (Table 2).

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Table . Sagatun informants.

Informant	Sex	Profession or education	Role and organization
A	Female	Nurse, master in mental health	Case manager in FACT[a] team in a specialist health service
B	Female	Social worker, specialized in mental health	Case manager in FACT team in municipality
C	Female	Nurse, specialized in mental health and addiction	Nurse in District Psychiatry Centre
D	Male	Specialized SW[b]	SW in District Psychiatry Centre

[a]FACT: Flexible Assertive Community Treatment.

[b]SW: social worker.

These professional informants' knowledge of the activities at SR and particularly the SEC and its perceived value was relatively scarce. Nevertheless, 3 of the informants had been on regular visits to the center and they had worked actively to introduce SR as a low-threshold service to patients they serve. None of the informants had inside information of the course, but all of them knew the existence of the course and knew of people having attended it. They all had the impression that this course represented a useful supplement to the existing public mental health services, both psychiatric specialist care and services provided locally by the municipalities. They were overall positive to this way of offering education and supposed that it gave the participants useful tools in order to manage both their illness and life in general. Transcripts of the interviews were scrutinized by thematic analysis. Two themes emerged—"Power balance" and "Knowledge gaps and overall challenges"—and those are presented comprehensively in the comparative analysis.

Comparison of the 2 RCs

Overview

The differences and similarities between these 2 cases, as guided by the Whipp and Pettigrew [27] framework (context, content, process, and outcome), are exhibited in detail in Multimedia Appendix 4. The most important empirical findings will be presented in the following:

Context

In Stockholm, a *regional* self-governed public health authority runs specialized psychiatry services and primary care, which offers frontline psychiatry services by general practitioners and multidisciplinary mental health teams. *Municipalities* are responsible for social psychiatry, which offers professional support to people with long-standing mental health issues as well as sheltered housing and social benefits.

The RC is an *embedded* activity in the psychiatry organization. Persons with user experience are salaried employees who cooperate with professional staff. They have gradually established activities within the organization to support users. The activities are guided by recovery principles, but the ambition is to avoid creating a tension between educational activities and care provided by the psychiatry organization.

Sagatun works in an environment where a *state* health enterprise organizes psychiatry services on a *regional* basis, including outreach district psychiatry offered by multidisciplinary teams. *Municipalities* are in charge of primary care offering some therapeutic services and medication, as well as supported housing, home care, and vocational training. Social benefits are administered by a governmental agency.

Sagatun is a *freestanding*, user-led center with a *long history*, offering a *broad spectrum of activities* including a social meeting place. It is an open, *low-threshold service*, guided by recovery principles. In addition, it is a *regional resource and competence center* with the task to promote user involvement and influence. Its personnel include persons with user experience and some professional staff.

Content

The Stockholm course consists of 5 half-day workshops. Course leaders are persons with lived experience employed by the psychiatry organization. Invited experts contribute by providing information and giving advice. Practical information is provided on how the care system works and what practical support is available. Sharing of experience among participants is an important part of the course. Training in how to communicate one's life situation is included. Activities cover a period of 5 years of experience and report 70 participants.

The Sagatun SEC consists of two 2-day workshops and additional 4-hour "recovery workshops" organized over a lengthy period of time. Course leaders are persons with lived experience who receive training and coaching by Sagatun staff. The focus is on recovery and communication, as well as exercises in coping strategies. Sagatun has over 10 years of experience and during that period, 450 persons have participated in the courses.

Mental health staff in Stockholm had concerns regarding the diagnosis-oriented health care system in Sweden, which mainly focuses on medication, sometimes to the extent of being the only treatment offered. This might harmfully strengthen a "patient identity" of service users potentially leading to an increased dependence on the health care system. They underscore the necessity for another approach in care that empowers users, encouraging them to become more active and committed to their recovery. To that end, the RC was seen as supporting a professional role that shifts away from this diagnosis-oriented approach (Interview theme: "Shifting away from a diagnosis-oriented healthcare system"). According to staff, meeting fellow users in different stages of recovery gave

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users new perspectives on one's condition and help to reassess the identity as patient. This could break the vicious circle of dependence and promote recovery. RC as an educational activity would be a useful contrast to the care environment, showing the possibility to lead a fulfilling life despite challenges arising from their mental health condition. Users would also learn to navigate the complex psychiatric care environment.

The Norwegian mental health workers had a varying knowledge of SR and the SEC ("Knowledge gaps and overall challenges"). Despite this, everybody had positive views of SR. They described SR as a user-led meeting place and arena where users can meet peers, participate in activities in-house, establish friendships, and participate in excursions and a variety of courses. SR is seen as assisting people to be included in a community that helps them to take responsibility for their own lives. Some set up visits for their patients to SR and accompanied them there. SR is a meeting place offering users a sense of belonging, an opportunity to see other people in the same life situation and to be oneself. Informants tell about patients having benefitted greatly.

Some obstacles for service users on an individual level were observed, but challenges on a system level were also identified. The former were mental health status, social functioning, difficult economic situations, ongoing substance abuse, lack of motivation, and poor engagement. Serious mental illness and earlier failed treatment efforts diminished the interest to attend courses. There was a lack of information about SR and SEC among many service providers. The course program should be distributed to mental health units well in advance in order to make it possible for staff to provide information to potential course participants. Due to tight schedules, service providers might have limited opportunities to bring patients to SR. Follow-up of service users is increasingly organized by municipalities rather than mental health units, increasing the range of services that users need to be informed about. Both groups of mental health professionals had varying insights into RCs but were inspired to reflect on their value and their own working environments as to patient-centeredness and empowerment.

Process

Participants of the Stockholm course are recruited by spreading the word at wards and outpatient facilities, often by psychiatry staff. This RC has no dedicated resources, but salaried SUEs manage the courses. They lead the workshop discussions and share their own experiences frequently. Participants are encouraged to speak up, and some participants are more active than others.

SEC participants are directly recruited by Sagatun using advertisements and spreading information among users. The courses are part of Sagatun's regular activities and funded through its budget. Persons with lived experience lead the courses which also include practical exercises. Special attention is given to verbal and nonverbal communication.

Stockholm staff interviewees reflected on how using an educational approach in care such as the RC can improve the collaboration between them as professionals and the users. They described the challenges encountered in psychiatric care, describing the roles and responsibilities they and users had. Staff were used to taking the lead in treating patients, particularly for those severely ill with limited understanding of their condition. This perceived professional responsibility can lead to an overly protective attitude, which could strengthen a traditional care model and hinder engaging users in service coproduction. The RC was seen as having the potential to align the expectations of users and professionals helping to express realistic goals. This mutual understanding could increase patient compliance to hospital care and treatment. Staff who understood their patients' situation were more prone to recognize their potential and capabilities and thus engage in collaboration ("Promoting co-care through education and peer learning"). Improved internal cooperation between psychiatry units could be brought about by the RC, as staff participating would meet patients in different stages of their recovery and realize the input of their colleagues. While acknowledging the value of the RC, some interviewees mentioned that they adopted a similar educational approach. They encouraged patients to take an active role in their care during meetings between staff and users to design individual care plans.

To create conditions for a sustainable implementation of the RC within the psychiatry organization was seen by many staff as an important objective. They expressed a willingness to participate in the RC and support its activities. Better knowledge of the RC, especially concerning its benefits, among the professionals would help them to inform their patients and recruit participants. Increased awareness among staff would be necessary for a successful integration of the RC into the organization ("Creating a sustainable implementation of the RC within the psychiatry organisation"). That would ultimately be dependent on the political decision makers and psychiatry managers being willing to prioritize this activity and supply it with resources in a climate with a single-minded focus on service production. Convincing arguments showing the benefits of the RC would be crucial. To that end, systematic evaluations assessing outcomes, user satisfaction, and potential cost reductions are needed. Those would, although, be ill-suited to demonstrate positive impacts on users' lives. Central to the sustainability of the RC is the employment of SUEs. The expertise and perspectives they bring to the organization are crucial.

Mental health staff interviewed about Sagatun reflected on the power balance between staff and users ("Power balance"). Little was said in relation to the SEC, but informants highlighted the importance of peer support workers (PSWs) in general and their role as "go-betweens" or "bridge builders" in mental health and substance abuse services. A majority also had personal experience of contacts with a PSW. They appreciated the knowledge and unique experience of PSWs. They communicated easily with patients, which made them useful in mental health services. In that way, they contributed to equalizing the power balance between service recipients and service providers as they use more of the patients' perspective compared with the professionals. PSWs are increasingly employed in mental health services but do not have formal roles as defined by decision makers. This does not raise ethical concerns, but it is felt

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important that PSWs are part of the system and do not disregard psychiatric treatments.

Informants further specified that PSWs can contribute to treatment settings as they can more easily reach out to users and use their language and metaphors that are understandable to patients, thus contributing to normalizing situations and making those less threatening. This will make it easier to involve the user in designing treatment plans. Sometimes PSWs are closely related to a Flexible Assertive Community Treatment team, although in their own specific role. They are door openers to treatments and a social glue in treatment settings—but not therapists. As some patients tend to listen more to PSWs, everybody should be offered to meet a PSW.

In summary, the reflections of staff in both cases covered communication and interaction with service users far beyond RCs. Many focused on the importance of the organizational culture or care philosophy and facilitating and hindering conditions for fruitful coproduction, including contributing to an RC.

Outcomes

Valuable to Stockholm users were a sense of belonging and a possibility to share with like-minded. The knowledge and practical skills acquired were also valued. The opportunity to identify and experience new roles and behaviors was empowering and reduced the feeling of stigma. The improved knowledge of services and self-management skills was felt to lead to a more efficient use of available health care services.

Professional staff in Stockholm appreciated that information in the RC was delivered from a patient perspective. They thought that the course helps to normalize mental illness and reduce stigma. Those who participated in the courses were encouraged to take a more personal than professional role, which made communication easier. Staff interviewed thought that the RC could help to change the present diagnosis-focused care model to one based on service coproduction, which, supported by peer learning, would reduce user dependence and promote recovery and, at the same time, increase their compliance with medical treatment. To that end, they were willing to participate in an RC and contribute to raising awareness within the organization. Employees with user experience are the key to a successful integration of the RC but would, in addition, require that political decision makers and managers give high priority to that activity, including allocating resources.

Users participating in the Sagatun courses appreciated the social forum and its good atmosphere in the facility. Lasting contacts with peers and professional staff arose. Participants learned useful methods to set limits in life and acquired knowledge about their legal rights.

Mental health staff interviewed about Sagatun said that they had limited knowledge of its activities, particularly the SEC. However, some had made regular visits to the center, and they had worked actively to introduce SR. None had inside information about the course, but all interviewed knew the existence of the course and knew of people having attended it. Many mentioned how important the PSWs were and emphasized that they could bring forward the user's perspective, communicate easily with users, and contribute to a more equal power balance between users and mental health professionals. A more active use of the SEC would require that service providers were better informed about Sagatun activities.

Discussion

Principal Findings

The principal findings in terms of similarities and differences as well as benefits and challenges when comparing an embedded versus a freestanding RC are the following:

The main similarities between recovery activities in Stockholm psychiatry and Sagatun are that both are led by persons with lived experience, focusing on supporting users in self-managing their lives through practical information and skills training. Sharing experience is an important part of the dynamics. Users experience that the courses are empowering and have the potential to reduce the stigma of mental illness. Mental health staff mostly appreciate the activities and inform their patients about the possibility to enroll, but they have limited knowledge about the content. The professionals feel that the activities potentially can lead to a more balanced relationship between professionals and users. However, no one mentions an impact on clinical practice or care arrangements.

There are major differences between the 2 sites. Stockholm psychiatry has almost a 20-year history of employing persons with lived experience with the task of enhancing user influence. They have introduced a number of routines to strengthen the position and rights of patients. One of the initiatives was the introduction of the RC.

Sagatun is a freestanding user-run facility established over 20 years and has a broad range of low-threshold services, including offering a physical meeting place and social activities in addition to self-empowerment support. It has a formal role as a regional resource and competence center and is, as such, well known both in mental health and local communities.

The Stockholm RC is an on-off experience; Sagatun offers continuity in terms of access to the center and participation in its various activities. Despite these differences, the perceived benefits are, by and large, the same. Users tell about benefits such as improved self-management skills. Mental health staff see the potential for a more balanced relationship between professionals and users, although there is little evidence of impact on professional roles and practices. In conclusion, these differences do not seem to be of importance in relation to perceived benefits, neither by users nor by mental health staff. Although staff appreciated the RCs and acknowledged the potential for improved collaboration with users, RCs did not seem to promote clinical practice changes.

When further scrutinizing outcomes, one has to look for nuances at best. Stockholm user participants emphasized as benefits the following: a sense of belonging, exchange of experiences, and practical knowledge helping to navigate the system (of care, social services, and support). They also felt a reduced social stigma. Sagatun clients appreciated the social forum offered by

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the center, acquiring knowledge of patients' rights and long-lasting contacts with peers.

To summarize, we could not see any decisive differences between the embedded RC of Stockholm and the freestanding Sagatun facility. In both cases, the general knowledge among mental health staff about the activities was scarce. However, those who knew about the courses tended to recommend them to their patients. There was no evidence in staff interviews that the courses had influenced clinical practice. At best, RCs could have an impact on the care culture, reducing a diagnosis focus and promoting client-centeredness and coproduction, and be a supplement to formal mental health services.

However, the case comparison offers potential explanations to what could contribute to a successful RC, both offering benefits to users, improving communication and collaboration between users and mental health professionals, leading to practice changes and enhanced user-centeredness.

Having persons with user experience employed as staff in a mental health service would create a companionship that could promote a better understanding among professional staff and a more balanced relationship supporting recovery. It could also promote the internal spread of recovery-supporting activities of benefit to users, also showing how it can complement and potentially reduce the need for psychiatric care.

When organizations such as Sagatun offering recovery activities receive an institutional status in the mental health field, that will increase the general understanding of their benefits, have a potential for wider outreach, and lead to mental health services actively seeking cooperation and potentially integrating those into their service strategies.

Organizing courses that offer practical advice about the service system will increase users' ability to navigate the system and self-manage. On the other hand, a well-thought-through psychoeducational approach with trained tutors or coaches offering skills training grounded in sensemaking and connectedness will create a firmer base for users to tackle challenges in everyday life. These are recommendations applicable to RCs in general, regardless of their organizational affiliation.

An initial assumption was that there would be differences in mental health staff views on the embedded and freestanding RC. In fact, there were few differences. Staff had, by and large, a positive image of the RCs but were not well informed about course activities. Those whose patients had participated in the courses had more knowledge and appreciated the contributions of the programs. Few saw the college as an activity that could complement their professional services, and there was no indication of impacts on their clinical practice. No one raised that RCs represent an educational effort which could complement clinical interventions. One reason might be that few of the staff had actively participated in an RC—this was the case in the embedded RC also.

In fact, most studies that have assessed the influence of RCs on mental health staff and their practice have been performed among professionals participating in RCs. Many of these studies focus on the value of coproduction during college activities. According to one of the studies, staff that had participated in RCs reported that the experience had changed their practices. They had gained increased understanding of service users' relations, realities, and experiences, and modified their assumptions and biases concerning users. In addition, they had moved to "recovery-oriented practice acknowledging user self-determination, the importance of peer support, and promoting strength-based approaches" [29]. The same was reported in 2 studies performed among NHS mental health staff [30,31]. A recent systematic review found that coproduction in RCs affected professionals' attitudes and the power dynamics between patients and practitioners and promoted a person-centered practice [32].

The value of working together was raised by Dalgarno and Oates [33]. As a result, senior clinicians had changed their perceptions of professional power and authority. A challenge, though, was the need to balance multiple roles and to see service users as colleagues. Reflecting on their clinical practice, these clinicians said that they had adapted their language to users and shared personal information with them. Another group of psychiatrists were aware of and had positive views of the RC concept. They had, however, concerns about its interaction with the medical model. There was a fear that some patients might reject their proposed medication. RCs were seen as complementary to mental health services [34].

Those observations were echoed by Crowther et al [35]. Developing new relationships with users led to valuing coproduction, changed perceptions of users, and increased job satisfaction. The authors also concluded that "a certain distance is needed in the relationship between the Recovery College and its host organisation if a genuine cultural alternative is to be created." On the other hand, separate organizations might mean lower staff awareness about the RC and less potential impact on formal mental health services [34]. These are interesting propositions to compare with benefits and obstacles of NHS Trust affiliation (access to professional support and higher visibility vs lack of support due to competing priorities and limited autonomy due to bureaucratic rules) [16].

The Stockholm RC was "fully integrated" into the psychiatry organization and not only affiliated. The same challenges were identified, though: lack of management support and dedicated resources. Sagatun, on the other hand, is placed in the community and governed and run by persons with lived experience. It has been claimed that RCs working with local community mental health teams contributing with new ideas for activities could be a source of inspiration. RCs were able to draw on resources and the expertise of those teams [16]. Although Sagatun was known and appreciated by local mental health teams, these did not participate in RC activities. Crowther et al [35] found that a "third sector" RC expands its outreach in the community and has a positive influence on public attitudes to mental health. That could possibly be the case in the Norwegian setting but was not assessed in this study.

If closer collaboration with users, including participating in RCs, is a key to developing more user-centered practices in mental health organizations, how could mental health professionals' willingness to more actively collaborate with

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users and engage in RCs be promoted? One of the authors discussed how social psychology theories might guide such an effort [36]. Showing the benefits of user involvement to professionals and how those resonate with their professional beliefs and goals will have a positive effect on their attitudes toward coproduction. Engaging professional champions to lead coproduction will create social pressure and establish norms that will attract other professionals to participate.

Methodological Considerations

This study has both strengths and weaknesses. Among strengths are that the authors have a decade of experience of the 2 sites with unlimited access and ongoing communication with RC staff. They also have detailed knowledge of the organizational context of the cases. An additional strength is the possibility to systematically compare RCs with differing organizational characteristics, situated in 2 countries: one is embedded in a psychiatry organization, which is part of a regional public health system, and the other is a freestanding charity governed by users with no formal contacts with public mental health services. A weakness is the limited size of the study in terms of informants. Being of qualitative nature, the results of this research have to be interpreted with caution and might have limited generalizability outside the studied regions.

Conclusions

This multiple case study compared an RC embedded in a psychiatry organization with a freestanding, user-led RC. The RC contents showed only small differences; the embedded included more practical advice of formal services available, while the freestanding focused on the practice of social skills. The benefits experienced by participants matched those reported in the literature, including less experience of stigma, improved coping skills, and a reduction of service utilization.

Layperson SUEs employed in the psychiatry organization focused on safeguarding patient rights and improving patient involvement but were anxious to emphasize the value of evidence-based psychiatric care. Mental health staff had limited knowledge of the RCs on both sites. They still had interesting reflections on their workplaces in relation to recovery. In the psychiatry organization hosting the embedded RC, professional staff highlighted the “diagnosis-orientation” of their workplace and thought that a wider exposure to the RC could support a reorientation and promote a more patient-centered care culture and, as a result, improve collaboration between clinical units. PSWs (laypersons with user experience) engaged at the freestanding center were said by mental health professionals to be “go-betweens” and “bridge builders” to mental health services.

Overall, the differences between the RCs in views both by RC participants and mental health staff were small. The assumption at the outset of the study was that higher awareness and patient-professional collaboration would be found in the embedded RC but was not supported by these findings. Still, recent literature gives some advice on how to build on the insights from this study. A more recovery-oriented environment in mental health is promoted by engaged mental health professionals who have witnessed the benefits by actively participating in RCs. They realize the importance of collaboration with users and can act as champions to trigger change in clinical practice and care culture. The organizational form of the RC and its proximity to formal mental health services seem to be of less significance. People are more important than places.

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Data Availability

Anonymized transcripts of interviews and documents analyzed are available from the authors upon reasonable request.

Authors' Contributions

Conceptualization and project administration: MB
Methodology: MB
Investigation: LA-A, RJR
Formal analysis: LA-A, RJR (lead), MB, HP (supporting)
Supervision: MB, HP
Writing – original draft: MB (lead), LA-A, RJR, HP (supporting)
Writing – review & editing: MB (lead), LA-A, RJR, HP (supporting)
LA-A and RJR have made equal contributions as first authors.

Conflicts of Interest

None declared.

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Multimedia Appendix 1
Interview guides.
[DOCX File, 15 KB - jopm_v18i1e91076_app1.docx]

Multimedia Appendix 2
Region Stockholm Psychiatry Organisation Patient School, Stockholm, Sweden.
[DOCX File, 25 KB - jopm_v18i1e91076_app2.docx]

Multimedia Appendix 3
Sagatun Recovery, Hamar, Norway.
[DOCX File, 31 KB - jopm_v18i1e91076_app3.docx]

Multimedia Appendix 4
Comparative analysis.
[DOCX File, 36 KB - jopm_v18i1e91076_app4.docx]

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Abbreviations

NHS: National Health Service
PSW: peer support worker
RC: recovery college
SEC: self-empowerment course
SR: Sagatun Recovery
SUEs: staff with user experience
UIC: user-influence coordinator

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Peer-Led Emotional CPR Program in Black, Indigenous, and People of Color Communities: Convergent Mixed Methods Study

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Abstract

Background: Black, Indigenous, and people of color (BIPOC) experience disproportionately negative mental health outcomes, including rising suicide rates, and persistent barriers to culturally responsive care. Systemic racism, discrimination, and historical trauma contribute to mistrust of traditional mental health systems. Peer-led approaches that center lived experience and shared cultural identity may offer culturally responsive alternatives that foster emotional connection and trust.

Objective: This study examined pretraining to posttraining changes in emotional well-being, empowerment, and interpersonal outcomes among BIPOC participants who completed Emotional CPR (Emotional Connection, Empowering, Revitalizing), a trauma-informed, peer-led mental health education program facilitated by BIPOC trainers.

Methods: A convergent mixed methods pre-post design was used. Eighty-five BIPOC participants completed validated self-report measures immediately before and after a 12-hour web-based Emotional CPR training delivered over 3 consecutive days. Outcomes included loneliness, empowerment, flourishing, hope, active-empathic listening, mindfulness, social connectedness, and affect. Paired-samples 2-tailed *t* tests examined pre-post differences. Seventeen participants participated in 2 posttraining focus groups conducted through Zoom. Qualitative data were analyzed using thematic analysis informed by phenomenological principles. Quantitative and qualitative findings were integrated during interpretation.

Results: Participants (N=85; mean age 41.9, SD 11.2 years; women: n=65, 76.5%) reported significant reductions in loneliness (P=.03; d=0.25) and significant increases in positive affect (P=.002; d=–0.37). Significant declines were observed in empowerment (P=.03; d=0.26), active-empathic listening (P=.02; d=0.26), flourishing (P=.02; d=0.27), and hope (P<.001; d=0.41). No significant changes were observed in social connectedness or mindfulness. Qualitative themes included empowerment through skill-building, emotional vulnerability, cultural trust and safety, challenges in sustaining confidence after training, and the application of skills in daily life. Participants described increased self-awareness and emotional openness, particularly within a culturally responsive training environment. Qualitative findings suggested that increased emotional awareness may have influenced posttraining self-assessments.

Conclusions: Participation in BIPOC-facilitated Emotional CPR training was associated with short-term reductions in loneliness and increased positive affect, alongside modest declines in self-rated empowerment and hope. Qualitative findings suggest that increased emotional awareness and engagement with systemic stressors may temporarily influence self-perceived competence. Ongoing reinforcement, mentorship, and follow-up sessions may support sustained empowerment and emotional resilience in culturally responsive peer-led interventions.

(J Particip Med 2026;18:e80029) doi:10.2196/80029

KEYWORDS

Emotional Connection, Empowering, Revitalizing; Emotional CPR; peer support; Black, Indigenous, and people of color; mental health education; trauma-informed care; empowerment; loneliness; mixed methods research; cultural safety

Introduction

Black, Indigenous, and people of color (BIPOC), a term used to describe individuals who identify as non-White and are often marginalized within dominant racial hierarchies, continue to face disproportionately negative mental health outcomes [1]. From 2018 to 2023, Black individuals and American Indian or Alaska Native communities experienced the most significant increases in suicide rates [2]. Despite the need, BIPOC individuals continue to face barriers to accessing behavioral health services [3]. Even when care is received, discrimination

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from providers can contribute to poorer outcomes [3]. These inequities, rooted in systemic racism, historical trauma, and mistrust of the mental health system, underscore the importance of culturally responsive support systems [1,4].

A growing body of research highlights the value of peer-to-peer models in mental health recovery, especially within BIPOC communities [5]. Prior studies demonstrate that peer-led interventions can reduce social isolation, increase engagement in care, and promote empowerment by centering lived experience and shared identity [5-8]. Recent qualitative evidence further demonstrates that peer-led groups promote relational safety and meaning-making through shared lived experience, which participants identify as a central mechanism of change [6]. These approaches are particularly promising in communities that have experienced historical marginalization and mistrust of traditional mental health systems [7,8].

In this context, we sought to examine whether participation in an Emotional CPR (Emotional Connection, Empowering, Revitalizing) intervention was associated with changes in emotional well-being, empowerment, and interpersonal skills. Emotional CPR is a peer-developed, trauma-informed mental health education and training program designed to equip community members with the skills and confidence to support individuals experiencing emotional distress or crisis [9-11]. Grounded in the recovery model, Emotional CPR emphasizes a person-centered approach that prioritizes lived experience, supportive relationships, emotional safety, and trust, and it is intended for application in community-based nonclinical settings [12]. Although Emotional CPR shares similarities with community-based interventions such as Mental Health First Aid, which equips laypersons to recognize and respond to mental health crises, the 2 approaches differ in emphasis. Mental Health First Aid focuses on symptom recognition, risk assessment, and referral pathways [13], whereas Emotional CPR centers on emotional presence, relational connection, and trauma-informed engagement.

Rather than concentrating on identifying disorders or directing individuals toward formal services, Emotional CPR emphasizes "being with" people in distress, fostering mutual emotional connection, and supporting empowerment within community contexts [9]. This relational and recovery-oriented orientation distinguishes Emotional CPR from more clinically structured mental health literacy models and aligns it more closely with peer-support frameworks grounded in lived experience. Within this study, recovery is conceptualized as a person-centered process that emphasizes hope, empowerment, supportive relationships, and the capacity to live a meaningful life beyond symptom reduction [12,14].

To further support this recovery framework, the intervention was intentionally designed to be delivered by BIPOC trainers to support culturally responsive and community-centered engagement. This approach aimed to cultivate cultural safety and mutual understanding and to reduce the burden on participants to explain or justify their experiences. Creating a supportive environment that fosters personal growth, strengthens resilience to stress and adversity, and encourages cultural and spiritual development is central to recovery [14]. Feeling validated, heard, and understood by trusted community members, as well as by health and social service providers, may be beneficial for individuals navigating emotional distress and working toward sustained well-being [5,14].

This study examined the pretraining to posttraining changes among BIPOC participants who completed an Emotional CPR training facilitated by BIPOC trainers. Using a convergent mixed methods design, we assessed changes in participants' emotional well-being, empowerment, and interpersonal outcomes, alongside their lived experiences of the training. By focusing on culturally responsive, peer-led spaces, this study contributes to efforts to strengthen culturally responsive mental health supports for BIPOC communities.

Methods

Study Design

This study used a convergent mixed methods pre-post design, in which quantitative and qualitative data were collected during the same study phase, analyzed separately, and integrated during interpretation. The quantitative component assessed changes in self-reported well-being, empowerment, and social connectedness through validated psychological measures. In contrast, the qualitative component explored participants' experiences and perceptions through focus group discussions. The integration of both data types allowed for a deeper exploration of the training's effects and areas for future improvement.

Description of Emotional CPR Training

Emotional CPR is designed to be facilitated by individuals with lived experience of mental health challenges, including anxiety, depression, bipolar disorder, schizophrenia, and trauma. Facilitators may include peer support specialists, community members, and professionals such as educators, administrators, and first responders. The emphasis on lived experience and relational understanding reflects the program's grounding in peer support and recovery-oriented principles.

The Emotional CPR training is a 12-hour web-based course delivered over 3 consecutive days through live, synchronous videoconference sessions (Zoom). The curriculum includes the following modules: (1) establishing emotional connection, (2) recognizing and utilizing nonverbal communication, (3) fostering cultural empathy across different worldviews, (4) applying trauma-informed practices, (5) responding to emotional distress and suicidal ideation, (6) promoting empowerment, and (7) fostering revitalization.

Sessions combine didactic instruction with facilitated group dialogue, structured real-play exercises conducted in breakout rooms, and guided reflection activities. Modules are sequenced to move from foundational concepts of emotional connection and trauma-informed engagement toward applied practice in cultural empathy, responding to distress, empowerment, and revitalization. Experiential learning is integrated throughout the training to reinforce skill development and encourage reflective practice.

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Training Facilitators

Trainers facilitating Emotional CPR complete a structured 60-hour certification program that includes experiential training in trauma-informed engagement, cultural humility, crisis response, and supervised practice sessions, and they must demonstrate competency through evaluated real-play and a final assessment prior to certification [10,11]. In this study, a total of 7 certified trainers facilitated the sessions. Each training cohort included approximately 6 to 16 participants, with smaller breakout groups used for real-play and discussion exercises to support interactive learning and engagement.

Facilitators included individuals with lived experience of mental health challenges, as well as professionals such as peer support specialists, educators, and community-based practitioners. Facilitators identified as BIPOC, including Black/African American, Native American, and multiracial individuals. Many facilitators had personal and professional lived experience within the mental health system, including roles in peer support and community-based services, which informed their facilitation approach. Cultural relevance was not assumed solely on the basis of shared racial identity. Instead, it was operationalized through culturally responsive facilitation practices, including cultural humility, validation of diverse lived experiences, and the intentional creation of a space where participants could engage without needing to explain or justify culturally specific experiences. Facilitators drew on their lived experience and community-based knowledge to support relational engagement and trust-building.

Participants were recruited online through community-based networks and were not restricted by geographic location. As a result, participants likely represented diverse regional and cultural contexts within the United States; however, geographic data were not systematically collected. This limits the ability to assess the influence of shared place-based experiences on culturally responsive engagement within the training environment.

Ethical Considerations

The study was approved by the WCG Institutional Review Board (application number 1284189). All participants provided electronic informed consent prior to participation. Participation was voluntary, and participants could withdraw at any time without penalty. Data were deidentified prior to analysis and stored on secure, password-protected systems. Participants were not compensated for their participation.

Participants and Recruitment

Participants were recruited through community-based outreach efforts, including email listservs, social media announcements, and partnerships with community organizations serving BIPOC populations. Recruitment materials described the Emotional CPR training as a peer-led mental health education opportunity facilitated by BIPOC trainers. Interested individuals self-enrolled in the training through an online registration platform. Inclusion criteria required participants to (1) identify as Black, Indigenous, or a Person of Color and (2) be 18 years of age or older. Participants were not required to have lived experience with mental health challenges to enroll in the training, as the program is designed for a broad audience, including community members, individuals with lived experience, and professionals seeking to strengthen their capacity to support others in emotional distress. Lived experience with mental health challenges was not systematically assessed as part of the study. Participants were recruited online and were not restricted by geographic location; however, geographic data were not systematically collected, which limits the interpretation of shared cultural context related to place.

Of those enrolled in the training, 85 participants completed both presurvey and postsurveys. For the qualitative component, purposive sampling was used to invite survey completers to participate in focus groups. Invitations were distributed through email following training completion, and participants were selected based on availability and willingness to ensure diverse representation across gender and racial identities. A total of 17 participants participated in 2 focus groups (n=7, 41%; n=10, 59%).

Quantitative Data Collection

Participants completed a battery of validated psychological measures at 2 time points: immediately prior to the first training session (pretraining) and immediately following the completion of the third training day (posttraining).

Validated Psychological Measures

Herth Hope Scale

The Herth Hope Scale was used to measure hope across 3 dimensions: inner temporality and future, inner positive expectancy, and interconnectedness with others. This 12-item scale is reliable and valid for both older and chronically ill populations, with strong internal consistency (α=.84-.97) [15]. Sample items include “I have a positive outlook toward life,” “I have short- and/or long-range goals,” and “I feel scared about my future.” Responses were rated from 1 (strongly disagree) to 4 (strongly agree), with 2 reverse-coded items; higher average scores indicated higher levels of hope.

Empowerment Scale

The Empowerment Scale is a 28-item measure developed with individuals experiencing serious mental illness to assess perceived self-agency, control, and confidence. It has strong psychometric properties, including high internal consistency (α=.81), and demonstrated construct validity [16]. Sample questions include “I can pretty much determine what will happen in my life” and “People are only limited by what they think is possible.” Items were scored from 1 (strongly agree) to 4 (strongly disagree), with lower scores reflecting higher levels of empowerment.

Flourishing Scale

The Flourishing Scale measures psychological well-being across domains such as relationships, self-esteem, purpose, and optimism. This 8-item scale has demonstrated excellent reliability (α=.87-.91) and strong associations with other mental health indicators [17]. Sample items include “I lead a purposeful and meaningful life” and “I am competent and capable in the activities that are important to me.” Response options ranged from 1 (strongly disagree) to 7 (strongly agree), with total scores

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from 8 to 56; higher scores indicated greater psychological resources.

Mindful Attention Awareness Scale

The Mindful Attention Awareness Scale is a 15-item scale that assesses dispositional mindfulness through present-moment attention and awareness. It has high internal consistency (α=.82-.87) and strong validity across diverse populations [18]. Example items include "I could be experiencing some emotion and not be conscious of it until sometime later" and "I tend not to notice feelings of physical tension or discomfort until they really grab my attention." Items were rated from 1 (almost always) to 6 (almost never), with higher average scores reflecting greater mindfulness.

Active-Empathic Listening Scale

This scale evaluates the listener's emotional and cognitive engagement during interpersonal communication. The 11-item Active-Empathic Listening Scale is psychometrically sound, with high internal consistency (α=.80-.90) [19]. Sample questions include "I am sensitive to what others are not saying" and "I show others that I am listening by my body language." Items were scored on a 7-point scale from 1 (never or almost never true) to 7 (always or almost always true), with higher average scores indicating higher levels of active-empathic listening skills.

Social Connectedness Scale-Revised

The revised Social Connectedness Scale assesses an individual's sense of belonging and connection to others. This 20-item scale has been widely used, with strong internal consistency (α=.91) [20], although some psychometric limitations, such as response bias, have been noted [21]. Sample questions include "I feel distant from people" and "I find myself actively involved in people's lives." Items were scored from 1 (strongly disagree) to 6 (strongly agree), with negatively worded items reverse-coded; higher total scores indicated greater social connectedness.

Positive and Negative Affect Schedule

Positive and Negative Affect Schedule (PANAS) is a 20-item scale used to measure emotional states, including both positive and negative affect. The scale has excellent reliability (positive affect α=.86-.90; negative affect α=.84-.87) and strong construct validity [22]. Participants were asked how often they felt emotions like "interested," "distressed," and "ashamed" in the past week, using a 5-point scale from 1 (very slightly or not at all) to 5 (very much). Positive and negative items were summed separately; higher scores indicated higher levels of the respective affect.

UCLA 3-Item Loneliness Scale

This brief 3-item scale measures perceived social isolation and loneliness and is derived from the longer 20-item University of California Los Angeles (UCLA) Loneliness Scale. It has acceptable reliability (α=.72) and strong correlations with longer loneliness assessments [23]. Sample items include "How often do you feel that you lack companionship?" and "How often do you feel left out?" Items were rated from 1 (hardly ever) to 3 (often), with lower average scores reflecting lower loneliness levels.

Emotional CPR Scale

The Emotional CPR scale consists of items assessing beliefs and attitudes related to emotional support, presence, nonverbal communication, and self-care when supporting others in distress.

Reliability Analysis of Measures

The reliability of each scale was assessed using Cronbach α. Reliability analysis was conducted to determine the reliability and internal consistency of presurvey and postsurvey Emotional CPR, UCLA Loneliness Scale, Revised Social Connectedness Scale, Empowerment Scale, PANAS, Active-Empathic Listening Scale, Flourishing Scale, Mindful Attention Awareness Scale, and Herth Hope Scale. The results indicate that all presurvey and postsurvey scales have acceptable to excellent reliability and internal consistency since Cronbach α coefficients ranged from .63 to .91 (Table 1).

Table . Internal consistency and reliability (Cronbach α) of pretraining and posttraining measures (N=85).

Scale	Pretraining α	Posttraining α
Emotional CPR[a]	.68	.66
UCLA[b] Loneliness Scale	.79	.77
Social Connectedness Scale-Revised	.71	.90
Empowerment Scale	.77	.73
Positive and Negative Affect Schedule	.66	.71
Active-Empathic Listening Scale	.63	.64
Flourishing Scale	.91	.87
Mindful Attention Awareness Scale	.77	.72
Herth Hope Scale	.88	.89

[a]Emotional CPR: Emotional Connection, Empowering, Revitalizing.

[b]UCLA: University of California Los Angeles.

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Quantitative Data Analysis

Descriptive statistics were calculated to summarize participant characteristics. Internal consistency and reliability of each scale was assessed using Cronbach α. Pretraining to posttraining changes across outcome variables were examined using paired-samples 2-tailed *t* tests, and effect sizes were calculated using Cohen *d*. Cohen *d* values reflect the direction and magnitude of change from pretraining to posttraining, with positive values indicating higher posttraining scores and negative values indicating lower posttraining scores; effect sizes were interpreted using conventional benchmarks (0.20 for small, 0.50 for medium, and 0.80 for large), with scale directionality considered in interpreting substantive meaning. To explore potential gender differences over time, repeated-measures ANOVA were conducted with time (pre vs post) as the within-subject factor and gender as the between-subject factor. Statistical significance was set at $P<.05$. All analyses were conducted using IBM SPSS Statistics.

Qualitative Data Collection

Two focus group discussions were conducted through Zoom, with the first session held on January 6, 2025 (n=10, 59%) and the second on January 13, 2025 (n=7, 41%). Each session lasted approximately 60 minutes and was audio-recorded for accuracy. The lead researcher conducted both focus group discussions, and a professional transcription service was used to transcribe the recordings.

A semistructured interview guide was used to explore participants' experiences with the Emotional CPR training, covering the following questions:

1. How has the Emotional CPR training influenced your sense of empowerment?
2. In what ways has the training affected your ability to practice empathetic listening?
3. What impact has the training had on your well-being and overall sense of flourishing?
4. Did the training influence your sense of hope or optimism for the future?
5. How has the training shaped your social interactions and relationships?
6. Did Emotional CPR training alter your perspective on emotional distress, either in yourself or in others?
7. In what ways did the training address emotional challenges linked to systemic issues?
8. How has Emotional CPR training influenced your self-perception?
9. How do you anticipate applying the knowledge and skills gained from Emotional CPR moving forward?
10. What suggestions do you have for improving the effectiveness of Emotional CPR training?

The interview guide included questions aligned with the training objectives, which may have shaped or directed participants' responses toward specific domains of interest.

Qualitative Data Analysis

A reflexive thematic analysis informed by phenomenological principles [24] was used to analyze qualitative data. While the analysis emphasized participants' lived experiences and meaning-making, it also incorporated both inductive coding and deductive attention to domains reflected in the interview guide and training objectives. Transcripts were independently coded by 2 members of the research team using an iterative thematic process. Coding discrepancies were discussed and resolved through consensus to enhance credibility and dependability. Themes were generated through a reflexive and iterative analytic process that prioritized participants' language and interpretations while situating findings within the context of the training content. The integration of quantitative and qualitative strands is summarized in Table 2.

Table . Integration of quantitative and qualitative data.

Component	Quantitative strand	Qualitative strand	Integration purpose
Focus	Measured changes in self-reported well-being and interpersonal skills	Explored participants' lived experiences, perceptions, and meaning-making related to Emotional CPR[a] training	Developed a comprehensive understanding of measurable outcomes and experiential impact
Analysis approach	Statistical analyses conducted independently	Reflexive thematic analysis informed by phenomenological inquiry; inductive coding and iterative theme development	Findings compared at the interpretation stage to examine convergence, complementarity, and divergence
Key contribution	Identified statistically significant pre-post changes associated with the training	Illuminated how participants interpreted and contextualized those changes within personal and community contexts	Enhanced interpretive depth and clarified mechanisms underlying observed quantitative outcomes
Design type	Convergent mixed methods	Convergent mixed methods	Integration strengthened validity through triangulation and enriched understanding of training impact

[a]Emotional CPR: Emotional Connection, Empowering, Revitalizing.

Building on this approach, the analysis was designed to systematically identify patterns across participants' accounts while remaining grounded in the exploration of lived experience and meaning-making [24,25]. It focused on interpreting how participants described, understood, and made sense of their

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experiences with Emotional CPR training. A reflexive 6-phase thematic analysis process guided the analytic procedures [25]:

1. Data preparation and familiarization: Audio recordings were transcribed verbatim, and identifying details were removed to ensure confidentiality. Transcripts were imported into NVivo 12 to support data management. Members of the research team read and reread the transcripts to become deeply familiar with the content, noting preliminary impressions and experiential insights.
2. Generating initial codes: Transcripts were systematically coded to capture significant features of participants' lived experiences. Coding was primarily inductive and data-driven, while also informed by the domains reflected in the interview guide and training objectives.
3. Constructing themes: Codes were examined for patterns and grouped into candidate themes that reflected shared dimensions of experience. Attention was given to both semantic content and underlying meanings.
4. Reviewing and refining themes: Themes were reviewed in relation to the coded data and the full dataset to ensure coherence, distinction, and fidelity to participants' accounts. Redundant or unclear categories were refined or collapsed.
5. Defining and naming themes: Each theme was clearly defined to articulate its central organizing concept and its relevance to the broader experiential narrative.

Trustworthiness of the Qualitative Findings

Several steps were taken to strengthen the rigor of the qualitative analysis. Two members of the research team independently reviewed and coded the transcripts, meeting regularly to discuss differences and refine themes until consensus was reached. Including direct participant quotations in the *Results* section allows readers to see how interpretations are grounded in participants' own words.

The analytic process followed a structured and documented approach. Coding decisions and theme development were tracked throughout the analysis to ensure consistency and transparency. This process helped maintain alignment between the raw data and the final themes.

Reflexivity was also an important part of the analytic process. The lead researcher identifies as Black, which was particularly relevant given the focus of the study on BIPOC participants and facilitators. This shared cultural context contributed to building trust during focus groups and may have shaped how participants felt comfortable expressing their experiences. Throughout the analysis, care was taken to remain attentive to how lived experience and insider perspective could influence interpretation, ensuring that themes reflected participants' narratives rather than researchers' assumptions.

Integration of Quantitative and Qualitative Data

Qualitative themes were then examined alongside quantitative results to provide a comprehensive interpretation of the training's impact. This integrative step allowed experiential insights to contextualize and deepen the understanding of measurable outcomes.

By using thematic analysis informed by phenomenological inquiry, the study generated an interpretive account of participants' lived experiences rather than seeking to identify universal or essentialized structures of consciousness, defined here as fixed or generalizable features of experience. The findings highlight how Emotional CPR training shaped participants' perceptions of personal growth, relational connection, and emotional resilience within the BIPOC community.

Results

Descriptive Statistics

A total of 85 participants completed both pretraining and posttraining surveys. Of these, 65 (76%) identified as female participants, 17 (20%) as male participants, 2 (2%) as another gender, and 1 (1%) as Two-Spirit, transgender, gender-nonconforming, or nonbinary. Most participants were identified as Black or African American (70/85, 82%) and were employed full-time (64/85, 75%). The mean age of participants was 41.93 (SD 11.21; range 19 - 69) years (Table 3).

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Table . Sociodemographic characteristics of survey participants (N=85).[a]

Characteristic	Values, n (%)
Gender	
Male	17 (20)
Female	65 (76)
Other	2 (2)
Two-Spirit/transgender/gender-nonconforming/nonbinary	1 (1)
Race	
Black or African American	70 (82)
White	1 (1)
American Indian or Alaska Native	1 (1)
Asian	2 (2)
Black or African American and more than 1 race	1 (1)
Asian and more than 1 race	1 (1)
More than 1 race	9 (11)
Hispanic or Latino ethnicity	
Yes	11 (13)
No	74 (87)
Employment status	
Full-time	64 (75)
Full-time and other roles	1 (1)
Part-time	4 (5)
Volunteer	5 (6)
Unemployed	8 (9)
Retired	3 (4)

[a]Percentages are rounded to whole numbers because N<100.

Seventeen participants participated in the focus group discussions. Of these, 14 (82%) were identified as female participants and 3 (18%) were identified as male participants (Table 4).

Table . Sociodemographic characteristics of focus group participants (N=17).[a]

Characteristic	Values, n (%)
Male	3 (18)
Female	14 (82)

[a]Percentages are rounded to whole numbers because N<100.

Additional demographic characteristics beyond gender were not systematically collected for focus group participants, which limits the ability to further contextualize the qualitative findings.

Emotional CPR Item-Level Changes

Paired-samples *t* tests examined pretraining to posttraining changes in Emotional CPR scale items (Table 5). Significant increases were observed in items reflecting solution-focused support (P<.001), uncertainty in helping someone in distress (P<.001), and attempts to solve others' problems (P<.001). Significant decreases were observed in items related to being with another person (P<.001), understanding nonverbal communication (P<.001), emotional self-care (P<.001), and openness to new approaches (P=.008). No significant changes were observed in emotional awareness or trauma recognition.

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Table . Paired-samples *t* tests for Emotional CPR (Emotional Connection, Empowering, Revitalizing) item-level changes (N=85).

Item	Pretraining, mean (SD)	Posttraining, mean (SD)	*P* value	Cohen *d*
Emotional distress awareness	2.62 (0.93)	2.50 (1.05)	.21	0.14
Support—solving problems	2.95 (1.17)	3.40 (1.22)	<.001	–0.41
Support—being with someone	2.75 (1.02)	1.99 (1.09)	<.001	0.80
Trauma awareness	1.36 (0.53)	1.31 (0.51)	.20	0.14
Want to help but unsure how	2.81 (0.92)	3.28 (1.10)	<.001	–0.44
Emotional identification	1.85 (0.76)	1.76 (0.78)	.40	0.09
Sitting with strong emotions	1.48 (0.65)	1.44 (0.63)	.44	0.08
Sharing emotions	1.99 (0.97)	1.96 (0.94)	.77	0.03
Problem-solving tendency	2.60 (1.01)	3.32 (1.11)	<.001	–0.69
Meaning of “being with”	2.23 (0.89)	1.62 (0.75)	<.001	0.75
Self-nonverbal awareness	1.86 (0.68)	1.48 (0.59)	<.001	0.55
Comfort listening	1.63 (0.71)	1.39 (0.60)	<.001	0.43
Self-care before or after distress	2.26 (0.90)	1.86 (0.86)	<.001	0.45
Openness to new ideas	1.53 (0.68)	1.35 (0.63)	.008	0.29
Recognizing others’ nonverbal cues	1.86 (0.71)	1.54 (0.66)	<.001	0.44

Scale-Level Outcomes

Significant pretraining to posttraining changes were observed across several standardized measures (Table 6). Loneliness scores decreased (*P*=.02), and positive affect increased (*P*=.002). Significant declines were observed in empowerment (*P*=.03), active-empathic listening (*P*=.02), flourishing (*P*=.02), and hope (*P*<.001). No statistically significant changes were observed in social connectedness or mindfulness.

Table . Pretraining to posttraining changes across outcome measures (N=85).

Measure	Pretraining, mean (SD)	Posttraining, mean (SD)	*P* value	Cohen *d*
UCLA[a] Loneliness Scale	5.48 (1.71)	5.22 (1.46)	.02	0.25
Social Connectedness Scale-Revised	65.85 (6.62)	65.78 (5.92)	.90	0.01
Empowerment Scale	51.90 (6.51)	50.68 (6.03)	.02	0.26
PANAS[b] (positive affect)	55.14 (8.27)	58.15 (8.32)	.002	–0.37
Active-Empathic Listening Scale	12.88 (4.30)	11.89 (4.19)	.02	0.26
Flourishing Scale	16.04 (6.72)	14.77 (6.09)	.02	0.27
Mindful Attention Awareness Scale	7.64 (2.43)	7.72 (2.27)	.66	–0.05
Herth Hope Scale	19.57 (3.23)	18.51 (3.04)	<.001	0.41

[a]UCLA, University of California Los Angeles.

[b]PANAS: Positive and Negative Affect Schedule.

Qualitative Study Results

Qualitative analysis of focus group discussions identified 6 primary themes and related subthemes. Themes and representative participant quotations are presented in Table 7.

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Table . Themes and representative quotations from focus group discussions (N=17).

Themes and subtheme	Representative quotations
Empowerment through training	
Increased confidence	"I felt very empowered afterwards." "I definitely felt more confident in my approaches and how I want to engage with others."
Awareness of biases	"It diversified the lens and scope of which I understand and listen to the stories of others."
Personal growth	"It was a great growth opportunity for me." "It helped me ground myself to being a lot more positive."
Active listening and empathy	
Improved listening	"People need your ears, not always your mouth." "It taught me not to listen to respond but to truly listen to understand."
Nonverbal communication	"I'm mindful of my body language." "My skills in nonverbal connection with others have improved."
Managing personal triggers	"I have to check my personal experience because it could affect my ability to support others."
Emotional impact of training	
Emotional vulnerability	"Just sitting in silence and holding space can sometimes be the most effective support." "Being vulnerable without walls was important."
Self-care	"Put that oxygen mask on first."
Shared emotional experiences	"It let me know I wasn't alone in how I was feeling."
Building social connections	
Cultural safety and trust	"BIPOC[a] facilitators created a safe space." "Trust is a big thing in BIPOC communities."
Community connection	"The relationships built within the group had a strong sense of community."
Application of skills in daily life	
Personal application	"The training helped me parent better and connect with my child's emotions."
Professional application	"I use this in my personal life and at work with clients experiencing mental health challenges."
Training structure and recommendations	
Need for more time	"More time would allow more role-playing and sharing."
Ongoing support	"A follow-up group would help reinforce skills and allow people to practice more."

[a]BIPOC: Black, Indigenous, and people of color.

Qualitative Findings

Qualitative analysis of focus group discussions identified 6 primary themes: (1) empowerment through training, (2) active listening and empathy, (3) emotional impact of training, (4) building social connections, (5) application of skills in daily life, and (6) training structure and recommendations. Representative quotations are presented in Table 7.

Empowerment through training included increased confidence, greater awareness of personal biases, and personal growth. Participants described feeling more prepared to engage with others in emotionally supportive ways and more aware of how their communication patterns and assumptions influenced interactions.

Active listening and empathy reflected shifts in how participants approached conversations. Many emphasized learning to listen with intention rather than focusing on responding or solving problems. Participants also described an increased awareness of nonverbal communication and acknowledged the need to manage personal emotional triggers when supporting others.

The theme Emotional impact of training captured experiences of vulnerability, self-reflection, and self-care. Participants described emotionally meaningful discussions, particularly within culturally affirming spaces. The importance of maintaining personal boundaries and engaging in self-care when emotionally activated was also emphasized.

Building social connections highlighted the role of cultural safety and trust in shaping the training experience. Participants noted that having BIPOC facilitators contributed to a sense of openness and shared understanding. Several participants described developing a stronger sense of community during the sessions.

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Under Application of skills in daily life, participants reported using training principles in family interactions, professional settings, and peer relationships. Skills such as asking whether someone wanted listening or advice, maintaining boundaries, and being present in conversations were described as particularly useful.

Finally, Training structure and recommendations included suggestions for additional practice time, in-person options, follow-up sessions, and broader dissemination of training to professionals and youth populations.

Integration of Qualitative Themes With Quantitative Findings

The integration of qualitative and quantitative findings provides a more comprehensive understanding of how participants experienced the training. While quantitative analyses demonstrated reductions in loneliness and increases in positive affect, they also showed modest declines in empowerment, hope, flourishing, and active-empathic listening.

These qualitative themes provide context for the quantitative findings, particularly the observed declines in empowerment, hope, and active-empathic listening. Participants described increased self-awareness and emotional vulnerability following training, which may have temporarily influenced their self-evaluations of competence and confidence.

Reductions in loneliness were consistent with qualitative themes of Building Social Connections and Emotional Impact of Training. Participants described increased feelings of connection, cultural safety, and shared understanding within the training space. These relational experiences align with the observed decrease in self-reported loneliness.

In contrast, empowerment scores declined slightly, despite participants describing experiences of increased confidence and personal growth. Qualitative data suggest that the training may have heightened awareness of the complexities involved in supporting others, including recognition of personal biases and emotional triggers. This increased self-awareness may have influenced participants' posttraining self-assessments, resulting in more cautious ratings.

A similar pattern was observed for active-empathic listening. While participants described a deeper understanding of "being with" someone rather than solving problems, they also acknowledged the emotional effort required to practice these skills. This suggests that increased awareness of the challenges involved in sustained empathetic engagement may have contributed to modest declines in self-reported listening scores.

Declines in hope and flourishing may also be understood in light of the emotionally vulnerable discussions described in the qualitative findings. Participants engaged in dialogue related to trauma, systemic racism, and lived experiences. Although these conversations fostered connection and validation, they may have also surfaced unresolved stressors, temporarily influencing perceptions of well-being.

Taken together, the integrated findings suggest that the training promoted relational connection and emotional awareness while simultaneously increasing reflection on personal limitations and systemic realities. These processes may explain the combination of relational gains and short-term shifts in self-perceived empowerment and well-being observed in the quantitative data.

Discussion

Principal Findings

This study examined pretraining to posttraining changes among BIPOC participants who completed Emotional CPR facilitated by BIPOC trainers. Using a convergent mixed methods design, we integrated quantitative and qualitative findings to better understand participants' emotional and interpersonal experiences following the training.

Quantitatively, participants reported reduced loneliness and increased positive affect immediately after training. These findings were supported by qualitative accounts describing feelings of connection, validation, and cultural safety. Participants frequently emphasized that being in a space led by BIPOC facilitators fostered trust and openness. Statements such as "It let me know I wasn't alone in how I was feeling" reflect the relational environment that likely contributed to decreased loneliness. These results are particularly meaningful given the systemic challenges and racial stressors that affect BIPOC communities, where culturally resonant spaces for connection can promote belonging and support [26].

At the same time, modest declines were observed in empowerment, active-empathic listening, flourishing, and hope. Although participants described increased confidence and emotional awareness, qualitative findings suggest that the training increased recognition of emotional complexity, personal triggers, and systemic barriers. Greater self-awareness may have influenced posttraining self-ratings, resulting in more cautious evaluations of competence. Conversations about racism and systemic inequities can evoke strong emotional responses and may temporarily affect perceptions of agency [4].

Similarly, declines in active-empathic listening may reflect heightened awareness of the effort required to sustain emotional presence. Participants acknowledged that deep listening requires emotional regulation and self-reflection. This aligns with the literature on emotional labor, which suggests that engaging in emotionally intensive dialogue can affect one's capacity for sustained empathic engagement [27]. While positive affect increased, mindfulness and overall social connectedness did not change significantly, suggesting that while the training fostered immediate relational gains, the longer-term integration of skills into daily life may require continued reinforcement.

Declines in hope and flourishing also warrant attention. Participants described engaging in emotionally vulnerable conversations about trauma and lived experiences. While these dialogues fostered connection and validation, they may have simultaneously surfaced unresolved stressors. Research suggests that confronting systemic realities can influence hope and perceptions of well-being, particularly in marginalized communities [2,28]. Recent work on radical healing frameworks emphasizes that processes of naming and processing racial trauma may initially surface emotional strain before fostering longer-term resilience [28]. These findings highlight the

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complexity of short-term emotional shifts following reflective, trauma-informed interventions.

Comparison With Prior Work

These findings extend previous research on peer-led mental health interventions. Prior studies of peer support models demonstrate improvements in empowerment, engagement, and emotional well-being [5-8]. Recent knowledge syntheses further highlight that peer-based models strengthen relational continuity and trust within community mental health systems [8]. Similarly, earlier studies of Emotional CPR and peer-delivered interventions have demonstrated feasibility and preliminary effectiveness in community-based settings [10,11,29]. This study builds on this work by examining a culturally responsive implementation facilitated entirely by BIPOC trainers for BIPOC participants.

The reduction in loneliness aligns with the literature emphasizing the importance of culturally responsive spaces in fostering belonging and relational safety [26]. Increases in positive affect are also consistent with research linking emotional connection to resilience and stress buffering [30,31]. At the same time, the observed declines in empowerment and hope highlight that reflective and trauma-informed interventions may produce complex, nonlinear outcomes. Literature on emotional labor and counselor listening exhaustion suggests that engaging deeply with distress can temporarily affect self-perceived competence [27].

The findings also underscore calls for culturally tailored mindfulness and emotional regulation strategies within BIPOC communities [28]. While mindfulness scores did not change significantly, participants described increased awareness and reflection, suggesting potential areas for future adaptation.

Limitations

Several limitations should be considered. First, the study used a single-group pre-post design without a comparison group, limiting causal inference. Observed changes cannot be attributed solely to the intervention. Second, outcomes were measured immediately posttraining, and longer-term effects remain unknown. Third, all measures were self-reported and may be influenced by social desirability or momentary emotional states.

The sample consisted primarily of Black or African American participants and women, which may limit generalizability to other populations or BIPOC subgroups. Additional demographic characteristics of focus group participants were not collected, which limits the ability to contextualize qualitative findings across participant backgrounds. Additionally, participants had access to internet-enabled devices and were able to participate in web-based training, which may exclude individuals with fewer resources. Finally, while qualitative integration strengthened interpretation, future studies using longitudinal designs and control groups would provide more robust evidence.

Conclusions

Participation in a culturally responsive, peer-led Emotional CPR training facilitated by BIPOC trainers was associated with short-term reductions in loneliness and increases in positive affect, alongside modest declines in self-rated empowerment, hope, flourishing, and active-empathic listening. Qualitative findings suggest that increased emotional awareness and engagement with systemic stressors may influence short-term self-evaluations of competence and well-being.

These results highlight the importance of culturally responsive peer-led spaces in fostering connection and emotional safety, while also underscoring the need for follow-up support, mentorship, and continued skill practice to sustain empowerment and resilience over time. Future research should examine longer-term outcomes and explore strategies for reinforcing gains in culturally responsive mental health interventions.

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Data Availability

The datasets generated and analyzed during this study are not publicly available due to the sensitive nature of focus group discussions and participant confidentiality but are available from the corresponding author upon reasonable request and with appropriate institutional review board approval.

Authors' Contributions

Conceptualization: MM
Formal analysis: MM
Investigation: MM
Methodology: MM
Supervision: KLF
Writing – original draft: MM

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Writing – review & editing: KLF

Conflicts of Interest

KLF holds associate editor role for *JMIR Journal of Participatory Medicine* at the time of this publication. MM declare no conflicts of interest.

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Abbreviations

BIPOC: Black, Indigenous, and people of color
Emotional CPR: Emotional Connection, Empowering, Revitalizing
PANAS: Positive and Negative Affect Schedule

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Experiential Classes Plus Digital Logging in Antenatal Care for Pregnant Women in China: Mixed Methods Study

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Abstract

Background: Maternal health during the perinatal period is a global public health priority. While antenatal education is widely implemented, conventional lecture-based models often fail to achieve sustained behavior change. Innovative approaches that integrate experiential learning with digital support may enhance maternal knowledge, self-management, and pregnancy outcomes.

Objective: The aim of this study is to evaluate the feasibility and preliminary effectiveness of a combined experiential class and online logging intervention for pregnant women in China and to explore the mechanisms underpinning its impact on health practices and service experiences.

Methods: A mixed methods design was used in a district-level maternal and child health hospital in Beijing. In the quantitative arm, 40 women (intervention group, n=20; control group, n=20) were enrolled in a quasi-experimental comparison. Outcomes included knowledge-attitude-practice indicators, service satisfaction, and clinical birth outcomes. Given the limited sample size, a qualitative arm was conducted to complement statistical findings: semistructured interviews with 20 women (10 per group) were analyzed thematically. Quantitative and qualitative results were integrated during interpretation to provide a comprehensive evaluation.

Results: Compared with the experiential class alone, the combined intervention was associated with higher knowledge scores (mean difference 1.6 points, 95% CI 0.8-2.4), stronger adherence to recommended health practices (composite adherence score difference 1.0, 95% CI 0.4-1.6), and higher overall service satisfaction (mean difference 0.6, 95% CI 0.2-1.0). Across multiple domains, a higher proportion of participants in the intervention group met dietary, exercise, and supplementation recommendations. Clinical outcome differences were exploratory, as the study was not powered for these end points. Qualitative analysis revealed 3 mechanisms, such as empowerment and self-efficacy, practice and persistence, and systemic/environmental support, through which the intervention influenced experiences and practices.

Conclusions: The experiential class plus online logging model is feasible and acceptable in a real-world antenatal setting. Although limited by a small sample size, findings suggest that the intervention improves maternal knowledge, health practices, and service experiences and may inform future adequately powered trials to evaluate pregnancy outcomes. Qualitative insights highlight mechanisms of health practice change and provide contextual depth, underscoring the value of mixed methods designs in maternal health research.

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KEYWORDS

maternal health; antenatal education; experiential learning; digital health; mixed methods; China

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Introduction

Maternal health during the perinatal period remains a major global public health priority. Despite significant progress in reducing maternal mortality worldwide, complications, such as gestational diabetes mellitus, hypertensive disorders of pregnancy, and anemia, continue to contribute substantially to adverse maternal and neonatal outcomes [1,2]. The World Health Organization (WHO) emphasizes that most maternal morbidity and mortality are preventable through timely interventions, health promotion, and improved access to high-quality care [3]. In China, the Healthy China 2030 strategy underscores maternal and child health as a key domain, with specific targets for improving antenatal care (ANC) coverage, optimizing service quality, and reducing complications [4,5]. However, changing sociodemographic trends, including advanced maternal age, increased prevalence of obesity, and sedentary lifestyles, have exacerbated risks and raised new challenges for maternal health promotion [6,7].

The perinatal period represents both a vulnerable and transformative stage. Physiological and psychological changes heighten women's susceptibility to stress, anxiety, and health complications, while simultaneously creating a heightened motivation to adopt healthier behaviors [8,9]. Evidence demonstrates that maternal lifestyle behaviors, including balanced nutrition, regular exercise, appropriate weight management, and adherence to medical guidance, are critical determinants of pregnancy outcomes and long-term maternal and child health trajectories [10,11]. Nevertheless, translating knowledge into sustained practices is not straightforward. Pregnant women frequently report difficulties in maintaining dietary modifications, establishing exercise routines, and managing stress, even when aware of recommended guidelines [12]. This "knowledge–practice gap" highlights the limitations of existing antenatal education models in bridging intention with behavior.

In China, antenatal education is widely available but often delivered in a didactic, lecture-based format within hospital settings. While such programs increase awareness, they frequently fail to address the complexity of behavior change, the need for continuous reinforcement, or the psychosocial dimensions of pregnancy [13,14]. Such didactic communications, positioning women as passive recipients rather than active participants, lack interactivity and may, thus, reduce motivation, undermine confidence, and leave critical needs unmet, such as emotional reassurance, social connection, and patient–provider trust [15]. To mitigate this gap in antenatal education, experiential and participatory learning approaches have been engaged and increasingly recognized as promising strategies to ensure that antenatal education is practical, engaging, and responsive to the lived experiences of pregnant women. Unlike traditional lectures, experiential classes emphasize active engagement through demonstration, simulation, and discussion [16,17], helping women translate abstract knowledge into practical skills and, in turn, enhancing comprehension, self-efficacy, and readiness for behavior change [18,19]. It should also be noted that experiential teaching, as a pedagogical approach, may entail an intention-behavior gap [20], which could be magnified by the complex external environments and practical barriers characteristic of pregnancy [21,22]. At the same time, digital health interventions, including mobile applications, online tracking tools, and peer support platforms, offer continuity of care beyond the clinic, providing real-time monitoring, feedback, and social reinforcement [23,24]. In China, the widespread adoption of platforms, such as WeChat, creates opportunities for embedding low-cost, scalable, and culturally integrated digital health solutions into routine ANC [25].

Although both experiential education and digital interventions have demonstrated potential independently, limited research has integrated these approaches into a combined model and evaluated their effects in real-world antenatal settings. Moreover, most existing evaluations rely predominantly on quantitative outcomes, leaving the mechanisms through which such interventions influence maternal engagement and health behaviors underexplored [26,27]. This study addresses these gaps by piloting an experiential class reinforced with a 7-day online logging program in a district-level maternal and child health hospital in Beijing, designed to test whether digital reinforcement can enhance the pedagogical effects of experiential learning, particularly by strengthening maternal self-efficacy and translating readiness into actual practice changes. A mixed methods design was adopted to capture both measurable outcomes and explanatory insights. The quantitative component assessed changes in knowledge, health practices, satisfaction, and pregnancy outcomes between intervention and control groups, whereas the qualitative component explored participants' lived experiences and explanatory mechanisms of change. Accordingly, the aim of this study was to evaluate the feasibility and preliminary effectiveness of this combined intervention, with particular attention to its impact on maternal self-efficacy and health practices, and to generate insights to inform the design of longer-term, scalable antenatal education programs.

Methods

Study Design

This study employed a convergent mixed methods design [28], combining a quasi-experimental quantitative comparison with qualitative inquiry. The quantitative arm assessed changes in maternal knowledge, health practices, satisfaction, and pregnancy outcomes between intervention and control groups. Recognizing the limitations of a relatively small sample size, the qualitative arm was designed to complement quantitative findings, provide explanatory depth, and explore mechanisms of practice change. Quantitative and qualitative results were analyzed separately and integrated during the interpretation stage to enable a comprehensive evaluation.

Setting and Participants

The study was conducted between January and December 2024 in a district-level maternal and child health hospital in Beijing. Women attending routine ANC were invited to participate in the quantitative arm. Eligibility criteria included singleton pregnancy (24 - 34 wk gestation), ability to attend antenatal classes, access to a smartphone for WeChat use, and provision

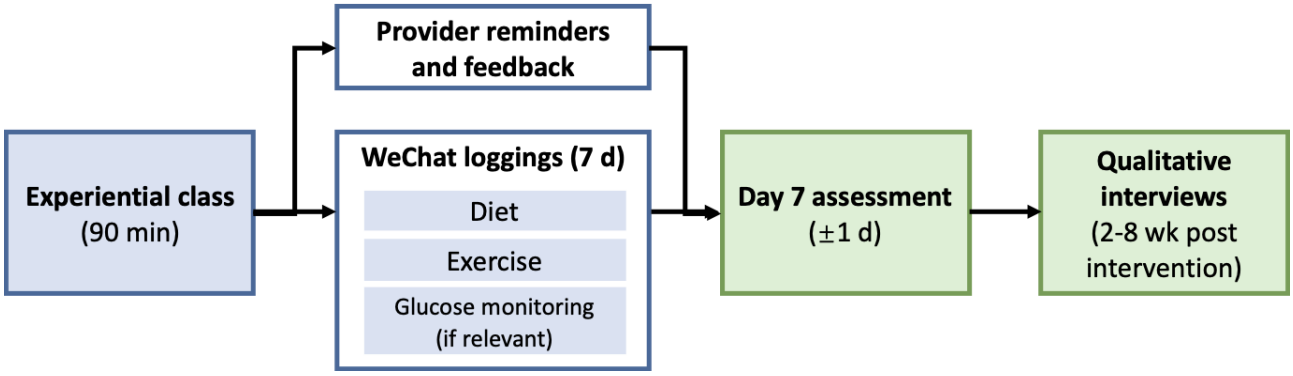
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of informed consent. Exclusion criteria included severe pregnancy complications (eg, preeclampsia, placenta previa requiring hospitalization), preexisting metabolic or cardiovascular conditions, and cognitive or communication difficulties. A total of 40 women were enrolled, with 20 attending an experiential antenatal class only (control group) and 20 attending the same class followed by a 7-day online logging program (intervention group). As part of routine study management, participants in each arm were also connected via a closed WeChat group. The qualitative arm was nested within this cohort. Twenty women, drawn purposively from both groups to ensure variation in age, parity, and engagement levels, were invited for in-depth interviews (10 intervention and 10 control). Participants were anonymized using alphanumeric codes (DK01-DK10 for intervention; WDK01-WDK10 for control).

Intervention

The intervention comprised 2 components. First, all participants attended a 90-minute session delivered by obstetricians, midwives, and nutritionists. This session combined lecture-style teaching with demonstration, role-play, group discussions, and practice exercises, and covered key topics, such as pregnancy nutrition, gestational weight management, prevention of gestational diabetes and anemia, and safe physical activity. The control group received this standardized experiential class only. The intervention group was enrolled in a WeChat-based miniprogram for 7 consecutive days, during which they were asked to log daily information on diet; exercise; and, where relevant, blood glucose monitoring. Health care providers monitored entries, provided reminders, and offered personalized feedback through the miniprogram, ensuring continuity of support beyond the classroom. The overall intervention workflow is shown in Figure 1. Thus, the 2 groups differed only in the presence of the digital logging component.

Figure 1. Intervention workflow. All participants attended a 90-minute experiential antenatal class. The intervention group additionally used a WeChat miniprogram for 7 consecutive days to log diet, exercise, and (where relevant) glucose monitoring, supported by provider reminders and WeChat-based messaging feedback. Outcomes were assessed on day 7 (±1 d) in both groups; qualitative interviews were conducted 2 to 8 weeks post intervention.



In addition, separate closed WeChat groups were established for the intervention and control arms to facilitate routine communication, study management, and responses to participants' questions. Group access was restricted to enrolled participants and required manual approval by the group administrator (a research team member; the same administrator managed both groups). There was no fixed discussion theme; however, participants were informed that irrelevant content or commercial advertisements were not permitted. The study team proactively posted logging reminders and the miniprogram entry link in the intervention group only, whereas the control group did not receive proactive messages. In both groups, staff responded to questions raised by participants. Personalized feedback on the logged content was delivered to individual participants within the miniprogram rather than posted in the group chat.

Data Collection

Outcomes assessed corresponded to the quantitative result domains that include maternal knowledge, health practices, service experience, and selected clinical outcomes. Knowledge, health practices, and service experience were assessed once at a standardized 7-day postclass follow-up for both groups. During the 7-day period, participants in the intervention arm logged diet, exercise, and (where applicable) glucose readings via a WeChat miniprogram with provider feedback, whereas controls received the class without any digital component. A structured knowledge–attitude–practice questionnaire [29] was administered on day 7 (±1 d). The knowledge section comprised 7 items on pregnancy nutrition, weight management, gestational diabetes mellitus prevention, and anemia recognition, yielding a total score of 0 to 7 (1 point per correct response). Health practice indicators were coded as binary according to prespecified thresholds: dietary management ≥5 days/week, physical activity ≥3 times/week, regular supplement use (daily or every other day), and sharing health information with family (occasionally/often). Service experience was measured on a 5-point Likert scale (clarity of communication, respect for needs, personalization, and overall satisfaction). Clinical outcomes (labor duration, delivery mode, perineal trauma, postpartum hemorrhage, gestational complications, and neonatal outcomes such as birth weight, asphyxia, and malformations) were abstracted from medical records.

For the qualitative data, semistructured interviews were conducted 2 to 8 weeks after the intervention. The interview guide explored (1) emotional responses to the program, (2) perceived changes in knowledge and behavior, (3) experiences of peer and provider interaction, and (4) views on the applicability of learned strategies in daily life. Interviews lasted

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10 to 25 minutes, were audio-recorded, transcribed verbatim, and anonymized prior to analysis.

Data Analysis

Quantitative data were analyzed using SPSS version 25.0 (IBM Corp). Descriptive statistics were used to summarize baseline characteristics and outcome measures, with continuous variables presented as means and SDs and categorical variables expressed as frequencies and percentages. Group comparisons were explored using χ^2 or Fisher exact tests for categorical data and independent-samples *t* tests for continuous data where appropriate. However, given the modest sample size, emphasis was placed on reporting effect sizes and 95% CIs to indicate the magnitude [30] and direction of differences rather than relying solely on *P* values for statistical significance. All quantitative findings were interpreted as preliminary trends and considered alongside qualitative results to provide a more comprehensive understanding of the intervention's impact.

Qualitative data from semistructured interviews were analyzed thematically following the Braun and Clarke 6-step approach [31]. Transcripts were read repeatedly for familiarization, coded independently by 2 researchers, and iteratively developed into themes through discussion and refinement. Discrepancies were resolved by consensus, and representative quotations were selected to illustrate key points. Rigor was enhanced through member checking with a subset of participants and triangulation with class records and log data. Integration of quantitative and qualitative findings occurred at the interpretation stage: while the quantitative results identified patterns of change in knowledge, behaviors, and outcomes, the qualitative analysis provided insight into the mechanisms through which these changes occurred, thereby adding contextual depth and explanatory power.

Integration of findings was conducted at the interpretation stage using a convergent mixed methods approach. Quantitative results identified measurable changes in knowledge, behaviors, satisfaction, and selected clinical outcomes, whereas qualitative narratives offered insights into the processes and mechanisms underlying these changes. The 2 strands were brought together to assess complementarity, convergence, and divergence: quantitative trends pointing to improved dietary adherence, supplement use, and self-monitoring were supported by qualitative accounts of enhanced confidence, emotional reassurance, and peer support; observed differences in maternal outcomes were contextualized by participants' descriptions of how new practices were adopted and sustained. In this way, the integration of datasets provided a more comprehensive understanding of both the effects and the pathways of the intervention than either method could yield alone.

To ensure the validity and trustworthiness of the findings, several strategies were adopted across both components of the study. For the quantitative analysis, descriptive statistics and effect sizes were reported in addition to *P* values, with 95% CIs used to illustrate the precision of estimates. Given the limited sample size, findings were interpreted cautiously as preliminary trends rather than definitive effects. For the qualitative component, rigor was enhanced through independent dual coding, iterative theme development, and resolution of discrepancies by consensus. Member checking was undertaken with a subset of participants to confirm the resonance of interpretations with their lived experiences, and triangulation with classroom records and digital log data was applied to strengthen confirmability. Reflexive notes and coding logs were maintained to document analytic decisions, ensuring transparency and dependability. Finally, the integration of quantitative and qualitative findings followed a structured convergent mixed methods framework, which enabled the systematic comparison of results and enhanced the overall credibility of conclusions by drawing on multiple sources of evidence.

Ethical Considerations

The study protocol was reviewed and approved by the Ethics Committee of Beijing Daxing District Maternal and Child Health Hospital (approval number: LLSC2024014). All participants provided written informed consent prior to participation. Participants did not receive any financial compensation, reimbursement, or other incentives for participation. The study complied with the principles of the Declaration of Helsinki. Data confidentiality was safeguarded through anonymization and the secure storage of both quantitative and qualitative materials.

For the digital component, the WeChat miniprogram collected only study-relevant behavioral logs (diet, exercise, and glucose values, where applicable) and did not require participants to enter national identification numbers or unrelated personal data. Access to the administrative interface was restricted to authorized study staff via password-protected accounts. Exported datasets were deidentified prior to analysis and stored on encrypted, access-controlled institutional computers. Any participant quotations used in reporting were anonymized.

As communication also occurred within closed WeChat groups, residual privacy risks inherent to social messaging environments could not be fully eliminated, including participant-initiated screenshots or secondary sharing beyond the research team's control. To mitigate this, group membership was restricted to enrolled participants with manual administrator approval, and participants were informed at enrollment not to disclose identifiable or highly personalized information in the group chat.

Results

Quantitative Results

A total of 40 pregnant women completed the quantitative component of the study, with 20 assigned to the intervention group (experiential class plus online logging) and 20 to the control group (experiential class only).

Baseline Characteristics

Baseline demographic and obstetric characteristics were generally compared between groups (Table 1). The mean maternal age was 33.6 (SD 3.9) years in the intervention group and 31.8 (SD 4.6) years in the control group. Gravidity and parity were similar across groups (mean 1.75, SD 1.07 vs mean

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1.85, SD 1.04; mean 1.4, SD 0.60 vs mean 1.3, SD 0.66). Mean prepregnancy BMI was 21.9 (SD 1.6) in the intervention group and 23.9 (SD 4.2) in the control group, with mean corresponding prepregnancy weights of 58.0 (SD 4.8) kg and 62.7 (SD 9.9) kg. Height was also comparable (mean 162.2, SD 6.1 cm vs mean 161.3, SD 6.0 cm). The proportion of primiparas was slightly lower in the intervention group (26/40, 65% vs 32/40, 80%). Mean gestational age at delivery was 39.1 (SD 1.0) weeks in the intervention group and 39.1 (SD 1.2) weeks in the control group. No statistically significant differences were observed between groups at baseline.

Table . Baseline characteristics of participants (N=40).

Characteristic	Intervention (n=20)	Control (n=20)
Age (y), mean (SD)	33.6 (3.9)	31.8 (4.6)
Gravidity, mean (SD)	1.75 (1.07)	1.85 (1.04)
Parity, mean (SD)	1.4 (0.60)	1.3 (0.66)
Height (cm), mean (SD)	162.2 (6.1)	161.3 (6.0)
Prepregnancy weight (kg), mean (SD)	58.0 (4.8)	62.7 (9.9)
Prepregnancy BMI, mean (SD)	21.9 (1.6)	23.9 (4.2)
Primiparity, n (%)	13 (65)	16 (80)
Gestational age at delivery (wk), mean (SD)	39.1 (1.0)	39.1 (1.2)

Incremental Effects of Online Logging on Maternal Knowledge, Health Practices, and Satisfaction

At the postintervention assessment, women in the intervention group demonstrated significantly higher knowledge scores, stronger adherence to healthy practices, and greater satisfaction with services compared with the control group (Table 2).

The mean knowledge score was 6.8 (SD 0.9) in the intervention group and 5.2 (SD 1.1) in the control group, corresponding to a mean difference of 1.6 points (95% CI 0.8-2.4). Correct response rates for specific domains were also consistently higher: weight management (18/20, 90% vs 13/20, 65%; risk difference 25%, 95% CI 4%-46%), gestational diabetes prevention (19/20, 95% vs 12/20, 60%; risk difference 35%, 95% CI 15%-55%), and anemia recognition (16/20, 80% vs 11/20, 55%; risk difference 25%, 95% CI 3%-47%).

Intervention participants also showed stronger adherence to recommended practices. The mean composite adherence score was 3.3 (SD 0.7) in the intervention group compared with 2.3 (SD 0.9) in the control group (mean difference 1.0, 95% CI 0.4-1.6). Dietary adherence (≥5 days per week) was achieved by 17 out of 20 (85%) intervention participants versus 12 out of 20 (60%) controls (risk difference 25%, 95% CI 2%-47%). Similarly, 16 out of 20 (80%) intervention participants engaged in regular exercise versus 11 out of 20 (55%) controls (risk difference 25%, 95% CI 3%-47%), and 17 out of 20 (85%) intervention participants reported consistent supplement use versus 10 out of 20 (50%) controls (risk difference 35%, 95% CI 12%-58%). Knowledge sharing with family members was also more common (16/20, 80% vs 13/20, 65%), although the risk difference (15%, 95% CI –8% to 38%) included 0, suggesting that this trend was not statistically robust.

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Table . Maternal knowledge, behavior adherence, and service satisfaction between groups at postintervention assessment.

Indicator	Intervention (n=20)	Control (n=20)	Mean/risk difference (95% CI)
Mean knowledge score (0 - 7), mean (SD)	6.8 (0.9)	5.2 (1.1)	1.6 (0.8 to 2.4)
Weight management knowledge correct, %	90	65	25 (4 to 46)
GDM[a] prevention knowledge correct, %	95	60	35 (15 to 55)
Anemia recognition correct, %	80	55	25 (3 to 47)
Composite behavior score (0 - 4), mean (SD)	3.3 (0.7)	2.3 (0.9)	1.0 (0.4 to 1.6)
Dietary adherence (≥5 d/wk), %	85	60	25 (2 to 47)
Exercise adherence (≥3 times/wk), %	80	55	25 (3 to 47)
Regular supplement use, %	85	50	35 (12 to 58)
Health knowledge sharing with family, %	80	65	15 (–8 to 38)
Overall satisfaction score (1-5), mean (SD)	4.6 (0.5)	4.0 (0.6)	0.6 (0.2 to 1.0)
Clarity of provider communication, %	100	90	10 (–5 to 25)
Respect for personal needs, %	100	85	15 (–1 to 31)
Receipt of personalized advice, %	95	70	25 (6 to 44)
Overall satisfaction, %	95	80	15 (–4 to 34)

[a]GDM: gestational diabetes mellitus.

Service experience outcomes also favored the intervention group. Overall satisfaction scores were higher (mean 4.6, SD 0.5 vs mean 4.0, SD 0.6; mean difference 0.6, 95% CI 0.2-1.0). A higher proportion of intervention participants reported clear communication (20/20, 100% vs 18/20, 90%; risk difference 10%, 95% CI –5% to 25%) and respectful care (20/20, 100% vs 17/20, 85%; risk difference 15%, 95% CI –1% to 31%), though the 95% CI included 0. Receipt of personalized advice (19/20, 95% vs 14/20, 70%; risk difference 25%, 95% CI 6%-44%) was consistently higher in the intervention group. Overall service satisfaction reached 19 out of 20 (95%) in the intervention group compared with 16 out of 20 (80%) in controls (risk difference 15%, 95% CI –4% to 34%).

Across all knowledge, health practices, and service experience indicators, mean values and proportions in the control group were consistently lower than those in the intervention group, indicating a general trend favoring the addition of online logging, although some confidence intervals crossed 0.

Effect on Maternal and Neonatal Outcomes

Clinical outcomes were exploratory. Given the pilot sample size, the study was not powered to detect differences in maternal or neonatal end points; therefore, between-group differences should be interpreted as preliminary and hypothesis-generating rather than evidence of clinical benefits (Table 3). Mean labor duration was 7 hours 36 minutes (SD 247 min) in the intervention group compared with 8 hours 11 minutes (SD 255 min) among controls. Postpartum blood loss was lower in the intervention group (mean 398, SD 105 ml vs mean 447, SD 138 ml). Moderate-to-severe perineal trauma occurred in 8 out of 20 (40%) intervention participants versus 10 out of 20 (50%) controls. No clear differences were observed for cesarean section rates (10/20, 50% vs 9/20, 45%).

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Table . Maternal and neonatal outcomes.

Outcome	Intervention (n=20)	Control (n=20)
Weight gain (kg), mean (SD)	12.2 (4.8)	11.3 (3.7)
Postpartum blood loss (ml), mean (SD)	398 (105)	447 (138)
Labor duration, mean (SD)	7 hr 36 min (247 min)	8 hr 11 min (255 min)
Perineal trauma (≥II), n (%)	8 (40)	10 (50)
Cesarean section, n (%)	10 (50)	9 (45)
Preterm birth, n (%)	2 (10)	2 (10)
Neonatal birth weight (g), mean (SD)	3286 (431)	3269 (449)
Low birth weight, n (%)	1 (5)	1 (5)
Neonatal asphyxia, n (%)	1 (5)	1 (5)
Macrosomia, n (%)	0 (0)	0 (0)
Congenital malformation, n (%)	0 (0)	0 (0)

For neonatal outcomes, mean birth weight was 3286 (SD 431) g in the intervention group and 3269 (SD 449) g in the control group. Low birth weight occurred in 1 out of 20 infants (5%) in each group, and neonatal asphyxia was also reported once in each arm. No macrosomia or congenital malformations were observed. Because these events were rare and the sample size was small, the absence of adverse neonatal outcomes should not be attributed to the intervention.

Qualitative Results: Mechanisms of Change

Thematic analysis of postintervention interviews revealed 3 interrelated mechanisms of change through which the experiential class and online logging intervention shaped women's experiences and practices: (1) empowerment and self-efficacy, (2) practice and persistence, and (3) systematic and environmental support.

Empowerment and Self-Efficacy Mechanism

Women consistently described gaining reassurance, confidence, and emotional support through the acquisition of knowledge, social interaction, and guidance from providers. These processes collectively enhanced their sense of self-efficacy. Clear explanations of physiological changes, delivery processes, and preparation for procedures reduced fear and built confidence:

> 了解了这些知识之后，说实话就不是特别害怕了…了解了之后对生孩子还是挺有信心的。*(After learning this knowledge, to be honest, I was no longer that afraid… once I understood what to expect, I felt much more confident about giving birth.)* [WDK02]

Information about managing pregnancy risks also alleviated stress and created a sense of control:

> 通过一日课程门诊，我就知道该如何去控制，然后心理压力就没那么大了。 *(Through the one-day course clinic, I learned how to control it, and my psychological stress was much less.)* [WDK01]

Beyond knowledge, women valued social interaction and trust in providers, which contributed to both informational and emotional empowerment:

> 在群里面互动，互相学习，还有结交了几个比较好的朋友。 *(In the group we interacted and learned from each other, and I even made a few good friends.)* [DK08]

> 首先信心上是给我们了一个很大的支持，因为我们知道只要遵医嘱就会有好的结果。 *(First of all, it gave us a great deal of confidence, because we knew that as long as we followed the doctor's advice, there would be good outcomes.)* [DK19]

These accounts suggest that individual empowerment was reinforced by collective efficacy. Peer support and shared learning strengthened the women's confidence to engage in healthy practices, laying the foundation for sustained practice change.

Practice and Persistence Mechanism

Building on enhanced self-efficacy, women described attempts to implement healthy practices, such as dietary adjustments, exercise, and blood glucose monitoring. Self-discipline and perseverance were recurrent themes, but the sources of motivation differed between groups. In the control group, women primarily relied on their own willpower:

> 靠毅力…课程上他不给了那个那八段锦什么的，基本上一周我都会跳个两三次。 *(I relied on willpower… in the class they gave us the Baduanjin exercises, and basically I practice them two or three times a week.)* [WDK03]

In the intervention group, accountability and continuity through logging and interaction with providers or peers were emphasized:

> 会有医护人员给我们监控，比如说我们吃了多少东西去打卡，什么时候该运动，什么时候该加餐…所以说这个特别好。 *(Health care staff would monitor us-for example, what we logged about food intake, when we should exercise, when and how to add snacks. This was really very good.)* [DK09]

> 自己一个人有的时候确实难以坚持…有一个伙伴一起，这样比较容易坚持下来。 *(On your own it's really hard to keep going. Usually, you need a coach*

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> *or a partner, that way it's much easier to stick with it.)* [DK03]

Some intervention participants further described how sustained practice became habitual, with long-term benefits that even carried over into subsequent pregnancies:

> 比如现在我怀二胎…在抽静脉血的时候，那血糖都是一切都是正常的…不是有一种叫*21*天定律吗？坚持*21*天过后，然后你后面的你就形成了一种自然规律了。*(For example, now I'm pregnant with my second child… when they tested my blood, everything was normal. There's that saying about the 21-day rule-if you stick to something for 21 days, afterwards it becomes a natural routine.)* [DK04]

We interpreted such statements as perceived trajectories of practice changes rather than verified long-term outcomes because the logging and quantitative assessment occurred only within the first week.

Women also noted reviewing their own past logging records to reinforce ongoing practices change:

> 我会经常回顾之前孕期拍照打卡的那些照片…现在我的三餐它的搭配跟之前差多少？*(I often look back at the photos I logged during pregnancy… and compare how my meals are balanced now versus back then.)* [DK05]

These narratives suggest that participants perceived the logging component as increasing accountability and short-term persistence over the 7-day period. However, given the brief intervention and follow-up window, sustained practice maintenance or habit formation cannot be established in this study.

Systematic and Environmental Support Mechanism

Despite strong self-efficacy, participants emphasized that practice changes were shaped and sometimes constrained by systemic and environmental factors. Work schedules, family roles, and institutional arrangements acted as either facilitators or barriers. For instance, lack of time due to work hindered adherence:

> 饮食时间不规律，下班太晚，晚饭吃得比较晚，然后也没时间运动，这是个瓶颈。*(My meal times are irregular-after work it's too late, dinner ends up being very late, and then there's no time to exercise. That's a real bottleneck)* [DK02]

On the other hand, adherence can also be influenced by family:

> 家人做什么就吃什么…我家里人本身就比较注重这个养生这一边，所以就还是很好坚持的。*(I just eat whatever my family cooks… fortunately, they are very health-conscious, so it's easy for me to stick with it.)* [WDK04]

Institutional factors such as class timing also created participation barriers:

> 有的时候主要是周六周日比较好一点，他就经常是在周二周四这种的，其实时间上有点不太恰当。*(It would be better on weekends, but the sessions were often on Tuesdays or Thursdays, which really wasn't the most convenient.)* [WDK07]

These findings illustrate that even when women were motivated and empowered, insufficient system-level support could undermine the sustainability of practices, whereas strong family and institutional backing enabled empowerment and practices to translate into lasting change.

Discussion

Principal Findings

This mixed methods study evaluated the feasibility and short-term, preliminary effects of integrating experiential antenatal classes with a 7-day digital logging component in a district-level maternal and child health institution setting in Beijing. We observed short-term improvements in maternal knowledge, selected self-reported practices, and service satisfaction, alongside underpowered and nonsignificant clinical trends (such as reduced labor duration and postpartum blood loss). Thematic analysis further illuminated a chain of mechanisms of change: self-efficacy was enhanced collectively by knowledge from experiential learning and interpersonal interaction and, in turn, translated into daily health practices under the influence of external supports or barriers. Together, these results provide new evidence that bridging participatory education with digital accompaniment can address persistent gaps in maternal health promotion.

Comparison With Existing Evidence

The quantitative analysis demonstrated a significant incremental effect provided by experiential classes and online logging on the knowledge and practices of participants in the intervention group. The further enhancement of these 2 indicators could be associated with each other. Knowledge gains are driven by feedback loops enabled by online logging practices. For example, women posting photos of meals or asking doctors questions via WeChat allow doctors or peers to correct misconceptions or address individual gaps. This is consistent with recent literature. For instance, He et al [32] found that WeChat‐based prenatal education's real-time communication between patients and clinicians enables clarification of misunderstandings and strengthens comprehension. Wu et al [33] demonstrated that caregiver feeding knowledge was improved not just through message delivery but through caregiver queries and interactions in online groups. Furthermore, regular practices facilitated by online logging can be seen as an extension of experiential learning. Concrete action and reflection can deepen understanding and embed skills in daily routines, helping knowledge "stick" in practice [16].

The intervention group's superior behavioral outcomes suggest that the digital logging component reinforced continuity of support. However, the results from similar digital interventions are mixed: some trials show strong improvements in adherence and dietary or gestational weight outcomes, whereas others report minimal or no practice changes beyond standard care [34-36]. Our qualitative findings suggest another contributing mechanism: digital logging made shared goals more explicit, and therefore, participants reported feeling socially motivated.

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It aligns with the concept of collective efficacy, where group norms and peer visibility contribute to sustained practices. Studies in participatory interventions show that when group members believe in shared capability and observe others' progress, adherence is more likely [37,38].

Although differing in scale, participants in both control and intervention groups reported that gaining knowledge through antenatal education helped reduce nervousness and fear. In our quantitative results, both groups rated high satisfaction with services. This finding resonates with other studies of interactive or group-based antenatal education (small classes, discussions, etc), such as Augar et al [39] and Brixbal et al [40]. There is also evidence that good satisfaction contributes to continuity of care and positive health outcomes [41,42]. These mechanisms are consistent with contemporary ANC guidance that places women's experience, communication quality, and continuity of support at the center of care [11].

Additionally, participants in our study reported that both external and environmental conditions inhibited and facilitated practice change. This is consistent with qualitative evidence. For example, Escañuela Sánchez et al [43] show that even when women have awareness and motivation, social norms, stigma, and poor interaction with health care professionals often block effective weight management practices. Similarly, Jhaveri et al [44] in Uttar Pradesh find that structural opportunity barriers, such as lack of transport, limited food availability, and financial constraints, prevent pregnant women from translating knowledge into consistent nutrition, ANC attendance, or supplement intake. These findings reinforce that didactic changes (knowledge alone) are insufficient and practice changes depend critically on environmental support and opportunity.

Implications for Practice and Policy

The convergence of quantitative improvements and qualitative insights underscores the feasibility of scaling this model in urban ANC settings. The intervention required minimal additional resources beyond routine classes, leveraging an existing and widely adopted digital platform (WeChat) for continuity of care. As China continues to prioritize maternal and child health under the Healthy China 2030 strategy, integrating participatory education with digital reinforcement could serve as a cost-effective approach to optimize antenatal services, particularly in tertiary hospitals where patient volume and complexity are high. Furthermore, the qualitative findings identified emotional reassurance, trust, and peer connection as important dimensions of care that are not adequately captured by traditional clinical indicators but are essential for improving service quality and women's lived experiences. However, we must acknowledge that scalability may differ substantially outside urban district hospitals. In rural or low-connectivity areas, limited internet access, lower smartphone penetration, and constrained staffing may reduce feasibility or require alternative modalities (eg, SMS text messaging–based prompts, offline-capable tools, or community health worker support). Implementation should be adapted to local digital infrastructure and population needs rather than assumed transferable from an urban, digitally literate sample.

Strengths and Limitations

To our knowledge, this is the first study integrating experiential antenatal classes with digital logging in maternal health promotion. The mixed methods design not only allowed for outcome measurement but also provided explanatory insights into mechanisms of change. By situating the intervention in a district-level maternal and child health hospital rather than a tertiary setting, the study reflects the real-world context where most women receive ANC, thereby enhancing external validity. The intervention itself was low cost and built on existing tools such as WeChat, making it adaptable and scalable in diverse settings. Moreover, outcomes were assessed across multiple dimensions, including knowledge, practices, satisfaction, and clinical indicators, broadening the evaluation scope and practical relevance of findings.

Nonetheless, limitations should be acknowledged. The modest sample size and quasi-experimental design without randomization limit statistical power and raise the possibility of residual confounding. In addition, knowledge, practices, and satisfaction were assessed only once post intervention, and the digital logging component was restricted to a short 7-day period, leaving the long-term sustainability uncertain. Furthermore, implementation relied on clinicians' voluntary after-hours engagement to provide feedback, which may affect scalability under routine service conditions. When scaled, this model may require explicit workflow design (eg, protected time, standardized feedback templates, tiered escalation rules, or task-shifting to nurses/health educators) to avoid increasing clinician burden. Semiautomated reminders and rule-based feedback could preserve responsiveness while reducing manual workload but should be evaluated for safety and acceptability. Finally, participants were recruited from a single district-level hospital in Beijing, which may limit generalizability to other regions or lower-level facilities.

In addition, internal validity threats should be considered. First, the nonrandomized allocation and the small sample size increase the risk of selection bias and residual confounding (eg, baseline motivation, family support, and prior digital health engagement). Second, contamination is possible if participants shared information across groups. Third, key behavior outcomes relied on self-report and may be influenced by social desirability or Hawthorne effects. Future studies should use randomized (or cluster-randomized) designs with allocation concealment where feasible, incorporate objective behavioral indicators (eg, wearable activity data or clinic-verified glucose logs), and include longer follow-up periods to assess maintenance.

Equity considerations are also important. The digital component may preferentially benefit women with higher digital literacy, stable smartphone access, and supportive household environments. Women with limited autonomy, heavy caregiving/work burdens, or privacy concerns may be less able to log consistently or engage in provider messaging. Future implementation should include equity-oriented adaptations (eg, simplified logging, optional voice input, family-inclusive education when appropriate, and alternative low-tech reinforcement pathways).

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Future Directions

Future studies can test longer logging periods (eg, 4 - 12 wk) and/or periodic "booster" check-ins (eg, weekly prompts or trimester-based logging windows) to evaluate maintenance, burden, and engagement trajectories over time. Future research should evaluate this combined model in larger, multisite randomized controlled trials with longer-term follow-up to determine the sustainability of effects. Incorporating objective measures of practice changes, such as wearable physical activity trackers or biochemical indicators, would enhance validity beyond self-reported outcomes. Given that external and family environments strongly influence maternal practices, future studies should also explore family-inclusive education models. Moreover, investigating adaptation in resource-constrained settings will be essential for assessing scalability and equity. Finally, research into the mechanisms behind digital logging, such as accountability, social motivation, and feedback loops, could inform the design of more targeted and effective digital components.

Conclusion

This study provides preliminary evidence that integrating experiential antenatal classes with digital logging is a feasible, acceptable, and potentially effective model for promoting maternal health practices in China. The intervention improved knowledge, adherence, and satisfaction, with qualitative insights clarifying mechanisms of practice changes. While further research with larger samples is needed, the combined experiential-digital model offers a promising pathway for bridging the gap between knowledge and sustained health practices in ANC.

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Data Availability

The datasets generated and/or analyzed during this study are not publicly available due to hospital data protection policies but are available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization: LM (lead), ZS (equal), XW (supporting)
Methodology: ZS (lead), XW (equal)
Data curation: ZS
Formal analysis: FY (lead), XW (equal)
Writing—original draft: FY (lead), ZS (equal), XW (supporting)
Writing—review and editing: ZS (lead), FY (supporting), XW (supporting)
Funding acquisition: LM (lead), SZ (equal), YS (supporting)
Project administration: SZ, YS

Conflicts of Interest

The authors declare that they have no conflicts of interest relevant to this manuscript.

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Abbreviations

ANC: antenatal care
WHO: World Health Organization

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Patient Involvement to Promote Empathy in Preclinical Medical Students: Cross-Sectional Intervention Study

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Abstract

Background: Despite increasing patient involvement in medical education, research has predominantly focused on involvement in small-group teaching. This study explored what it means to actively and meaningfully involve patients in large-group, lecture-based teaching while avoiding historical paternalistic approaches.

Objective: This study aimed to describe the design, implementation, and evaluation of a novel curriculum component involving patients in early-year biomedical, clinical, and social science teaching to promote empathy in medical students.

Methods: A 6-step approach to curriculum development was applied to guide the design of this curriculum component, enhancing the existing curriculum by hosting real patients in lectures to add a genuine and authentic patient voice. The design process was supplemented by a coproduction workshop with patients, educators, and students. Patients were recruited to take part via local health care networks and the University of Leicester Patient and Carer Group. Nine modules in years 1 and 2 hosted patients in lectures across the 2023-2024 academic year. A student feedback questionnaire based on previous similar published studies was developed to assess engagement and achievement of learning outcomes.

Results: First- and second-year students (N=604) attended mandatory biomedical, clinical, and social science lectures hosting patients throughout the 2023-2024 academic year. In total, 65.6% (396/604) of students completed feedback questionnaires at the end of the year. Most students (340/391, 87%) reported that including patients in lectures increased their feelings of empathy, and 77.5% (307/396) reported that their inclusion improved their engagement with learning.

Conclusions: The novel inclusion of real patients and their stories in biomedical, clinical, and social science lecture-based teaching has the potential to improve student learning and enhance feelings of empathy toward patients. Our findings are reproducible and transferable, and the intervention was well received by students.

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KEYWORDS

patient involvement; empathy; medical education; patient engagement; preclinical education; curriculum intervention

Introduction

Background

Clinical empathy has multiple benefits for patient care [1] and practitioner health and well-being [2]. Empathy is usually considered to be a multidimensional construct incorporating affective, cognitive, behavioral, and moral components [3]. A recent systematic review of empathy definitions identified 6 components of empathy: exploring, understanding, shared understanding, feeling, therapeutic action, and maintaining boundaries [4]. These components overlap with the 2002 definition of clinical empathy in health care by Mercer and Reynolds [5]: the ability to understand the patient's situation, perspective, and feelings; communicate that understanding to them; and act on it in a helpful and therapeutic way.

Empathy is central to health care education [6] and is recognized internationally as a professional competency expected of medical students and physicians [6-8]. However, despite its importance, empathy appears to decline during medical school [9,10]. While there is no consensus on the most effective means of teaching empathy [11-14], a systematic review of 26 trials demonstrated that empathy can be taught [14] and that specific sustainable interventions integrated into the curriculum are likely to be most effective [13].

There is current evidence suggesting that empathy can decline in students during the transition from preclinical to clinical-based education [9,10]. Some studies report that an

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undue focus on biomedical knowledge [15,16] often detached from the lived patient experience in the preclinical years contributes to this [16]. Other studies suggest that involving patients and their stories more consistently could help boost empathy [17-19], promote human attributes [18], support a focus on the psychosocial aspects of illness [19], encourage active learning [20], and enhance knowledge construction and clinical reasoning [21]. Despite the potential to benefit medical students, patients and their stories are rarely involved to support learning in the biomedical science–focused curriculum.

Study Objectives

Historically, patients have been used, often unethically, in lecture theaters as "passive props" to illustrate pathophysiology [22]. This is reflective of an outdated, paternalistic era of medicine [22,23]. With a move toward patient partnerships [24], patients' roles in medical education have become increasingly active [22], with patients and educators keen to find new, innovative ways to support patient involvement in medical education [25]. To address the lack of patient participation in the biomedical science curriculum, we developed, implemented, and evaluated a curriculum component that aims to promote empathy by involving real patients in lecture-style teaching for biomedical- and clinical-focused modules.

Our research questions were as follows: (1) What benefits to learning and engagement do students report when patients contribute to biomedical and clinical science lectures? (2) Does the inclusion of real patients and their stories in lectures during the early-year biomedical, clinical, and social science curriculum have the potential to enhance student empathy?

Methods

We followed the six-step approach to curriculum development and implementation in medical education by Kern et al [26]: (1) problem identification and general needs assessment, (2) targeted needs assessment, (3) goals and objectives, (4) educational strategies, (5) implementation, and (6) evaluation and feedback. We refined our curriculum component by eliciting the ideas and opinions of medical educators, students, patients, and carers in a coproduction workshop.

Problem Identification and General Needs Assessment

The General Medical Council emphasizes that medical students should cultivate a person-centered approach throughout their training, recognizing that placing patients at the center of care is fundamental to safe and ethical practice [27]. Educators and curriculum developers advocate for the integration of the biopsychosocial model (a framework for understanding health and illness that highlights interactions among biological, psychological, and social factors) throughout the early years, not as an adjunct but woven into teaching. This encourages students to learn a holistic approach to patient care [28] and holistic reasoning alongside biomedical sciences [29]. Medical students highlight that early exposure to psychosocial narratives enhances empathy, communication, and understanding of illness, particularly in the context of chronic and complex conditions [30]. Finally, patients recognize the importance of using a biopsychosocial lens from the outset to support person-centered values in future health care professionals [31].

Targeted Needs Assessment

Leicester Medical School (LMS) describes its curriculum as integrated, patient focused, and with "teaching and learning based around patients and their needs" [32]. However, with notable exceptions [33], an audit of the curriculum (unpublished) revealed that most year 1 and 2 modules are biomedical and clinical science–based and use the lecture theater setting, which is devoid of exposure to real patients.

Curriculum Development

Goals and Objectives

The goal of this intervention was to develop and deliver a curriculum component and evaluate the impact of involving real patients in biomedical and clinical science lectures on student empathy. We anticipated that having real patients contribute to lectures would support students in achieving the following intended learning outcomes:

- Being able to connect clinical science concepts to real-world patient presentations and scenarios
- Acquiring a deeper appreciation of the psychological and social impact of illness and disease on patients' lives
- Starting to recognize the benefits of developing an empathic approach to patient care through reflection and discussion of patient experiences

Educational Strategy

Lectures have been, and continue to be, an efficient and standardized opportunity to deliver knowledge to large groups of students. However, this strategy is often teacher focused and can fail to engage students in active learning [34]. Active learning is student focused and aims to engage students by providing opportunities to interact, think, and discuss what they have been exposed to [35]. While the preclinical years at medical school tend to be focused on knowledge acquisition in the basic sciences, they are also an opportunity to provide formative lifelong learning and preparation for clinical practice [36]. Introducing real patients to lecture-based teaching of biomedical and clinical skills provides opportunities for students to interact and engage with their learning [37]. This educational strategy, added to the existing curriculum as a new component, can help students meet the required learning objectives, including knowledge acquisition; better understand patient perspectives; and help them prepare for future practice [35-37].

Coproduction Workshop

Coproduction involves key stakeholders working together, sharing power and responsibility from the beginning of a project [38,39]. A coproduction workshop was convened at the start of this project to engage stakeholders and improve the quality and relevance of this initiative [40], using an approach that is becoming increasingly popular [39]. The workshop included 3 medical educators (all module leads in the first 2 years of medical school [phase 1] at LMS), the project lead (RW) and another author (AB-W), 2 community patient representatives from the University of Leicester Patient and Carer Group, and 2 volunteer medical students. Students, educators, and patients

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broadly agreed that the desired outcomes of involving patients in biomedical science teaching were to (1) link theory to practice (and patient presentations) and (2) develop students' understanding of the psychosocial impact of disability and/or disease. There was much discussion regarding possible approaches to involving patients in lectures, with the patient representatives keen to see their stories and experience interwoven and clearly relevant to the particular topic of the lecture. Student representatives felt that the opportunity to ask patients questions in lectures would be helpful, although there was some concern from educators about how this would be managed, particularly if questions were not appropriate or if there were no questions when students were prompted to ask them. The use of interactive tools in lectures for students to ask questions anonymously, for example, was discussed as a possible solution.

Educators and patient representatives discussed ways in which patient involvement in lectures could be evaluated, for example, through student feedback. Student representatives within the workshop identified possible challenges here, with frequent requests to provide feedback possibly being burdensome for students. However, patients felt that some form of feedback and evaluation of their involvement in lectures would be helpful, and it was agreed by educators that this should be a mandatory part of the intervention. Strategies discussed included a short debrief with patients and educators immediately after the lecture and specific student groups (eg, student societies with an interest in education) being asked to provide feedback following lectures hosting patients.

All workshop participants raised potential challenges. Educators were concerned about managing students who failed to engage or connect with learning and avoiding disruptive or distracting behavior. There was also concern that nonclinical educators may not feel confident about hosting patients in their lectures. Patient representatives felt that patients may be reluctant to travel to the university to engage for a short time (perhaps only 10-15 minutes). Patient representatives put forward concerns about potential consequences for patients involved and the need for a clear brief and clearly defined role for patients about what their involvement would mean. The group acknowledged that the intervention could cause patient anxiety about revisiting negative experiences, fear of judgment from students, and concern about confidentiality [22].

On the basis of findings from the coproduction workshop, modifications were made to the original intervention. Patient and educator representatives agreed that preparation for patients, carers, and educators would be key to ensure confidence, with the following measures put in place: patients should be provided with an overview of the lecture topic before taking part, patients should be given a clear idea of how their story is relevant and what aspects of their story would be most useful, patients should be given enough time to ensure that they are well prepared, and patients should be offered a debrief immediately after the event and a follow-up meeting several weeks after to provide any relevant student feedback. In addition, patients would be compensated for their time and support. Patient representatives in the workshop strongly felt that involving experienced patients would likely help lower the risk of experiencing discomfort or trauma if students appeared disengaged or engaged in unprofessional conduct. A standard operating procedure was developed to support both patients and lecturers once involved.

Curriculum Intervention

Permission to undertake this curriculum component was sought by internal stakeholders, including the head of the medical school and phase 1 (year 1 and 2) leads. Meetings were held with individual module leads to explain the intervention, encourage engagement, and offer support. Once a module lead agreed to take part, we worked to identify which lectures could host a patient and what type of patient or aspect of illness, treatment, or recovery would best fit. Patients were recruited through a variety of patient networks (including local, regional, and national patient groups; the University of Leicester Patient and Carer Group; and through clinical contacts at local primary and secondary care trusts). Patients who agreed to take part met with the lecturer to gain an understanding of the lecture structure and content and plan their contribution.

Curriculum Evaluation

The achievement of the intended learning outcomes was assessed by gathering student feedback at the end of the year. We developed an evaluation questionnaire consisting of 7 questions using a 5-point Likert scale and a free-text question. The questions were guided by those presented in a previous related study [19] and developed by 2 authors (RW and JL). The questions aimed to assess student perception of their engagement, learning, and satisfaction with lectures involving real patients. The questionnaire was distributed to students via an online platform. Free-text responses to the question "Are there any other comments you have about patients in lectures?" were analyzed to identify patterns through thematic analysis. Thematic analysis involves initial familiarization with the data, followed by coding, development of themes, and reporting of the findings [41]. There are concerns about the limitations of open-ended survey questions in supporting rigorous qualitative insights [42]. Data collected in this way may only consist of a few lines (or less) and may lack "attention to context and...conceptual richness" [43]. However, LaDonna et al [42] and others recognize that written survey responses can enhance findings, corroborate answers to closed-ended questions, and inspire new avenues of research. They propose strategies to guide free-text analysis and provide more meaningful findings, which were used to inform the analysis of data in this study.

Ethical Considerations

Ethics approval for this evaluation was obtained from the Medicine and Biological Sciences Research Ethics Committee at the University of Leicester (42549-rw205-ls:medicine). There was no potential harm to participants. Any personal information that could directly identify participants will be removed or coded before study data are shared. Despite these measures, anonymity was not guaranteed. All patients were given a participant information leaflet and asked to give their consent for the lecture to be filmed. Participants were not offered compensation.

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Results

From the 18 modules in phase 1, a total of 11 (61.1%) module leads agreed to take part in the initiative. However, 18.2% (2/11) of these modules did not host patients (1 due to staff sickness and 1 because no patient could be found). Of the 9 modules (accounting for 9/18, 50% of phase 1 modules) that did host patients, 4 were first-year modules and 5 were second-year modules. Table 1 provides an overview of the modules included and details on the patients who were hosted in the lectures.

Table . Overview of the modules taking part in the initiative and patients hosted in the lectures.

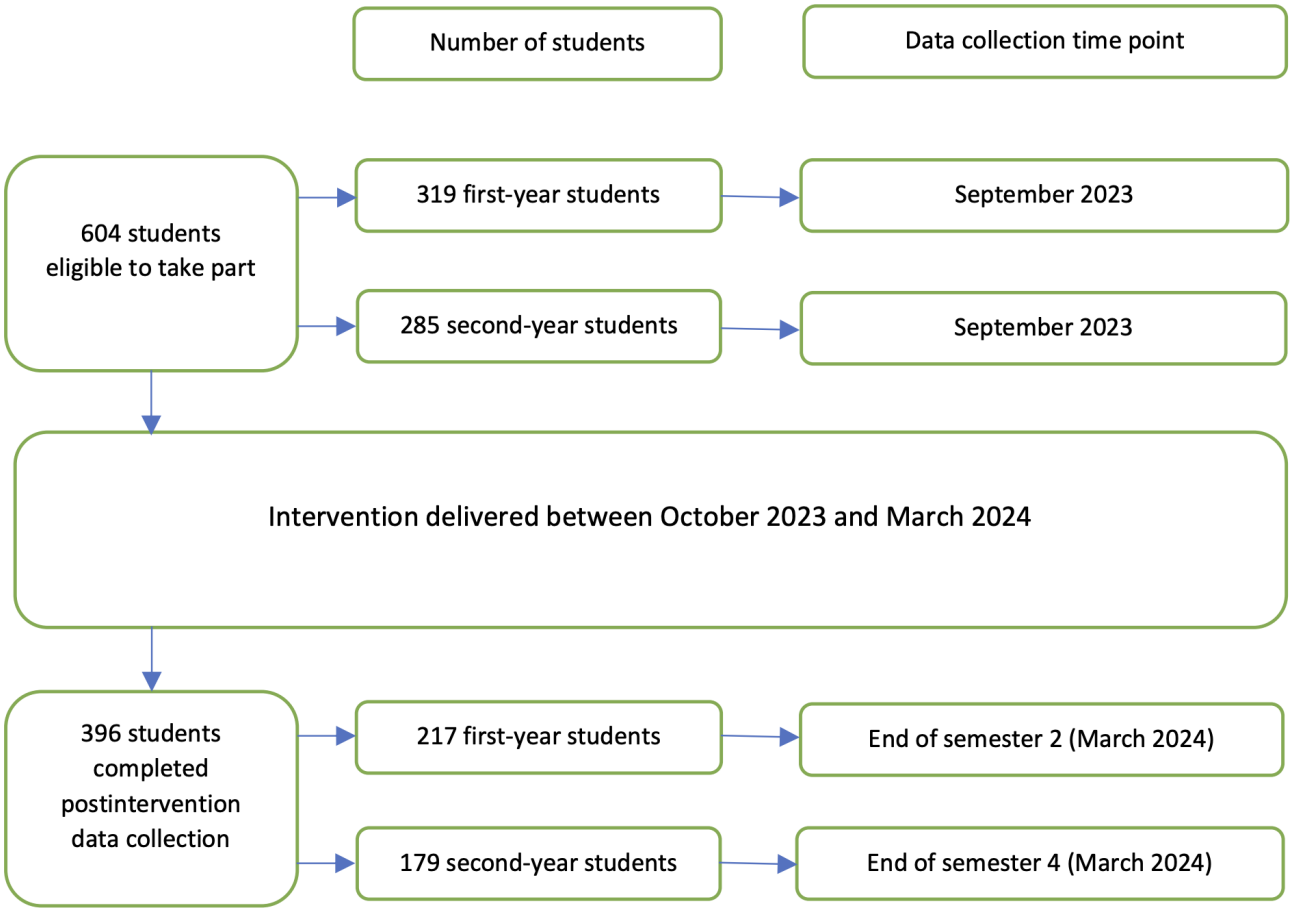
Name of module	Year	Semester	Name of lecture	Patient presentation
Medical Cell Biology and Genetics	1	1	Genotype, phenotype, and inheritance	Cystic fibrosis
Population and Social Science	1	1	Long-term conditions	Multiple sclerosis
Cardiovascular System	1	2	Congenital heart disease	Congenital heart disease (AVSD[a])
Musculoskeletal System	1	2	Back pain	Chronic back pain
Reproductive System	2	3	Menopause	Menopause
Respiratory System	2	3	Asthma	Asthma
Urinary System	2	3	Chronic kidney disease and dialysis	Peritoneal dialysis
Clinical Pharmacology Therapeutics and Principles of Prescribing	2	4	Epilepsy	Epilepsy (patient DNA)
[b]Integration for Clinical Application	2	4	Breast disease	Breast cancer

[a]AVSD: atrioventricular septal defect.

At the end of the year, all students were invited to complete the feedback questionnaire. A total of 396 students completed the evaluation (396/604, 65.6% response rate), with 217 (54.8%) first-year students and 179 (45.2%) second-year students taking part. In total, 1.5% (6/396) of the students did not answer all 6 evaluation questions but were included in the evaluation data. Figure 1 provides an overview of participant demographics and data collection time points.

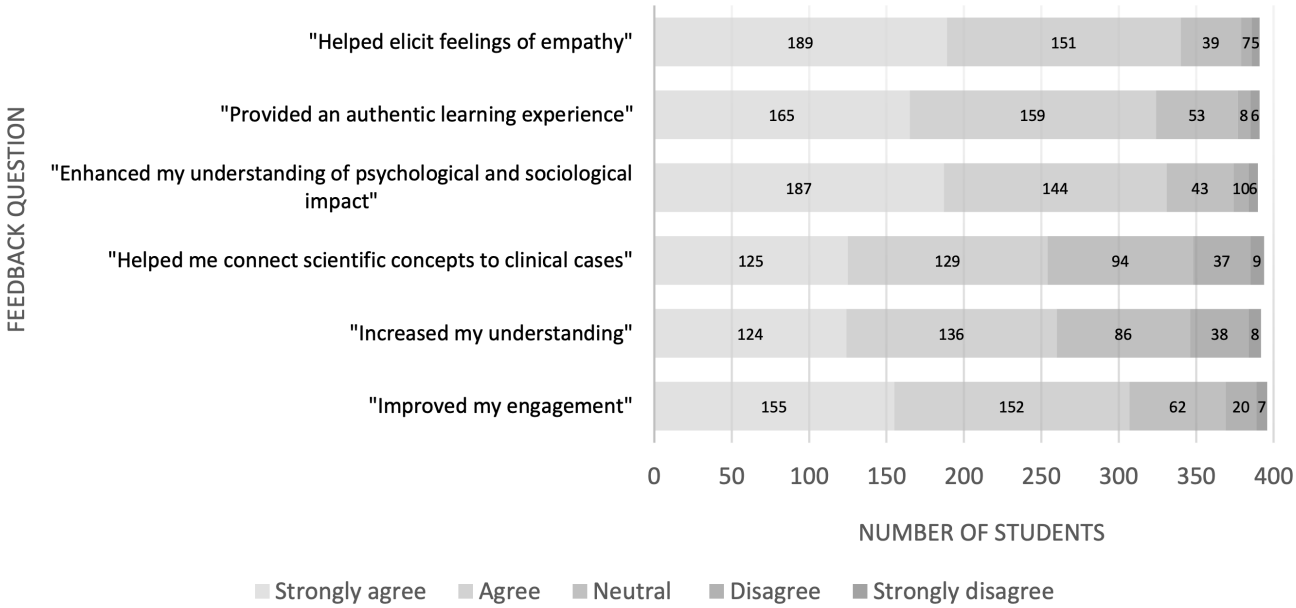
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Figure 1. Overview of participant information and data collection time points.



Following the intervention, 87.0% (340/391) of the students agreed or strongly agreed that it helped elicit feelings of empathy. Most students (331/390, 84.9%) agreed or strongly agreed that including patients in lectures helped enhance their understanding of the psychological and social impact of a disease. In total, 77.5% (307/396) of the students agreed or strongly agreed that having patients involved in lectures improved their engagement. Figure 2 provides an overview of the findings. Nearly three-quarters of the students (281/396, 71.0%) agreed or strongly agreed that they would like to see more patients involved in lectures in the future.

Figure 2. Overview of student feedback following participation.



In total, 8.8% (35/396) of the students provided free-text comments, and 2 themes emerged from these data. The first was “patients in lectures enhance understanding” (the most dominant theme). Students commented on how real stories

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helped them connect the subject matter to patient lives and described a deeper understanding and awareness when patients presented in lectures. In the second theme, "patients in lectures can present limitations," students described some potential challenges of patients in lectures, including worrying that patients may feel uncomfortable and a lack of time in lectures to really engage with patients. Table 2 provides an overview of each theme with examples of supporting comments.

Table . Summary of free-text comments from students.

Theme	Description	Examples of supporting comments
Patients in lectures enhance understanding	Students described how patients attending their lectures enhanced their learning by helping them connect the subject matter to real stories. They described a deeper sense of understanding through an awareness of the psychosocial impact of illness. Students felt that the presence of patients in lectures created a more personal learning experience and helped foster empathy.	• "They are all really lovely and they help me understand their condition and how it impacts them better." • "It's so helpful and helps deepen understanding and empathy." • "Can we have more patients please in lectures when talking about clinical conditions. It makes them more engaging and more personal." • "Diseases are more memorable when I can associate it to a patient." • "I think having a patient come in revitalised my passion for medicine and reminded me why I came to medical school. It also helped me to better understand the physiology and pathology and helped me remember it better." • "They were good in telling us their stories and helping us understand the impacts on their lives and patients lives in general."
Patients in lectures can have limitations	Some students found patients presenting in lectures to be less helpful, feeling that their input would be better in small-group sessions or on clinical placement. Some students worried that patients looked uncomfortable at times and seemed a little unsure of their role, possibly leading to students feeling unsure of how to engage. Students also felt at times that the experience could have been better; for example, they reported that patients were at times difficult to hear and some lectures ran over the allotted time when patients attended, leaving students finding it harder to concentrate for longer.	• "Some have been really clear, but some seem nervous and waffle a bit too much." • "I feel like a video entry from the patients would have the same effect. I also found that often the patients looked like they felt uncomfortable and the students were reluctant to ask personal questions in front of the lecture theatre." • "Their stories are interesting but I don't feel like I learn anything new than from the case studies and placements." • "Lectures overrun when we have patients and it's harder to concentrate." • "It can be hard to engage in the whole lecture theatre. It might be more helpful to have them in smaller groups, but I understand it may be more difficult." • "We should be able to ask them our own questions."

Discussion

Principal Findings

To the best of our knowledge, this paper is among the first to describe the design, implementation, and evaluation of a wide-reaching educational strategy that integrates real patients to promote empathy across the biomedical, clinical, and social science components of the medical school curriculum. We recognize that similar initiatives may be underway elsewhere and would welcome engagement with others working in this area. Students overwhelmingly reported that the inclusion of patients in science-based lectures helped elicit feelings of empathy and agreed that the intervention benefitted their engagement with teaching and learning.

Overall, our findings broadly support those of previous studies in this area. A systematic review of 49 studies reported that patient involvement in education in medical school can improve student understanding of person-centered care [44] and, therefore, empathy [45]. However, none of the studies included in this review described the introduction of real patients in lecture-based pathophysiology teaching. Other studies have identified that students value interactions with patients, reporting finding real patient encounters to be authentic and instructive [46], and that patients can help link theory with reality, enhance learning [46], and improve learning satisfaction [47]. Our evaluation adds to a growing body of evidence on the advantages of including real patients across the spectrum of medical education and in more innovative ways [19,47]. Specifically, it is rare to introduce real patients in lectures focused primarily on pathophysiology teaching.

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Strengths and Limitations

A strength of this evaluation is that it describes the development and delivery of a wide-reaching curriculum component. Our response rate to the postintervention survey was high, especially given the frequent requests that medical students receive to complete evaluations or participate in research [48,49]. Our findings identify that this addition to the curriculum is feasible and sustainable. There are some limitations to this evaluation. First, concerns were raised about the generalizability of our findings. This was a single-site evaluation for first- and second-year medical students. There are additional resources required to develop and implement this strategy across multiple sites, including the potential additional work required from faculty. To mitigate this, medical schools are required to promote a person-centered approach to health care throughout their programs [27], so lecturers already often include videos or vignettes (which must be identified and integrated into the lecture). There is also a cost associated with setting up the system of including patients in the lecture theaters. Our comprehensive standard operating procedure minimizes the set up and organizational resources required for future educators who wish to implement our curriculum component. We also note that our medical school has a patient involvement group who were happy to contribute to the delivery of this initiative. In addition, we worked with primary care colleagues at LMS to identify and recruit patients in general practice. Many medical schools have similar patient groups and networks that could be similarly helpful. Second, it was beyond the scope of this evaluation to formally explore patient experiences; however, we acknowledge that the patient experience does need exploring. We are currently conducting research to better understand the patient perspective when presenting in lectures, including any potential harms. A third limitation was that our evaluation did not describe the 4 types of evaluation by Kirkpatrick and Kirkpatrick [50], whose outcomes of hierarchy evaluate training methods at four levels: (1) reaction of the learner, (2) the degree to which the learning takes place, (3) how well the learning is assimilated into the learner's practice or behavior, and (4) the degree to which the learning outcomes are met as a result of the training. We did not assess actual learning or changes to behavior or practice as a result of the intervention. Finally, while lectures are mandatory at LMS, there is no record of attendance kept, and it was not possible to identify whether students who completed the evaluation attended all or just some of the lectures hosting patients.

Involving patients in early-year teaching of biomedical and clinical science offers students a meaningful and motivating way to connect theoretical knowledge with real-world clinical practice. Patients from primary care settings provide ideal contexts for this intervention, offering a diverse range of experiences with conditions, chronic disease management, and preventative care. These real-life contexts not only illustrate the application of science but highlight the complexity and continuity of health care. Students will also begin to develop a broader understanding of the health care system, including social determinants of health and the realities of delivering care in community settings, right from the start of their training. There are inherent challenges, as already discussed, with inviting patients to attend lectures. However, there are many potential benefits to students in terms of fostering empathy toward patients, enhancing engagement with learning, and increasing awareness of the psychological and social aspects of health and illness. A future focus on the long-term impact on empathy and whether this intervention can help halt or reverse the documented decline in medical student empathy [9,10] during training is needed.

Conclusions

Integrating real patients and their stories into biomedical and clinical science lecture-based teaching is a novel application. The introduction to real patients throughout the early-year biomedical, clinical, and social science curriculum was well received by students. It can support engagement with learning and promote feelings of empathy in students, with the potential to mitigate the risk of decline in empathy among medical students.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

RW and JH conceived and designed the evaluation. JL gave advice on the design. RW and JL recruited module leaders to take part in the evaluation. AB-W led the design and delivery of the coproduction workshop with support from RW. RW, JL, AB-W, AD, and CD supported the rollout of the initiative across the curriculum component. JL, AD, and CD supported the recruitment

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of participants and evaluation process. RW analyzed and interpreted the data and drafted the manuscript. All authors approved the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

LMS: Leicester Medical School

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“Tough Things You’re Going to Have to Go Through”: Dyadic Interview Study Including the Perspectives and Needs of Patients and Their Caregivers Post-Hematopoietic Cell Transplant

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Abstract

Background: Patients undergoing hematopoietic cell transplant (HCT) and their caregivers are under a significant amount of stress throughout the HCT process with fear of disease recurrence, graft failure, and many other HCT-related complications. However, the needs and perspectives of patients undergoing HCT and their caregivers as dyadic units over the peri-HCT period are continuing to be studied and are an evolving field of research.

Objective: To better understand patient and caregiver perspectives throughout the HCT course, patients undergoing HCT and their caregivers were able to opt-in to interviews at multiple time points post-HCT as part of a larger study, Roadmap 2.0 (an app intervention trial to support caregivers of patients undergoing HCT).

Methods: Semistructured, dyadic (patient and caregiver) interviews took place around hospital discharge, day +30, +60, +90 and +120 post-HCT. Patient and caregiver discussions at each interview centered around a variety of topics including desired post-HCT information, coping, and additional resources for patients and their caregivers with the goal of gathering feedback to better inform future studies after Roadmap 2.0 and better understand the needs and perspectives of patients undergoing HCT and their caregivers. Interviews were transcribed and double-coded with inductive and deductive content analysis using the framework method to identify key findings.

Results: A total of 10 patient-caregiver dyads participated, resulting in 48 dyadic interviews (1 patient died). Multiple findings emerged out of these rich discussions, including the progression from immediately post-discharge to when patients undergoing HCT and their caregivers were further out from HCT. The progression was as follows: “desire for data and tracking” to “need for specific restrictions and outline on forward progress,” to “need for additional directed information as progressing forward,” to “bigger picture and getting back to life,” and concluding with “reflection and fear.” Most patients and caregivers felt they were provided sufficient general anticipatory guidance throughout the HCT process but called for more specific expectations and guidance on a variety of issues. Many patients and caregivers used multiple coping strategies during HCT, with their coping strategies largely staying consistent over time. Additionally, the need for further acknowledgment and focus on the stress HCT places on caregivers was frequently discussed.

Conclusions: Patients undergoing HCT and their caregivers were largely satisfied with the information and anticipatory guidance they were given but stressed a desire for more specific information throughout their HCT course. A variety of coping strategies are used by patients and their caregivers post-HCT, and these were consistently used over time. However, increased awareness and acknowledgment of the strain HCT places on caregivers are needed within the health care setting and in the general population. Future directions include continued incorporation of qualitative interviews with patients and caregivers as HCT-related interventions and apps.

Trial Registration: ClinicalTrials.gov NCT04094844; https://clinicaltrials.gov/study/NCT04094844

(J Particip Med 2026;18:e81971) doi:10.2196/81971

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KEYWORDS

hematopoietic cell transplant; HCT; bone marrow transplant; BMT; apps; mobile health; caregivers

Introduction

Hematopoietic cell transplant (HCT) is used to treat both malignant and nonmalignant conditions, using cells from self (autologous) for solid tumors and some lymphomas or donor (allogeneic) for hematologic malignancies and a wide range of other conditions. In both cases, high-dose chemotherapy and/or radiation is used prior to the infusion of hematopoietic stem cells, putting patients at high risk for infections and other complications [1,2]. While HCT and supportive care for HCT complications have greatly improved over the recent decades, there remains a relatively high risk of morbidity and mortality related to HCT [1-4]. Whether receiving an autologous or allogeneic HCT, a full-time caregiver is typically needed for an extended period (up to multiple mo or even longer). Only recently has more public acknowledgment and research been published, acknowledging and focusing on the stress experienced by caregivers of patients undergoing HCT, with caregivers reporting psychosocial distress and diminished quality of life [5-7].

Over recent years, a variety of studies have aimed to help providers and researchers better understand the challenges faced by individuals undergoing HCT and their caregivers as well as determine how best to reach and support them [8-15]. The app, BMT Roadmap, was created by Runaas et al [8] at the University of Michigan over a decade ago with the goal to provide information and support for caregivers of patients undergoing HCT. BMT Roadmap has been developed iteratively, incorporating feedback from rigorous user testing, to create its most recent version, Roadmap 2.0. Roadmap 2.0 incorporates positive, resilience-building activities and was designed for the outpatient setting [9]. In 2020, a mobile randomized controlled trial of Roadmap 2.0 was started (NCT04094844) [16].

In the Roadmap 2.0 study, the randomization was at the caregiver level, with an intervention arm of caregivers receiving a menu of positive activities, access to caregiver forums within the app, and a variety of informational guides for caregivers (Figure 1; Multimedia Appendix 1). Caregivers in the control arm received no positive activities, caregiver forums, or informational guides. Caregivers in both arms received a Fitbit that tracked steps and sleep and displayed these results in graphical form in the Roadmap 2.0 app (Figure 1). Caregivers in both arms were asked to record their mood score (scale 0-10) in the Roadmap 2.0 app, which was also displayed in graphical form (Figure 1). The study's primary endpoint was caregiver quality of life at day +120 as measured by the Patient-Reported Outcomes Measurement Information System Global Health Scale, hypothesizing that caregivers in the intervention arm will have better quality of life when compared to caregivers in the control arm [16]. After 2020, the Roadmap 2.0 study was expanded to include other centers outside of the University of Michigan, extending to Oregon Health & Science University (OHSU) in 2021. The manuscript of the outcomes of the Roadmap 2.0 was recently published, and while there were no significant differences found between the intervention and control groups by Patient-Reported Outcomes Measurement Information System Global Mental or Physical Health Scales, daily mood of caregivers in the intervention arm improved significantly over the course of the study [17].

As an opt-in addition to the Roadmap 2.0 study when OHSU opened as a second center, patients and their caregivers were offered semistructured, dyadic interviews at a variety of time points throughout the study (around hospital discharge, day +30, +60, +90, and +120 post-HCT). The inclusion of this optional portion of the study was to investigate the hypothesis that the support needed for patients and caregivers during the HCT process is both unique to each person and dyad as well as dynamic across the HCT course, which is commonly observed by clinicians throughout the post-HCT course. Additionally, we hoped to gain a better understanding of the support needed by patients and caregivers to further optimize future versions of BMT Roadmap and other mobile health and technology interventions for patients undergoing HCT and their caregivers .

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Figure 1. Screenshots from the Roadmap caregiver user interface. (A) Menu of positive activities available in the app. (B) Menu of chat forums available to caregivers. (C) Caregiver resource documents available in the app. (D) Tracking graphs of mood entries as well as sleep and steps imported from the Fitbit. Source: Rozwadowski et al [16], originally published in *JMIR Research Protocols*. This is an open-access article distributed under the terms of the Creative Commons Attribution License (CC BY 4.0).

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Methods

Ethical Considerations

Institutional review board approval was granted at OHSU and oversight approval granted at the University of Michigan, which served as the central or single institutional review board (HUM00176584). The risks and benefits of the study were explained and informed consent was obtained prior to the conduction of optional interviews. All study procedures were conducted in accordance with ethical standards at OHSU and the University of Michigan as well as in accordance with the Declaration of Helsinki. Inclusion criteria for the opt-in interviews were the same as Roadmap 2.0 study inclusion criteria, which included patient age of at least 7 years, caregiver age of at least 18 years, patient and caregiver access to an iPad or cell phone, and patient and caregiver ability to read and understand English. Patient privacy and confidentiality were maintained. Monetary compensation was not provided as part of the study. However, study participants were able to keep their Fitbit following the study.

Sample and Data Collection

During the consent or assent for Roadmap 2.0, patients and their caregivers were also offered participation in the opt-in interviews. As patients approached discharge, days +30, +60, +90, and +120 post-HCT, patients and/or their caregivers were contacted in person, via email and/or via telephone to arrange semistructured dyadic interviews. Only dyadic interviews were conducted at each of these times with the hope that having both the patient and their caregiver discussing topics together would provide more insight and feedback compared to an individual (patient or caregiver) interview alone. Post-discharge interviews took place within 7 days of discharge. Day +30, +60, and +90 interviews took place up to 2 weeks prior to or as late as 2 weeks following these time points. The day +120 interview took place up to 1 month prior to or as late as 1 month following this time point.

Interviews took place in person or via telephone, aside from 1 interview where the caregiver was present on video call. AJ completed the interviews with adult patient dyads, and two other research staff members completed the interviews with the adolescent patient dyad given that AJ provided direct care to the adolescent patient. All staff completing interviews were trained in qualitative methods. All interviewers were women, and field notes were taken during the interview for reference following the interview. Interviews were audio-recorded. Interview questions spanned a variety of topics including perspectives on important and missing information during the HCT process, coping, future intervention or app design ideas, and Roadmap 2.0 feedback (Figure 2).

Figure 2. Interview script. BMT: bone marrow transplant.

General semistructured interview questions (both caregiver and patient participants)

1) In your opinion, what information is most important for you to have post-transplant?
2) Would an app with this information be beneficial to you?
3) If you could design an app or additional intervention post-transplant, what would it involve?
4) Do you think this additional app or intervention would be helpful, burdensome, or neutral?
5) What information do you feel was missing during your stay? For days +30, +60, +90, and +120: What do you wish you had been told between discharge and now?
6) Do you have an interest in tracking some of your symptoms post-transplant? Which ones would you want to track?
7) Are you interested in tracking your sleep, heart rate, and temperature post-transplant?
8) What has helped you cope post-transplant?

BMT Roadmap 2.0-directed questions (both caregiver and patient participants)

1) What do you think of BMT Roadmap 2.0, wearable sensor, and positive activities (if applicable)?
   - What do you find most helpful?
   - What do you find least helpful?
2) Would you change anything about any of the above (add, change, or take away)?

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Data Analysis

Babbletype transcription (Babbletype Inc) was used to transcribe all interviews verbatim. Following transcription, interviews were double-coded by 2 team members (E Smeallie and CR) using NVivo 12.0 (Lumivero). A codebook used in prior BMT Roadmap studies was initially modified to better reflect the interview script [15,16] (Multimedia Appendix 2). Coding by content analysis was both inductive and deductive, using the framework method [18]. As the prior codebook was not organized into themes and the main analytic approach consisted of content analysis, findings were identified rather than the organization of codes into categories and then into themes. Field notes were available for reference but were not directly used for codes. Additionally, the framework method was used to give the research team the ability to analyze the data across the whole data set in addition to grouping by interview time point as well as grouping by dyad [18].

At multiple points during the coding process, team members (E Smeallie and CR) completing coding met with AJ to discuss discrepancies, a consensus was reached when discrepancies occurred, and the codebook was modified as needed. When approximately half of the interviews were completed, a preliminary analysis across all interviews was conducted. Following completion of all interviews, a subsequent analysis was conducted across all interviews, at each time point, and within each dyad over time.

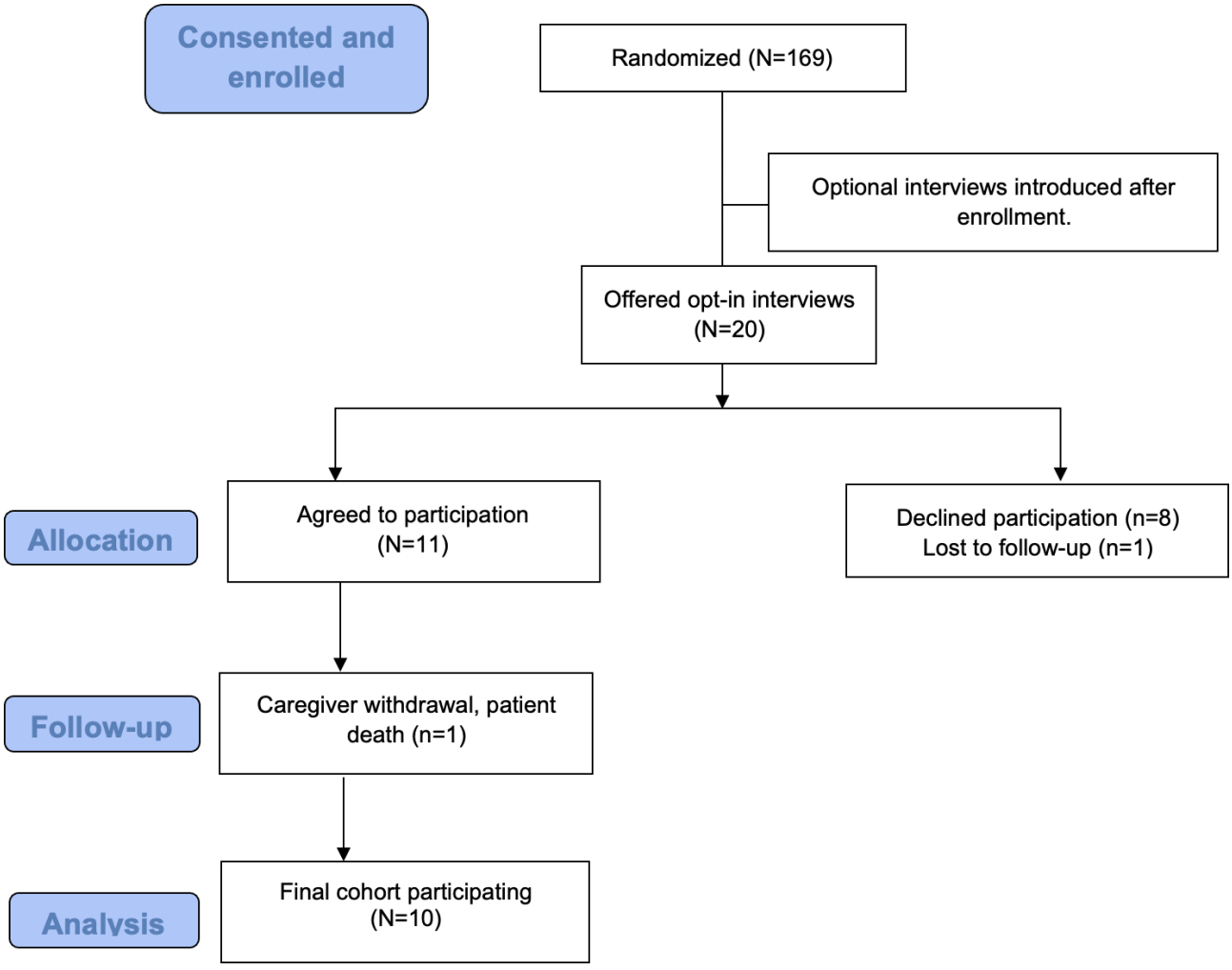
The COREQ (Consolidated Criteria for Reporting Qualitative Research) was used as part of the manuscript preparation (Checklist 1).

Results

Interview Results

Interviews took place from November 2021 to July 2022. A total of 20 dyads were offered opt-in interviews. Eight dyads declined, and 1 dyad was lost to follow-up, leaving 11 patient-caregiver dyads who initially opted in for the interview portion of the study. One caregiver withdrew from the study prior to the start of the interviews, and the patient died prior to first hospital discharge, resulting in 10 remaining dyads (Figure 3). Of the 10 dyads, 9 were adult patient-caregiver dyads and 1 was an adolescent patient-caregiver dyad. Among all, 7 dyads were patients and their caregivers from OHSU, and 3 dyads were from the University of Michigan. A total of 7 of the caregivers were part of the positive activities intervention arm. Additional demographics of patients and their caregivers are listed in Table 1.

Figure 3. CONSORT flowchart



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Table . Patient and caregiver demographics.

Characteristics	Patients (n=10)	Caregivers (n=10)	Combined (N=20)
Age, median (range)	54.5 (15-73)	58 (42 - 68)	56 (15 - 73)
Sex, n (%)			
Female	2 (20)	9 (90)	11 (55)
Male	8 (80)	1 (10)	9 (45)
Race, n (%)			
White	9 (90)	9 (90)	18 (90)
Unknown	1 (10)	1 (10)	2 (10)
Ethnicity, n (%)			
Hispanic	1 (10)	0 (0)	1 (5)
Non-Hispanic	9 (90)	10 (100)	19 (95)
Disease, n (%)			
Leukemia	2 (20)	N/A[a]	2 (20)
Lymphoma	1 (10)	N/A	1 (1)
Multiple myeloma	4 (40)	N/A	4 (40)
MDS[b]	2 (20)	N/A	2 (20)
Aplastic anemia	1 (10)	N/A	1 (10)
Caregiver relationship, n (%)			
Parent	N/A	3 (30)	3 (30)
Spouse	N/A	5 (50)	5 (50)
Sibling	N/A	1 (10)	1 (10)
Daughter-in-law	N/A	1 (10)	1 (10)
Intervention or control arm, n (%)			
Intervention arm	N/A	7 (70)	7 (70)
Control arm	N/A	3 (30)	3 (30)

[a]N/A: not applicable.

[b]MDS: myelodysplastic syndrome.

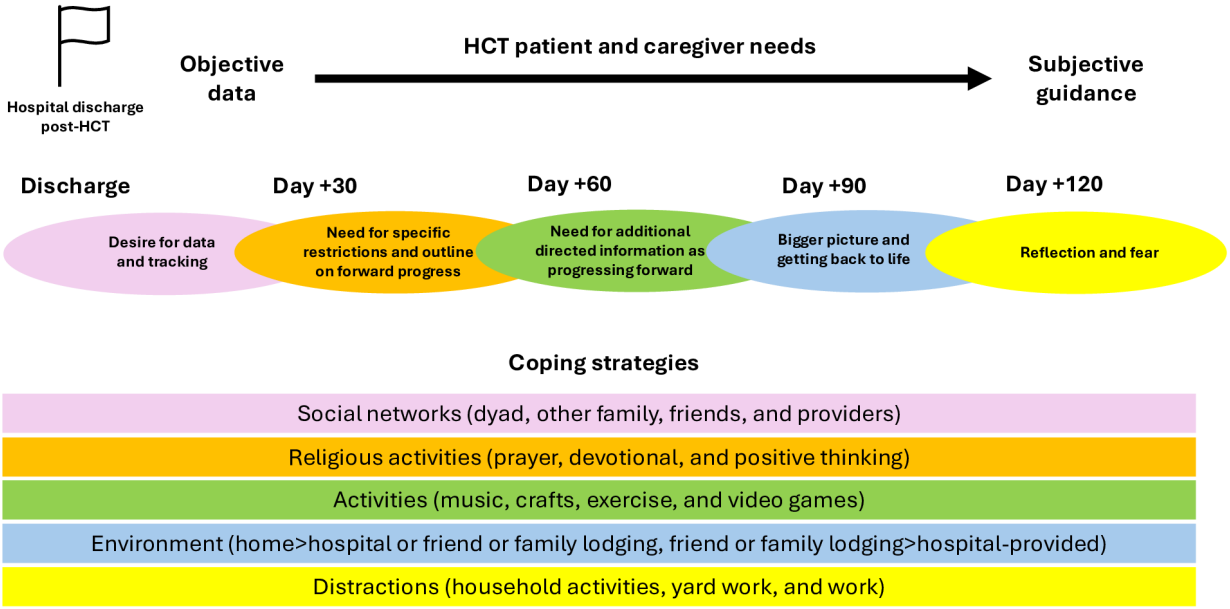
Interviews ranged from 10 to 47 minutes (median=21 min). A total of 48 interviews were completed (1 patient died prior to completion of all interviews). Two interviews were unable to be transcribed due to technological reasons, resulting in 46 interviews that were double-coded and analyzed.

While the interview script was consistent throughout the study, overall findings emerged at earlier and later time points looking across all dyadic interviews as they progressed through the post-HCT course. Over time, dyads moved from “desire for data and tracking” and “need for specific restrictions and outline on forward progress” to “need for additional directed information as progressing forward” to “bigger picture and getting back to life” to “reflection and fear.”

The importance of coping strategies was highlighted with “coping through social networks” being very common among both patients and caregivers. In addition to social networks, multiple other coping strategies were discussed by both patients and their caregivers. The strategies used for patients and their caregivers largely stayed consistent throughout the interviews over time. Interview findings as well as coping strategies are visually represented in Figure 4.

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Figure 4. Qualitative interview findings and coping strategies. HCT: hematopoietic cell transplant.



Each finding is described in detail in the following sections with representative quotes within the sections as well as additional quotes in Table 2. In addition to the findings, multiple caregivers highlighted the stress they are under while caring for a patient undergoing HCT, and their experiences are described in further detail after the description of the findings. Finally, a goal of the study was to specifically gather feedback on the Roadmap 2.0 app and study, which is outlined at the end of the results.

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Table . Additional representative quotes for findings.

Finding	Representative quote(s)
Desire for data and tracking	*I am looking at the labs. I'm always looking at his chemistry panel to see what I need to do to boost his whatever he needs to push protein, stuff like that. I think for things going south, I'm probably not just looking at temp. It's his eyes, his energy, and stuff like that*. [Caregiver, postdischarge]
	For me, I'm mostly looking at the vitals. [Patient, d +30]
Need for specific restrictions and outline on forward progress	*It's hard because you're in no man's land because you've never experienced this before. You just are trying to go through that puzzle, figure it all out. Even from now, where is he going to be like in six months from now? What are we looking for long-term? It's just a thousand things go through your mind that you want to have answers to but nobody really has answers to.* [Caregiver, postdischarge]
	What I can and can't do because right now my legs are so weak but they don't want me to do anything. [Patient, d +30]
Need for additional directed information as progressing forward	*I'm thinking more on what they can and can't eat when they get home...Support on things that he shouldn't be eating and just like things that he could do.* [Caregiver, d +60]
	I'd want to know what you are shooting for in regards to numbers because I didn't know that those low, low numbers that weren't even in the normal range got me concerned because of how low – Is something wrong? I'd like to know that that's okay to be in lower numbers. I guess I just need to have a comfort feeling that – I don't know how you would do this, but I need to have comfort that everything is okay, this is what you're looking at, this is what you can do, this is how you progress. I guess an explanation of what to expect. [Caregiver, d +60]
Bigger pictures and getting back to life	*It's hard to transition them to live. You've got to light a fire under them.* [Caregiver, d +90]
Reflection and fear	*The recovery can occur to me in many different ways…In my case, I have persistent MDS* [myelodysplastic syndrome] *and it seemed to be done in the hospital, but now after the biopsy, it's still there. It's not a relapse, it's not a remission, it's not a recurrence….It would have been much more helpful had we been aware of the possibilities of what we could be facing.* [Patient, d +120]
	I think the biggest thing since day 100 when we left is just not really knowing…what the status of him is. That's just coming down off of the last three months, I'm sure. [Caregiver, d +120]

Desire for Data and Tracking

Earlier in the post-HCT course, patients and their caregivers discussed tracking vital signs and movement via the wearable, recording signs and symptoms, and wanting more data (vitals and laboratories from clinic visits) more often when compared to later time points. Some caregivers also mentioned finding comfort in knowing and tracking data to assess how the patient was doing.

> *[L]ike between his last appointment the other day and today's, one of the numbers went down just a little bit, that would be a great thing to know, because we have three or four days between.* [Caregiver, postdischarge]
>
> [Yes, just tracking the recovery and like she caregiver said, everything is on track and we're headed in the right direction. That's the big thing, is just keeping track of how everything is and how well I'm doing and how she's doing herself.] [Patient, day +30]

Need for Specific Restrictions and Outline on Forward Progress

While the majority of patients and caregivers did not feel information was missing in their anticipatory guidance, most patients and caregivers wanted to know specifics on what the patient could or could not do based on their recovering immune system. Additionally, most patients and caregivers called for an explanation from their providers earlier in the post-HCT course on how to move forward and heal rather than the general recommendations they were provided.

> *It would be helpful to know what to do going forward, and for how long. Restrictions and what I have to do to keep safe and things like that.* [Patient, postdischarge]
>
> *[W]hen we asked certain questions of the nurses and that sort of stuff, we got a lot of generalities. It's understandable generalities. Every patient is different. Part of my recovery in the hospital, some of the caretakers there, 'Wow, you're doing far better than most do.' What could I lag at? Again, something informational...It depends upon the patient, everybody*

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is different, but I'd like a little more information than just that. [Patient, day +30]

Need for Additional Directed Information as Progressing Forward

As the patients and the caregivers progressed through the first weeks and months after discharge, they continued to express a desire for information specific to restrictions and limitations as the patients continued to improve.

It's just a lot easier now than it was when we first got released, I'll say that. It's a little overwhelming when you first get discharged. At this point we're home now, and it's almost back to normal, besides knowing what he can and can't eat and the meds he's got to take every day, which is even less than when we got discharged. [Caregiver, day +60]

What can or can't be done? I still feel like I have a lot of questions about that. What's appropriate for me to do and not appropriate? [Patient, day +60]

Bigger Picture and Getting Back to Life

While patients and caregivers discussed the desire for a longer-term plan and outlook earlier in the post-HCT course, a strong need for this information came through during the interviews at later points post-HCT. Additionally, patients and caregivers both mentioned the challenges of transitioning out of the immediate post-HCT stage.

[Y]ou get to this point and you're starting to think, 'I'm going to go back to the real world. Can I handle that, or is it really this good? Are things going to be okay?' It's just a lot of different feelings that come out that you haven't really even had to deal with before. [Patient, day +60]

[T]hat's what I'm looking at. It's, 'Here's how to resume your life.' [Patient, day +90]

Reflection and Fear

Following contemplation of the "bigger picture and getting back to life," patients and caregivers continued to reflect on what they had just been through with the weight of their underlying diagnosis and fear of rejection, relapse, or other complications despite how far they had come post-HCT.

I think about the future now...I want to be able to know what to look for if it is coming back. [Caregiver, day +120]

It's probably been more of the emotional part of it, for me. I don't know what [he] is experiencing...it's been a lot of crisis to crisis to crisis. Now it's like, 'Oh! There's no crisis.' I think dealing with that has been more of a challenge for me. I didn't know it would be quite that hard...I think that surprised me. [Caregiver, day +120]

Another key finding, relevant across time periods, was that many patients and caregivers described social networks as critical to their coping (coping through social networks). Many caregivers also commented on the stress of caregiving for a patient undergoing HCT.

Coping Through Social Networks

While there was significant variety in coping strategies used by the patients and their caregivers throughout the HCT course, most patients and caregivers had some social network component to their coping. Additionally, most patients and their caregivers used the same or similar coping strategies throughout the study period. One patient, when asked about how he coped post-HCT, answered "my wife," at nearly every interview. Almost all patients and caregivers mentioned coping through interactions with caregivers, family, friends, or other groups of people who supported them post-HCT.

At the darkest time, I called my sister when he was in the hospital. It was so bad and I don't think I was prepared for how bad it was going to be. I just called her and poured my heart out into her. She really helped me. [Caregiver, day +30]

I tell you, where I work, I have a lot of ladies there, golfers, and they've been really awesome...I've been blessed. [Caregiver, day +120]

Both an adolescent and young adult patient mentioned the importance of communicating with their friends via social media and/or gaming platforms throughout their post-HCT course, providing them with a sense of belonging during a time of isolation.

Talking to people and playing video games. [Patient, day +30]

For me, I think it's really just been hanging out with my friends online. I actually just checked right now, checked Discord to see if anyone was on. Not yet, it's early in the day and they're probably still at work or at school, but just hopping in. There's a group server that we have, so there's just a general chat that people will sit in while they play games or do whatever on their computer. You just pop in...Just sit there and talk about whatever. [Patient, day +90]

Challenges of Caregivers of Patients Undergoing HCT

In addition to the above findings, which were common across caregivers and patients, caregivers reiterated the challenges and stress they face when caring for a patient going through HCT. While health care systems and society at large are continuing to work on supporting caregivers, the caregivers in this study provided a call to continue to improve their support, particularly as they face a variety of new stressors during HCT.

It's just hard to think sometimes as a caregiver. I just really have been a lot more aware of how it takes – Even to go exercise or do things for yourself at all, when your person that you're taking care of isn't at their best or you're really concerned, it's just you lose part of your brain too. Energy, willpower, and stuff. That's been really an eye-opener for me, even though I've been a mom for years. [Caregiver, day +90]

I would like something specifically, a program for the caregiver. I get nothing. They don't even ask me

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> *how I'm doing when we go to these appointments. That's disappointing.* [Caregiver, day +60]
>
> *[T]here's a higher level of understanding and resources and outreach and support for a patient than there are for the caregiver. Their [care]givers are expected to be everything...there are not a whole lot of resources on that. Then there's, I think, an assumption from friends, family, and peers. 'If you're a spouse, that's your job.' I don't think there's an understanding of how it changes [going through HCT].* [Caregiver, day +90]

Roadmap 2.0 and General App Feedback

During the interviews, we also asked for structured feedback from both patients and caregivers on Roadmap 2.0 and apps in general. Prior studies by our group and a portion of the larger Roadmap 2.0 study focused on the feedback related to the intervention specifically as a way to continuously improve technology interventions going forward.

Outside of some technical issues, patients and caregivers were overall satisfied with the study and the Roadmap 2.0 app.

> *I liked the Gratitude Journal, reminding me to stay positive and grateful for the good things. The Engaging with Beauty, I always think that's important too, just find the beauty in everything even if you're at the hospital...Pleasant Activity Scheduling I like, and the Savoring. It's just all reminders just to do things that are pleasant or positive.* [Caregiver, day +30]
>
> *I actually like the whole thing. Just to be able to go in, just be able to jot down something in different areas that I was thinking about. I like the Fitbit, it makes sure I'm moving. Overall, I'm pretty satisfied with the whole program-type thing.* [Caregiver, day +60]

Some patients and caregivers, however, mentioned that they prefer other apps and wearable devices (eg, newer version of Fitbit with additional features). Additionally, some patients and caregivers had coping and intervention strategies for stress that they preferred to use instead of Roadmap 2.0 (eg, reading their Bible or journaling).

> *I tried wearing the Fitbit so that it's pulling in the data but I'm not really an app person. I'm not playing with those Roadmaps or Fitbits or whatever.* [Patient, day +60]

In addition to specific feedback on Roadmap 2.0, patients and caregivers were asked about app design for the post-HCT setting more generally. The majority of responses centered around an "all-in-one" type of app, where they could access their appointments, test results, and have additional resources (information related to medications, HCT complications, or coping strategies). Many patients and caregivers suggested a more interactive user interface (particularly on the patient-facing app) with exercise plans, activity, and mental health suggestions based on wearable or other input data (eg, heart rate, sleep, and mood), as well as sharing information between the patient and caregiver.

Discussion

Principal Findings

In this study, patients actively undergoing HCT and their caregivers engaged in semistructured interviews on their perspectives related to important and missing HCT information, app or intervention design, coping, and provided specific feedback on Roadmap 2.0 as an opt-in portion to the larger Roadmap 2.0 study. Patients and their caregivers showed that they have dynamic needs across the initial post-HCT period, initially focusing on objective data points (ie, laboratories and vital signs) and later transitioning to more long-term subjective guidance. Additionally, the importance of social connections and other coping strategies for both the patient and caregiver was individualized to some extent, but was consistently used throughout the initial post-HCT period. These interviews, as highlighted in the quotes above, led to multiple rich comments and ideas for improving their care broadly as well as specifically, with the hope to apply these findings to future interventions and apps for patient-caregiver dyads, including future versions of the BMT Roadmap app.

The next version of the Roadmap app is in its planning phase with the goal to make the app interface more interactive with a "just-in-time" approach where a patient or caregiver will receive additional prompts or suggestions after entering data. For example, a caregiver rating their mood 2 on a scale of 10 within the app may receive a positive message of encouragement or be provided additional resources after entering their low mood score. Additionally, our group has been exploring additional interventions to support caregivers during the peri-HCT period with multiple caregiver support projects underway, including specific work on how to capitalize on a caregiver's social network for support with needs and tasks [19]. While implementing the rich feedback gathered in this study promptly will help support some patients and their caregivers, we need additional studies to gather further patient and caregiver perspectives to improve the reach of the app.

As patients and their caregivers transition from the hospital to the outpatient environment, where vital signs and labs are checked much less frequently, participants' "desire for data and tracking" resonating in earlier time points post-HCT is not surprising. Similarly, participants' "need for specific restrictions and outline on forward progress" is also fitting for earlier in the post-HCT course when one of the primary goals is to discharge from the hospital and it is impossible to give directed guidance on every potential exposure situation the patient and their caregiver are going to face outside of the hospital. Additionally, about 12% (3318/28,356) of adult autologous transplant patients and 24% (4201/17,213) of adult allogeneic transplant patients experience unplanned readmission to the hospital within 30 days of discharge for a variety of complications that span from minor, short hospital stays to life-threatening illnesses, making outlines of the future difficult to predict early in the post-HCT course [20].

As patients and caregivers spend more time outside of the hospital after discharge, additional anticipatory guidance is certainly needed in keeping with participants' "need for

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additional directed information as progressing forward." During the second and third months after HCT, patients are likely beginning to regain strength and overall feel better, making it more difficult to remember that their immune system is still immature and they are at continued high risk for infections.

Between 3 and 4 months after HCT, patients and their caregivers are typically allowed to return home if they needed temporary local housing due to their home being outside of the immediate area of the HCT center and their appointments are spaced out further. Just prior to and around this time, patients and their caregivers begin wondering what returning home and the follow-up plan will look like, and thus a desire for the "bigger picture and getting back to life," which is commonly observed clinically and confirmed in this study. Additionally, similar to the anxiety experienced around the time of discharge, "reflection and fear" occur just prior to and just after day +100 and were discussed by multiple patients and caregivers during the day +120 interview.

Finally, the stress HCT places on patients and their caregivers was significant, and coping through a variety of mechanisms unique to each patient and their caregivers was observed. It is not surprising that similar coping strategies were used throughout the HCT process given that many patients and caregivers experience a prior diagnosis (malignant or nonmalignant) that later leads to a recommendation for HCT. Thus, their coping skills were tested prior to proceeding to HCT. Despite having previously tested coping strategies, many caregivers drew attention to the challenges of caregiving for a patient undergoing HCT [1]. Additional quantitative, qualitative, and mixed methods studies are needed as we gain further insight into these stressors and attempt to implement strategies to improve the burden of caregivers of patients undergoing HCT.

Strengths and Limitations

This study has multiple strengths including a geographically diverse sample and the use of repeated interviews over time, which allowed for building trust and a deep understanding of interviewees' experiences. Multiple dyadic interviews were conducted at a variety of time points, allowing for triangulation and increased trustworthiness of the data to enhance both the validity and reliability of our data. Additionally, having the majority of interviews conducted by AJ allowed for increased consistency between interviews. Coding of the data by more than one researcher outside of the interviewers brought additional perspectives and provided reflexivity which guarded against bias in the interpretation. In terms of limitations, these interviews were optional and thus were more likely to involve individuals with more polarized views (either very positive or very negative). The interviews were limited in numbers compared to the larger study, which was a result of OHSU staff entering the study later and conducting the interviews. However, based on general qualitative study guidance, we believe our sample size was sufficient to achieve saturation of findings. Additionally, the majority of caregivers who opted in to these interviews were on the intervention arm of the Roadmap trial, which may have influenced the results (ie, they had additional positivity resources and could be more likely to have positive views and responses to questions). As the interview script consisted of semistructured questions, responses may certainly be more limited in comparison to fully open-ended questions. While overall the dyadic interview method is felt to be a strength in terms of allowing the patient and caregiver to engage in a richer discussion together, it is possible that either the patient or the caregiver was not fully comfortable sharing some responses in front of the other during these interviews. It was also notable that the majority of caregivers were White females of White male adolescent and adult patients, limiting the generalizability of their experiences. It was a goal amongst our group to reach more diverse populations of patients and caregivers in our smaller studies to better inform our larger upcoming studies.

Conclusions

The field of mobile health and technology continues to expand, and apps are rapidly being developed. Health apps make up a smaller niche and are increasingly being used. Integration of these apps with the electronic health record is beginning to be done as well [21,22]. With this in mind, engaging end users (eg, patients, caregivers, and providers) in the design process of these apps is extremely important for usability as well as improving these interventions. This study shows the strengths of mixed methods design for intervention design and improvement, highlighting where patients undergoing HCT and their caregivers need further information, guidance, and support during the HCT process.

Results of the larger Roadmap 2.0 study have recently been published, focusing primarily on quantitative findings [17]. Based on our prior work and results of this study, we plan to continue to incorporate qualitative interviews in future Roadmap studies to further understand the patient and caregiver experience as well as determine additional patient and caregiver needs and resources post-HCT. Prior to the next Roadmap study, our group is conducting a variety of smaller studies to optimize the next Roadmap platform and other patients undergoing HCT and caregiver interventions going forward.

While these studies are still underway and our understanding and recommendations will continue to mature, we believe the results of this study offer general suggestions to health care providers and social support networks of patients undergoing HCT and their caregivers. First, as patients undergoing HCT and their caregivers progress through the post-HCT trajectory, providing specific advice where possible is appreciated, whether based on the provider's recommendation or institutional practices, such as outlining and reviewing dietary and activity restrictions at regular intervals. While general advice is appreciated, subjective guidance specific to each patient and caregiver situation is also appreciated. Finally, acknowledgment of and support for caregivers of patients undergoing HCT during the peri-HCT period is needed. Potential suggestions could include having a member of the care team check in with the caregiver at clinic visits in addition to improving respite programs for caregivers of patients undergoing HCT to allow them time for their own health (eg, time to exercise, nap, or run errands without fear of leaving the patient alone).

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Data Availability

Complete qualitative data (deidentified transcripts) will be made available upon request. Requests for data should be sent to the corresponding author.

Authors' Contributions

Conceptualization: AJ, E Shereck, SWC
Formal analysis: AJ
Funding acquisition: SWC
Investigation: AJ, E Smeallie, CR
Methodology: AJ, E Shereck, SWC
Project administration: MR
Resources: MR
Supervision: E Shereck, SWC
Validation: E Smeallie, CR
Writing – original draft: AJ
Writing – review & editing: AJ, E Smeallie, CR, MR, E Shereck, SWC

Conflicts of Interest

None declared.

Multimedia Appendix 1
Roadmap 2.0 app multicomponent featured defined.
[DOCX File, 126 KB - jopm_v18i1e81971_app1.docx]

Multimedia Appendix 2
Codebook.
[DOCX File, 16 KB - jopm_v18i1e81971_app2.docx]

Checklist 1
COREQ checklist.
[PDF File, 83 KB - jopm_v18i1e81971_app3.pdf]

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Abbreviations

COREQ: Consolidated Criteria for Reporting Qualitative Research
HCT: hematopoietic cell transplant
OHSU: Oregon Health & Science University

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Developing a Parent-Focused Decision Aid to Promote Child-Inclusive Shared Decision-Making in Pediatric Oral Immunotherapy: Pragmatic Exploratory Feasibility Study

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Abstract

Background: Shared decision-making is increasingly valued worldwide in pediatric care; nonetheless, its application in Japanese clinical practice remains in its early stages, particularly in areas with substantial medical uncertainty, such as food allergy (FA) management. Although oral immunotherapy is a promising option for children with FA, its long-term effectiveness and safety remain under evaluation, providing families with limited evidence to navigate emotionally complex decisions. Despite this clinical uncertainty, decision aids (DAs) are beneficial for organizing information and supporting patients and families in making value-congruent choices. Involving children in these decisions is increasingly recognized as ethically and developmentally appropriate. DAs clarify treatment options and promote informed collaborative decisions. However, most DAs target adult users and do not explicitly encourage engagement with children's views.

Objective: This study aimed to develop a culturally adapted DA for Japanese parents by considering their children's preferences and perspectives.

Methods: A paper-based DA was developed through iterative alpha testing and finalized by a multidisciplinary team. In total, 9 parents of children eligible for oral immunotherapy participated in this study and received the DA. Although intended for parents, the DA was structured to prompt reflection on the children's involvement in decision-making. Parents completed structured questionnaires before and 1 week after receiving the DA to assess uncertainty, anxiety, and the burden of FA management. A total of 4 children completed the quality-of-life (QoL) questionnaire. Subsequently, all 9 parents and 4 children participated in semistructured interviews. Parents discussed how they used the DA, their perceptions of its clarity, and their interest in involving their children in decision-making. The children shared their thoughts about participating in decision-making.

Results: All 9 parents read the DA and completed the follow-up assessment (100% retention rate). Among them, 4 children participated in pediatric QoL assessments and interviews. Parents' Decisional Conflict Scale scores significantly decreased from 58.3 (SD 29.9) at baseline to 26.7 (SD 24.1) postintervention (t_8=2.65; P=.03). The values clarity subscale also significantly declined, from 73.1 (SD 30.6) to 25.9 (SD 26.2) (t_8=4.50; P=.002). No significant changes were observed in parental anxiety and QoL. Overall, 7 of the 9 parents explained the treatment options to their child, and 6 reported actively seeking their child's feelings. The interview results suggested that the DA was associated with a shift in the family dynamic "from protecting to partnering."

Conclusions: Culturally adapted DAs appear practical and acceptable to Japanese families when making pediatric FA treatment choices. Facilitating parent-child dialogue may promote more inclusive decision-making. Nevertheless, further research with larger samples and longer follow-up periods is warranted to confirm these findings and refine the tool.

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KEYWORDS

decision support techniques; shared decision-making; food hypersensitivity; oral immunotherapy; parents; child; family-centered care; quality-of-life

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Introduction

Background

Pediatric food allergies (FA) affect approximately 8% of children worldwide and present ongoing medical and psychosocial challenges to patients and their families [1-3]. Oral immunotherapy (OIT) has emerged as a therapeutic option alongside traditional allergen avoidance and emergency preparedness; notably, it is gaining popularity in several countries, including Japan. Nevertheless, OIT involves considerable daily workload and prolonged commitment; moreover, it can provoke mild-to-moderate symptoms and, on rare occasions, anaphylaxis [1,4,5]. Thus, because multiple reasonable options exist and value concordance influences outcomes, OIT is a prototypical preference-sensitive decision. Therefore, these trade-offs should be evaluated systematically through shared decision-making (SDM), which aligns with the family's values and risk tolerance. Additionally, the Canadian Society of Allergy and Clinical Immunology (CSACI) guidelines emphasize that SDM is ethically and clinically essential for OIT, ensuring that families make informed and personalized decisions [6].

SDM is a clinical practice model that integrates the best available evidence with patients' and families' values and can improve knowledge, reduce decisional conflict, and enhance adherence [7-9]. As a framework that supports the implementation of SDM, the Ottawa Decision-Support Framework (ODSF) identifies decisional needs, such as knowledge deficits, unclear values, and insufficient support, and organizes tailored interventions to address them [10,11].

Within the ODSF, patient decision aids (DAs) represent primary implementation vehicles, delivering evidence-based information, structuring value clarification, and prompting supportive dialogue. Recent systematic reviews have demonstrated that DAs are effective across diverse clinical contexts in increasing knowledge, promoting value-concordant choices, and reducing decisional conflict [10,11].

Implementing SDM in pediatrics entails additional complexity layers arising from a triadic structure, health care providers, caregivers, and the child, in which developmental stages, family roles, and emotional dynamics intersect [12,13].

Uncertainty regarding diagnosis, prognosis, and treatment outcomes constitutes a significant barrier to SDM in complex pediatric care; moreover, hierarchical power imbalances during clinical encounters further impede its implementation. Similarly, continuity of care, access to accurate and balanced information, and communication skills exert substantial influence. These patterns, synthesized in a recent scoping review of pediatric community health services, underscore the need for approaches supporting equitable partnerships and high-quality information exchange [14]. Furthermore, parents' strong protective orientation may limit the elicitation and incorporation of children's preferences. Thus, developmentally appropriate support for child participation and deliberately structured collaborative partnerships between parents and clinicians are essential [1,12,13]

In pediatric FA, anxiety regarding accidental exposure and ongoing at-home care workload imposes condition-specific emotional and practical burdens on families [1,6]. These condition-specific burdens intensify general barriers to pediatric SDM, making it necessary to design decision supports that not only structure information and value clarification but also surface and integrate the child's developmentally appropriate perspective alongside parents' values [14-16].

Knowledge Gap and Study Aim

In Japan, pediatric OIT is not widely recommended in routine clinical practice, and many families rely primarily on allergen avoidance within tolerated ranges [5]. Nonetheless, domestic preliminary reports [4] have documented an increasing number of institutions offering pediatric OIT, currently exceeding 100 nationwide. Despite this growth, opportunities for families to view OIT as a realistic option and engage in SDM that incorporates their children's preferences remain limited.

Importantly, these dynamics are more pronounced in the Japanese clinical context, where deference to medical authorities and high-context communication may amplify hierarchical power imbalances and hinder SDM implementation [17,18].

During emotionally charged visits, families may find it difficult to voice uncertainties, hopes, or questions [1,19]. Although children have the right to express their views on matters affecting them [16], meaningful participation in medical decisions remains limited. Moreover, Japan lacks OIT-specific DAs, and existing developments largely originate from outside Japan, leaving a gap in culturally adapted support. Consequently, there is a need for DAs that go beyond information provision and value clarification to activate dialogue, meet emotional needs, and enable parents to incorporate developmentally appropriate children's views and feelings into their decisions. Therefore, this study aimed to develop and evaluate the feasibility and acceptability of a culturally adapted, parent-focused DA designed to facilitate child-inclusive dialogue in pediatric OIT settings in Japan.

Methods

Study Design

We conducted a pragmatic exploratory feasibility study to assess the newly developed DA for families eligible for pediatric OIT. This type of feasibility work commonly enrolls 10 - 30 participants, which is an adequate range for identifying procedural issues and evaluating the initial signals of effect [20,21]. Guided by this benchmark, we enrolled 10 parents and 5 children. One parent-child dyad withdrew before the baseline assessment; therefore, the analyses included 9 parents and 4 children (N=13). Each participant completed structured questionnaires at baseline and 1-week postintervention, followed by a brief semistructured interview. To effectively integrate quantitative and qualitative data, numeric measures (eg, decisional conflict, state anxiety, and QoL) were paired with interview feedback (eg, parent-child communication and DA usability) [22,23]. This study was not powered to test efficacy but did generate preliminary data and highlight practical issues that should be addressed before a larger trial.

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DA Development

We developed a parent-focused booklet DA to support SDM by prompting parents to elicit and consider their child's views and, where appropriate, to collaborate with the child, following a systematic development process [24], adhering to the Japanese adaptation of the International Patient DA Standards Instrument version 4.0, and meeting all 6 qualifying criteria [25].

Following the Ottawa Decision Guide, the DA is organized into 4 core sections: understanding the decision-making process, comparing treatment options, clarifying personal values, and assessing the current situation. To promote meaningful child involvement consistent with the UN Convention on the Rights of the Child [16], the DA includes brief information about the Convention and sample questions that parents can use to explore their child's feelings and is formatted as an easy-to-use booklet for parents and children (Table 1).

Table . Contents of the Let's Think Together About Treatment Options for Food Allergies decision aid.

Chapter	Contents	Setting
Option	• Guidebook objectives • Table of contents	• Read
Step 1	• Guidance on SDM[a] • How to make more informed decisions about treatment	• Read
Step 2	• Knowledge of illnesses and treatments available • Choosing between elimination and OIT[b] • Understanding food allergies • Understanding potential treatments and their characteristics • Understanding the lifestyle and psychological impact of treatments	• Read
Step 3	• Value-based decision-making • Clarifying what is important to you when you make a decision • Colum: Children's feelings about treatment • Let's ask your child about their feelings regarding the illness and treatment	• Read • Check • Read • Read and write
Step 4	• Treatment options that are currently under consideration • Clarifying your current feelings and organizing your concerns	• Read • Check

[a]SDM: shared decision-making.

[b]OIT: oral immunotherapy.

Development Followed a User-Centered, Multistage Process

Formative interviews were conducted with 14 stakeholders, 5 parents, 3 children, and 6 health care providers, by purposively sampling families that had previously considered OIT (proceeded vs continued elimination; approval number 19R-272). Children expressed a desire to learn about options and to be invited to participate in OIT decision-making. Their input informed the parent-facing DA by adding nonleading prompts to elicit parents' children's views and by adopting age-appropriate wording.

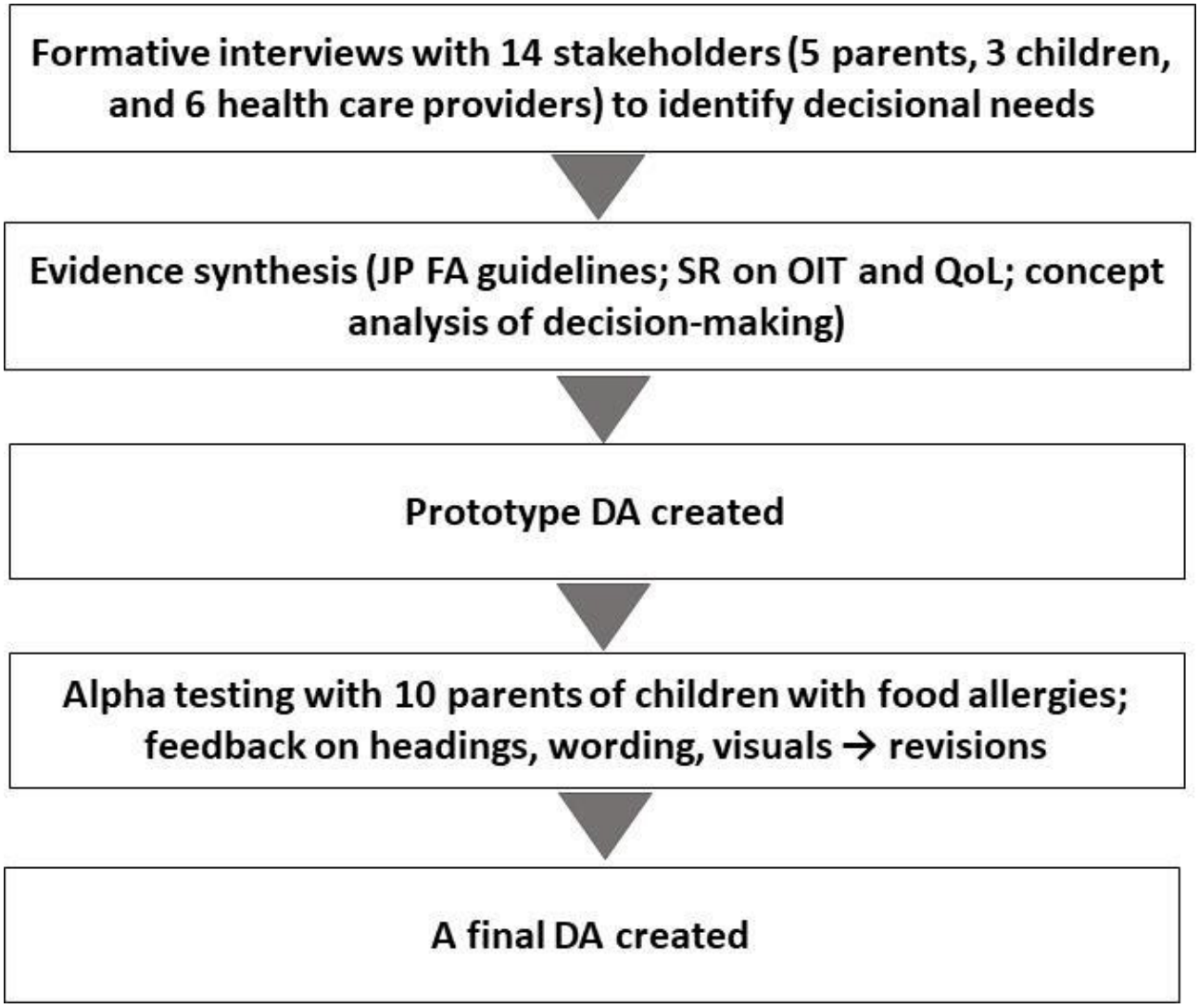
Next, we synthesized evidence from the Japanese clinical guidelines [5], a systematic review of the impact of OIT on QoL, and a conceptual analysis of decision-making in pediatric chronic conditions. Using these inputs, a multidisciplinary panel (SDM specialists, pediatric allergists, and nursing researchers) specified the content, wording, and layout and produced a paper prototype.

Subsequently, the prototype was alpha tested with 10 parents of children with FA who had previously been considered for an OIT decision (approval number 21R-020). Acceptability was high: 9 (90%) and 1 (10%) rated the DA as "Excellent" and "Very good," respectively. Parents judged the information to be balanced between elimination and OIT, and the feedback emphasized clearer headings, simplified language, and greater use of visuals. Revisions were made accordingly, and an improved DA was used here.

The development process is summarized in Figure 1, and the final DA is provided in Multimedia Appendix 1.

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Figure 1. Flow diagram of the decision aid development process. DA: decision aid; FA: food allergy; JP: Japanese; OIT: oral immunotherapy; QoL: quality of life; SR: systematic review.



Participants and Setting

The participants were recruited from a pediatric allergy outpatient clinic in Japan. Two groups of participants were eligible: parents and children. Parents could participate regardless of the child's age, whereas children were eligible only if they were in grade 1 or higher in primary school (typically ≥6 y). We set the eligibility according to the treating physician's clinical judgment regarding the appropriateness of discussing OIT in individual cases. In this study, "suitability for OIT" referred to children currently managed with an elimination diet for whom the physician judged that OIT could be considered and discussed as a potential option. Parent participation was not contingent on child participation; therefore, the parent and child sample sizes were not numerically matched.

The inclusion criteria are listed in Textbox 1.

Textbox 1. Inclusion criteria.

- Parents of children currently managed with an elimination diet for whom the treating physician judged that OIT could be considered and discussed.
- Children in grade 1 or above in a Japanese primary school (typically ≥6 y), with adequate cognitive capacity to participate in interviews and task-based procedures, and for whom the treating physician judged that OIT could be considered and discussed.

Recruitment and Consent

Physicians and nurses conducted the study during clinic visits. We used two invitation pathways: parent-only and parent-child invitations. For parent-only invitations, the physician or nurse explained the study to the parent and, if interested, asked the parent to contact the research team via the email address or phone number listed on the information sheet to minimize any perception of coercion. For parent-child invitations, the physician or nurse explained participation separately to the parent and the child using age-tailored information sheets (lower elementary, upper elementary, and junior high versions). The parents then confirmed the willingness of the child. Enrollment proceeded only when both parents and children expressed interest, after which the parents contacted the research team via email or phone. Before any study procedures, all parents

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provided written informed consent, and the children provided age-appropriate assent.

Intervention and Data Collection Procedure

Overview

We conducted this study between October 2022 and May 2023.

At the single participating clinic, we approached 10 parents and 5 children, and all agreed to participate. One parent-child dyad was excluded before baseline because OIT was initiated before questionnaire distribution; accordingly, this dyad was not included in the analytic sample. Data from 9 parents and 4 children who completed both the baseline and 1-week questionnaires and postintervention interviews were included in the analysis.

Baseline

After obtaining parental consent and child assent, the parents (9/9, 100%) and children (4/4, 100%) completed the baseline questionnaire.

DA Provided to Parents

At the next clinic appointment (2 - 4 wk later), a physician provided a brief, nondirective orientation to the DA, highlighting that multiple treatment options existed and that the DA offered tips and prompts for SDM. To avoid influencing DA use or evaluation, we provided no option-specific counseling.

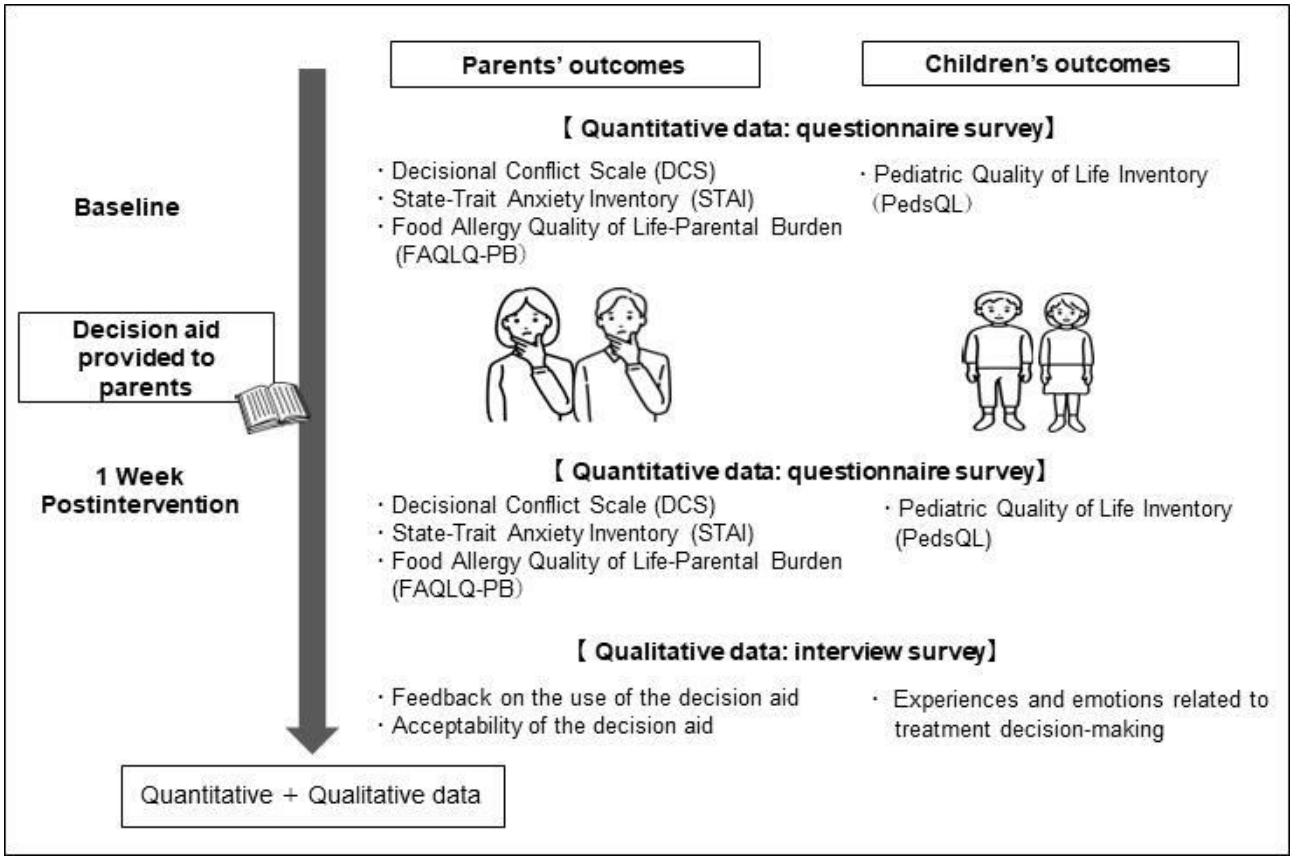
One Week Postintervention

At the 1-week follow-up, parents and children repeated the questionnaires and participated in brief semistructured interviews to explore their experiences with the DA.

Quantitative Outcome Measures

Guided by the ODSF, we prespecified the Decisional Conflict Scale (DCS) as the primary outcome and the State–Trait Anxiety Inventory, State Anxiety subscale (STAI-State), FA QoL–Parental Burden (FAQLQ-PB), and Pediatric QoL Inventory (PedsQL) as contextual measures, given evidence that DAs reduce DCS and improve decision quality [26,27]. We assessed parental outcomes, children's health-related QoL, and postintervention feasibility and acceptability. We used validated Japanese versions with published reliability and construct validity for the DCS, STAI-State, FAQLQ-PB, and PedsQL. Self-administered questionnaires were completed at baseline and 1-week postintervention. We measured postintervention feasibility and acceptability using study-specific items, as displayed in Figure 2.

Figure 2. Study flow diagram of recruitment, decision aid intervention, and 1-week follow-up.



Parental Outcomes (Pre- and Postintervention)

DCS, Japanese Version

This tool measures uncertainty and perceived difficulty in making health-related decisions [26]. The scale includes 5 subdomains: feeling informed, clarity of values, perceived support, uncertainty, and effectiveness of decision-making. Higher scores indicate greater decisional conflict. We chose this measure as the primary proximal outcome in the ODSF framework [10,27].

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STAI, Japanese Version

This tool assesses the situational (state) components of anxiety [28]. We used only the state anxiety subscale in this study. Higher scores indicate increased anxiety. We included this measure to index the emotional burden relevant to preference-sensitive choices, consistent with the ODSF [27].

FAQLQ-PB, Japanese Version

This tool evaluates the psychological and practical burden among parents managing a child with a FA; higher scores indicate lower QoL [29,30]. To capture family-level impacts beyond decisional cognition, QoL sensitivity to SDM-oriented interventions has been reported in pediatric asthma trials [31].

Child Outcomes (Pre- and Postintervention)

We used different versions of the Japanese version of PedsQL based on age groups (5 - 7, 8 - 12, and 13 - 18 y) [32]. Higher scores reflect better QoL. We used it as a low-burden, developmentally appropriate child outcome (self-report when feasible; parent-proxy otherwise) and prioritized proximal parental outcomes.

Parental Feasibility and Acceptability Items (Postintervention Only)

The following parental feasibility and acceptability items were used:

1. Two yes-or-no questions assessing parent-child engagement in decision-making: (1) “Did you explain the treatment options to your child?” and (2) “Did you ask your child how they felt about those options?”
2. Likert-type items on DA clarity, format, ease of understanding, perceived usefulness, and willingness to use similar aids in the future.
3. One open-ended question asked parents what additional information or support they would have found helpful.

Statistical Analysis

We analyzed quantitative data using IBM SPSS Statistics (version 25; IBM Corp). Descriptive statistics were calculated for each outcome. We used paired-sample *t* tests (2-tailed) to compare pre- and postintervention DCS, STAI, and FAQLQ-PB scores. We set statistical significance at $P<.05$.

Qualitative Data Collection and Analysis

Overview

One week following DA distribution, we conducted brief semistructured interviews with the participating parents (9/9, 100%) and children (4/4, 100%). All interviews were performed by the first author, a female registered nurse, academically trained in qualitative methods at the PhD level, with no prior relationships with participants or sites.

At the start of each interview, the participants were informed that the interviewer was an independent nursing researcher and university teacher with no prior relationship with them or the recruiting hospitals. We interviewed each participant once and recorded no field notes. After obtaining informed consent, we audio-recorded and transcribed all interviews. We provided the semistructured interview guides for parents and children in Multimedia Appendix 2.

Separateness and Modality

A trained interviewer conducted 9 individual parent interviews (5 in person, 4 online) and 4 child interviews (all in person). To maximize comfort, 1 child elected to be interviewed alone and 3 elected to be interviewed with a parent present.

Duration

Parent interviews lasted 20 - 40 minutes; child interviews lasted 10 - 30 minutes.

Data Management and Analysis

The transcripts were imported into NVivo 14 software (Lumivero) for data management. We analyzed the interviews using thematic analysis [33]. We analyzed parent interviews thematically using inductive semantic-level coding with iterative codebook refinement and peer debriefs. We summarized child interviews narratively (descriptive summaries with exemplar quotations) to contextualize parent themes and were not formally coded because of the small sample size in this feasibility study. We did not seek thematic saturation. We judged the analytical adequacy based on the coherence and stability of the parent themes and the illustrative value of the child narratives.

Data Presentation and Interpretation

To facilitate comparison, we used a side-by-side joint display that aligned each quantitative outcome row with a single qualitative column (related category and, when informative, a de-identified exemplar quotation) and positioned conceptually similar themes in parallel across the 3 measures (DCS, STAI-State, and QoL). Side-by-side displays are widely used in mixed-methods health research to integrate quantitative results with qualitative evidence and support interpretation [22,34].

Ethical Considerations

We conducted this study in accordance with the Declaration of Helsinki and the Ethical Guidelines for Medical Research Involving Human Subjects in Japan. The Ethics Review Board of our institution approved this study (approval numbers 22-AC044 and 22RC-040). All parents provided written informed consent and children provided age-appropriate assent. Interviews were audio-recorded with permission. We deidentified all data, removed potentially identifying information from transcripts and quotations, and stored files on password-protected systems accessible only to the research team. No compensation was provided.

Results

Parent-Child Characteristics

A total of 9 parents and 4 children participated in the study, and their characteristics are summarized in Table 2. Of the 9 parents, 8 were female. Their children, all deemed eligible for OIT by their physicians, exhibited a mean age of 7.6 (SD 4.2; range 2 - 14) years and were predominantly male (6/9).

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Table . Demographic and clinical characteristics of parent-child participants.

Characteristics	Participants
Parents (n=9)	
Age (years), mean (SD; range)	42.7 (5.7; 35 - 52)
Sex, n (%)	
Male	1 (11.1)
Female	8 (88.9)
Occupation, n (%)	
Home worker	5 (55.6)
Part-time job	1 (11.1)
Self-employed	2 (22.2)
Other	1 (11.1)
Children's age (years), mean (SD; range)	7.6 (4.2; 2-14)
Children's sex, n (%)	
Male	6 (66.7)
Female	3 (33.3)
Children's allergies (duplicate entries), n (%)	
Eggs	2 (22.2)
Peanuts	3 (33.3)
Other	7 (77.8)
History of anaphylactic shock, n (%)	
Yes	4 (44.4)
No	5 (55.6)
Children (n=4)	
Age (years), mean (SD; range)	10.75 (4.2; 7-14)
Sex, n (%)	
Male	3 (75)
Female	1 (25)
Children's allergies (duplicate entries), n (%)	
Walnut	3 (75)
Peanuts	2 (50)
Others	3 (75)
History of anaphylactic shock, n (%)	
Yes	2 (50)
No	2 (50)

Of these 9 families, 4 children who completed the postintervention QoL assessments and interviews comprised a nested subsample. These participating children had a mean age of 10.8 (SD 4.2; range 7 - 14) years; 3 were male and 1 was female. They were allergic (with duplicate counts allowed) to walnuts (3/4, 75%), peanuts (2/4, 50%), and other foods (3/4, 75%). Two of the 4 patients had a prior history of anaphylactic reactions, whereas 2 had no such history.

Quantitative Outcomes in Parents

Table 3 presents the detailed quantitative results. As the primary outcome, parental decisional conflict decreased from 58.3 (SD 29.9) at preintervention to 26.7 (SD 24.1) at 1 week postintervention, a mean reduction of 31.6 points (95% CI 4.09 to 59.11; t_8=2.65; P=.03; paired d=0.88). Improvements were particularly pronounced in the subscales of values clarity (mean 73.1, SD 30.6 to mean 25.9, SD 26.2; P=.002), perceived support (mean 48.1, SD 32.8 to mean 20.4, SD 22.1; P=.04), and uncertainty (mean 62, SD 32 to mean 30.6, SD 23.2; P=.04).

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Table . Parental outcome measures at baseline and postintervention following decision aid use.

Scores and subscales	Baseline, mean (SD)	1-week postintervention, mean (SD)	*t* test (*df*=8)	*P* value
DCS[a]				
Total	58.3 (29.9)	26.7 (24.1)	2.65	.03
Informed	54.6 (35.9)	25 (25)	1.89	.10
Value clarity	73.1 (30.6)	25.9 (26.2)	4.50	.002
Support	48.1 (32.8)	20.4 (22.1)	2.42	.04
Uncertainty	62 (32)	30.6 (23.2)	2.43	.04
Effective decision	54.9 (37.5)	30.6 (29.4)	1.59	.15
STAI[b]	37.9 (8.99)	35.9 (8.17)	2.03	.08
FAQLQ-PB[c]	25.6 (7.82)	26 (8.9)	−0.31	.77

[a]DCS: Decisional Conflict Scale.

[b]STAI: State–Trait Anxiety Inventory.

[c]FAQLQ-PB: food allergy QoL, parental burden.

For secondary outcomes, STAI-State decreased from 37.9 (SD 9) at preintervention to 35.9 (SD 8.2) at 1 week postintervention; the mean difference was 2 points (95% CI −0.27 to 4.27; t_8=2.03; *P*=.08), corresponding to a moderate standardized effect (paired *d*=0.68). FAQLQ-PB exhibited little change (mean 25.6, SD 7.8 to mean 26, SD 8.9); the mean difference was −0.4 points (95% CI −4.29 to 3.54; t_8=−0.31; *P*=.77), with a negligible standardized effect (paired *d*=−0.08).

Qualitative Explanations of Parental Outcome

Overview

Overall, 3 primary themes emerged from the interview data (Textbox 2). The first concerned communication with physicians, including environmental constraints and hesitation to voice concerns. The second pertained to emotional reactions and difficulties processing information related to treatment decisions. The third reflected emotional burdens, such as anxiety and uncertainty, which parents described before using the DA.

Textbox 2. Key category and illustrative quotations.

Difficulties in physician communication

- Time constraints: “Clinic is crowded; I hesitate to ask.”
- Need guidance: “When my child wants to eat, I’d like direction.”
- Uncertainty about asking: “I’m never sure how much I can consult.”

Challenges in obtaining reliable information

- Conflicting information: “Online advice is contradictory and confusing.”
- Information overload: “There’s so much data it’s overwhelming.”
- Child’s desire for autonomy: “I want to eat safely and have a say.”

Difficulties in coping with emotional uncertainty

- “I’m still anxious because there’s so much I don’t know.”

Difficulties in Physician Communication

These include difficulties related to interactions with physicians and obtaining reliable information. Within the first theme, parents described feeling constrained by busy clinical environments and were uncertain whether it was appropriate to voice their concerns. This was illustrated by comments such as “In outpatient settings, there are usually many people, so I felt it wouldn’t be right to take up too much time just for myself.”

Challenges in Obtaining Reliable Information

Under the second theme, parents reported frustration with conflicting or overwhelming online resources, for example, “Sometimes completely contradictory information comes up, right? I look things up because I don’t understand, but it just ends up confusing me even more” and “When I search the Internet, of course, information comes up. However, when I open it myself, there’s so much information that it becomes overwhelming.” These barriers appeared to directly contribute to high levels of decisional conflict before DA use.

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Difficulties in Coping With Emotional Uncertainty

Several parents described feeling anxious or overwhelmed when considering treatment options, particularly because of uncertainty and lack of prior knowledge. Expressions of worry, such as "I'm still anxious because there's so much I don't know," highlighted the emotional strain experienced before using the DA. Emotional stress often coexisted with difficulties in processing information and hesitancy about how to proceed.

DA Acceptability and Parent-Child Communication

Parental responses regarding the acceptability of DA and parent-child communication are summarized in Table 4. All 9 parents (9/9, 100%) reported having read the DA, supporting its feasibility for home use. Most parents responded positively when asked about its acceptability: 89% (8/9) answered "yes" or "somewhat yes" to "was the DA easy to understand?" Nevertheless, 33% (3/9) reported writing in the open-ended sections of the DA. Although this may limit engagement with the writing component, it does not reflect poor acceptability. Rather, parents explained that because an OIT decision was not imminent, they did not feel the need to record their thoughts at that time. Instead, DAs are primarily used as reading tools or discussion guides in family conversations.

Table . Parental responses on collaboration with children, decision aid acceptability, and additional needs with illustrative quotations.

Variables	Quantitative (n=9), n (%)	Key category and illustrative quotations
Collaborate		
Explained options to the child	• Fully, 5 (56) • Partial, 2 (22) • Limited, 1 (11) • None, 1 (11)	• Assessing understanding: "I realized my child was actually thinking about the treatment..."
Considered child's feelings	• Definitely, 4 (44) • Somewhat, 2 (22) • Neutral, 1 (11) • Not, 2 (22)	• Respecting feelings: "You can't move forward without asking the child first."
Acceptability		
Read the DA[a]	• Yes, 9 (100) • No, 0 (0)	• Guide usefulness: "Reading the guide made the steps clear to me."
Wrote in the DA	• No, 6 (67) • Yes, 3 (33)	• Family reflection: "It's good to take this home and think about it together."
DA clarity	• Definitely, 5 (56) • Somewhat, 3 (33) • Neutral, 1 (11) • Not very clear, 0 (0) • Not clear, 0 (0)	• Reassurance: "Written explanations gave me peace of mind and were incredibly useful."
Additional needs	—[b]	• Early information: "I would have liked to receive information about OIT right after the diagnosis." • Peer stories: "Hearing others' experiences would be helpful as a reference."

[a]DA: decision aid.

[b]Not applicable.

Additionally, DA facilitated parent-child communication. When asked, "Did you explain the treatment options to your child?" 78% (7/9) of the parents responded affirmatively. Moreover, 66% (6/9) said they "listened to their child's feelings about those options." Parents emphasized that the DA prompted them to consider and discuss their child's perspective and values in greater depth than before.

Furthermore, qualitative responses revealed that although some parents were reluctant to write in the DA, they found structured prompts helpful in organizing family discussions.

Parent-Child Collaboration and Pediatric QoL

Four parent-child dyads participated in this study. Table 5 presents each dyad's decision-making collaboration, along with the child's PedsQL scores and illustrative quotations.

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Table . Child engagement in decision-making processes and Pediatric Health-related Quality of Life; scores at baseline and 1 week postintervention following decision aid use.

Dyad (years)	Parent-reported items	PedsQL[ab] (child), baseline 1-week	Child voice	Decisional conflict	Preference direction	Child quotation
A (7 y)	• Explained options: yes • Asked feelings: somewhat agree	93.5, 93.7	Minimal ("mother decides")	Not expressed or low	Elimination	"My mother decides… I don't know."
B (10 y)	• Explained options: yes • Asked feelings: agree	97.8, 94.6	Clear (asks for dialogue)	Mild–moderate	Interested in OIT[c]	"I want to talk more… I've been kind of thinking about it."
C (14 y)	• Explained options: yes • Asked feelings: agree	97.8, 96.7	Clear (requests participation)	Low (direction set)	Favoring-OIT	"I'd like to try OIT and have a say when deciding."
D (14 y)	• Explained options: yes • Asked feelings: somewhat agree	92.4, 96.7	Clear (reasoned avoidance)	Low (stable stance)	Elimination	"I'm fine to keep elimination; I don't need treatment talks."

[a]PedsQL: pediatric health-related Quality of Life.

[b]Note: PedsQL indicates pediatric health-related QoL; higher scores reflect better HRQoL.

[c]OIT: oral immunotherapy.

All 4 parents (100%) reported explaining the treatment options to their children, and 3 of the 4 (75%) further stated that they asked how their children felt about those options. The PedsQL scores were uniformly high at preintervention (range 92.4 - 97.8) and demonstrated minimal change postintervention (range 92.4 - 96.7).

Child involvement varied by age. In lower elementary school (7 y), expressions of agency were minimal, and no verbalized conflict was noted (dyad A: "My mother decides… I don't know."). In upper elementary school (10 y), preferences were emerging yet ambivalent, with mild-to-moderate conflict (dyad B: "I want to talk more… I've been kind of thinking about it."). In junior high school (14 y), positions were clearer and conflict was low, but directions diverged, favoring OIT (dyad C) over continued elimination (dyad D). For example, the 7-year in dyad A stated, "My mother decides," whereas the 14-year in dyad C, after reading the DA with a parent, wished "to have a say." Multimedia Appendix 3 presents de-identified excerpts from the separate parent and child interviews, integrated and organized by dyad (A–D).

Discussion

Principal Findings

This feasibility study examined a culturally adapted parent-focused DA to support SDM for families considering pediatric OIT in Japan. Quantitative results indicated reduced parental decisional conflict, and interviews suggested greater engagement in parent-child dialogue and heightened awareness of children's involvement in decisions. Collectively, these findings provide preliminary support for integrating SDM tools into pediatric allergy care.

Reduction in Parental Decisional Conflict

The DA used in this study appeared to support a reduction in parental decision-making conflicts, particularly in the DCS subscales of value clarity, perceived support, and uncertainty. These results are consistent with those of previous trials on OIT-specific DAs [35]. Additionally, our study provides descriptive within-participant change data from clearly defined baseline measurements, suggesting that DA helps parents better understand treatment options and reflect on personal values in the context of complex, preference-sensitive decisions. When there was no single "correct" choice, the DA structure, which encourages clarification and comparison, may have contributed meaningfully to reducing decisional stress. Notably, changes observed over a 1-week period may reflect influences beyond DA exposure. Additional clinician contact or family discussions can improve perceived support and value clarity, whereas allergy-related events or conflicting online information can increase uncertainty and anxiety. These measurement effects may also have contributed. Interviews documented parent-child dialogue after DA receipt, consistent with gains in value clarity and support; however, because co-interventions and information seeking were not systematically recorded, observed DCS reductions should be interpreted as preliminary and potentially contingent on unmeasured influences. Conversely, emotional outcomes such as anxiety and QoL did not demonstrate any considerable changes. This divergence between the cognitive and emotional domains has also been noted previously, suggesting that reducing uncertainty does not always lead to

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immediate emotional relief, particularly in high-stakes decisions such as OIT, where safety concerns persist [3,19].

Emotional Outcomes and Narrative Support

To support an emotionally responsive SDM model, DAs should address factual content and users' emotional needs. Recently, a narrative review noted that parents contemplating OIT can be confused by inconsistent or nonevidence-based online information and often report anxiety about allergic reactions, highlighting the importance of SDM approaches and DAs that help address misinformation while acknowledging parental concerns. This is particularly crucial, as parental fear and anxiety are recognized globally as major factors influencing treatment decisions for chronic conditions such as FA [1-3]. Similarly, our qualitative theme of "difficulties in coping with emotional uncertainty" echoes that observation and underscores the importance of embedding affective support, such as patient stories or peer testimonials, within future iterations of the DA. Nonetheless, the lack of considerable changes in anxiety and QoL may reflect the limited short-term sensitivity of the scales used and the brief 1-week observation period. The used QoL measure, which focused on chronic allergy management, may have been insufficiently sensitive to capture short-term shifts resulting from the decision-making experience. Additionally, continued parental expressions of concern in the interviews suggested the persistence of underlying uncertainty about OIT and its long-term effects, even after DA use. Collectively, these findings highlight the need for DAs to include information and components offering emotional support, reassurance, and peer feedback. As emphasized in previous studies, SDM is both a cognitive and relational process that requires supportive communication and trust [9,10]. Narrative elements, such as stories from similar patients, can promote reflection, empathy, and engagement, particularly in emotionally taxing contexts such as OIT [9,36,37]. Although the DA emphasizes evidence-based content and parent-child dialogue, future versions may benefit from incorporating narratives or links to peer support to foster emotional reassurance and decision confidence [38].

Timing and Multifaceted DA Use

All the parents read and rated the DA positively, indicating their initial engagement. Nevertheless, the intensity and mode of use varied, underscoring that the parent-focused DA served multiple functions, information, dialogue prompts, and planning, rather than a single point-of-decision tool. Notably, many families continued to avoid allergens during the study and were not immediately pressured to initiate OIT. This context may have reduced the perceived need for written reflections or explicit decision-making.

Crucially, 1 parent expressed a desire for earlier intervention, stating, "I would have liked to receive information about OIT right after the diagnosis." Furthermore, our needs assessment revealed that families often seek clarity on the flexibility of OIT, specifically whether "treatment can be stopped and later restarted or tried again" after a period of discontinuation. These themes point to an anticipatory role for the DA, positioning it early to support understanding and planning, and not only immediate choice.

FA is a chronic condition that requires ongoing management, and treatment decisions may need to be reassessed as children grow and their lifestyles change [1,2,6]. For instance, starting daycare or school, increased exposure to shared meals, and a child's curiosity or desire for autonomy may prompt families to reconsider OIT, even after extended periods of allergen avoidance. Accordingly, families benefit from clear information about the revisitable and stepwise nature of OIT decisions, including the option to defer, pause, or reconsider treatment, so that the choice is not experienced as irreversible [1,2,6]. In pediatrics, decisions warrant periodic reappraisal as children mature and assume greater autonomy [15,39].

Prior work indicates that DAs are valuable for decision-making and reflective preparation. DAs can help patients clarify their values and enhance their readiness to make future choices. Additionally, they support preference articulation before clinical encounters [40], foster emotional engagement and reflective thinking through the inclusion of narratives [36], and allow patients to organize their concerns and values before consultations [19]. Future research should explore when and for whom such DAs should be offered to maximize their effects.

Facilitation of Parent-Child Collaboration

This feasibility study suggests that the DA serves not only as an informational tool but also as a prompt for parent-child dialogue, making children's perspectives and preferences, which are infrequently elicited during clinical encounters, more visible [1,13,41]. Several parents reported that they had not previously asked their child about treatment preferences, and some recognized clear opinions for the first time when using the DA. Concurrently, certain parental statements appeared to invite child compliance or deferral, potentially diminishing the child's own voice [14,41]. Conversely, when parents asked nonleading decision-related questions, children tended to offer fuller accounts, consistent with reports that interaction styles influence children's participation [13,15,39].

The observed pattern was consistent with developmental theory. In early school-age years, self-expression is limited; in upper elementary years, interest and nascent preferences emerge but often remain ambivalent; and in adolescence, positions become more autonomous and self-referential [1,15,42]. Aligning with this gradient, some children prefer to participate directly in decisions, whereas others choose to defer to their parents, underscoring the need for developmentally aligned and flexible support for SDM [13,43]. To support this flexibility, future iterations of the DA should incorporate explicit parent-facing guidance on strategies for child engagement tailored to different developmental stages. These findings are also concordant with those of reviews emphasizing both the importance of children's involvement in medical decisions and the heterogeneity in how that involvement is expressed [13,41].

Overall, parents can use DA to elicit and incorporate their children's views into clinical decision-making, and age-aligned design features are likely to be useful [12,15,39,42,43]. To translate these insights into practice, the proposed DA revisions add explicit, developmentally tailored parent guidance: meaning-making with concrete examples and illustrations in early school age; value prioritization by listing 2 to 3 advantages

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and concerns in upper elementary school; and self-referential reasoning combined with family consensus in adolescence. These staged supports enable children to select their preferred level of involvement and make triadic child-parent-clinician collaboration easier to implement. To build an evidence base, subsequent studies should evaluate age-stratified DA versions in larger, more diverse samples and co-design protocols for triadic collaboration that include parent-facing guidance [1,6].

Implementation in Japanese Clinical Settings

The DA includes prompts designed to help parents clarify their values and encourage dialogue with health care providers. However, several parents reported being unsure how to use the DA or feeling reluctant to ask questions because physicians were busy. Therefore, the effectiveness of DAs depends on both the content and the context in which they are introduced. Cultural norms in Japan, such as respect for medical authorities and hesitation to speak up, may inhibit families from actively engaging with decision-support tools, particularly during time-pressured consultations.

Unlike our Japanese setting, where deference to medical authorities and time pressure can dampen questioning, North American programs have actively evaluated and implemented OIT-focused, formal SDM workflows. A recent study reported a pediatric product-agnostic OIT DA with high acceptability and low decisional conflict among caregivers, positioning DAs as a practical adjunct to clinical encounters [35]. Consistent with this, national CSACI guidance [6] explicitly promotes patient-oriented, preference-sensitive OIT decisions, shared responsibility between families and the health system, and organizational solutions that embed SDM tools beyond the physician-patient dyad (eg, team-based introduction and previsit use). Conceptually, SDM in FA also emphasizes that clinicians must understand "where the patient is coming from," with DAs assisting values clarification rather than replacing dialogue, an approach that aligns with our qualitative finding that parents used the DA to "pause and reflect" even when consultation time was limited [1]. Taken together, these comparisons suggest that the previsit distribution and nonphysician-led onboarding of DAs are likely to mitigate Japan-specific barriers and facilitate shared deliberation within routine care.

Building on this mechanism, programs should specify when and for whom a DA is most useful. Likely triggers include decisional uncertainty, divergent family preferences, and limited consultation time. Clinicians can use brief, neutral cues to normalize values clarification without extending visits. Clear signposting on how to use the DA, age-appropriate sections for children, and plain-language summaries can further lower barriers where questioning is difficult.

Parents valued the credibility of the DA, noting that its development by health care professionals increased their trust in and willingness to use it. Additionally, receiving a DA allowed them to pause and reflect, suggesting that DAs can offer a psychological space that is not always available in typical consultations. The qualitative findings suggest that the DA served as a valuable reflective tool because the cultural context inhibited open questioning during consultations. Integrating SDM tools into routine care workflows, with endorsement from medical staff, can bridge cultural barriers and promote shared deliberation.

Implications for Health Care Practice and Policy

Mechanistically, the DA structured and balanced information helps organize concerns and form realistic expectations, thereby potentially reducing uncertainty. Nonleading decision-related questions from parents promote clarity of values and shared understanding within family conversations. Furthermore, developmentally aligned, parent-facing guidance can enable children to choose their preferred level of involvement and may facilitate triadic child–parent–clinician collaboration. These preliminary findings offer cautious insights into enhancing SDM in pediatric allergy care through improved health care practices and supportive policies.

Therefore, tailored strategies are crucial. Considering that health care organizations and their configurations vary considerably across countries, effective SDM integration warrants tailored workflow solutions [13]. The potential role of nurses in this context is particularly noteworthy. Nonphysician health care professionals, including nurses or educators, can efficiently introduce and support DA use, particularly in time-limited outpatient settings. Therefore, distributing the DA before clinical encounters or having nonphysician professionals, such as nurses or certified allergy educators, briefly introduce the tool may be more practical. Nurses, particularly certified allergy educators in Japan, may be well-positioned to facilitate DA use by initiating conversations, clarifying treatment options, and supporting family communication.

Furthermore, DA integration outside the consultation room is essential. Additionally, providing a digital version accessible at home or in waiting areas may help families engage with the content at their own pace, as previous studies have emphasized that DAs are more likely to be used outside consultations. Institutional measures, including SDM training and supportive care protocols, may gradually increase the clinical environment's readiness to incorporate decision-support tools. Furthermore, the successful integration of DAs and SDM principles into routine care will likely require a collaborative, multidisciplinary approach involving physicians, allied health professionals, and dedicated nursing staff. These directions are consistent with international recommendations, such as those of the CSACI, emphasizing the value of SDM in allergy care [6].

Beyond such system-level measures, the chronic and recurrent nature of FA itself underscores the need to prioritize the "knowledge" function of DAs. FA care entails recurrent choices across the child's life course, as developmental transitions (eg, entry to daycare or school, expanding peer eating contexts, and emerging autonomy) prompt families to revisit OIT even after prolonged avoidance. Acquiring accurate knowledge in advance is not only a proximal outcome of DA exposure but also an anticipatory resource for future deliberation. Consistent with the International Patient DA Standards, knowledge is a core component of decision quality [44]. Notably, a Cochrane review demonstrated that patient DAs consistently improve knowledge and the accuracy of risk perceptions and can be used before consultations without harming satisfaction or health outcomes [11]. Thus, incorporating a brief DA-aligned knowledge

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assessment would strengthen our evaluation and clarify the pathway by which an evidence-focused DA may reduce decisional conflict in the short term while supporting repeat decisions over time. Moreover, recent FA guidelines underscore structured education and consent as prerequisites for OIT preparation, reinforcing the rationale for early preparatory DA use to scaffold later reevaluations as circumstances change [6].

Limitations and Future Research Directions

This single-center feasibility study was limited by its small sample size. A post hoc sensitivity power analysis indicated that, at 2-sided α=.05 with 80% power, the minimal detectable standardized effect size was approximately 1.06 for n=9, indicating that only very large effects were detectable. While the primary outcomes (DCS) improved, estimates for the secondary outcomes (STAI and FAQLQ-PB) were imprecise; therefore, confirmation with adequately powered samples is warranted.

The participating children spanned a wide age range, and the analyses did not prespecify age stratification, rendering the observed age-related patterns descriptive rather than inferential. The 1-week follow-up was likely insufficient to capture the psychosocial effects. Coronavirus disease 2019–related constraints limited face-to-face interactions and may have influenced the recruitment and interview procedures. Finally, knowledge acquisition, which is an important target of DAs, was not measured. Future work should enroll larger and more diverse samples, including prespecified age strata, and extend the follow-up period to evaluate age-specific outcomes and engagement. Comparative qualitative approaches and case studies (eg, contrasting subgroups by age, disease severity, or parent-child dyad dynamics) may elucidate the context-dependent use of decision support. Iterative refinement of the parent-focused DA, together with co-designed, age-appropriate child components or digital modules, could improve process quality and enable the longitudinal assessment of knowledge gains.

Conclusions

A culturally adapted DA may mitigate parental decisional conflict and improve parent-child communication in Japanese pediatric FA care. Despite the small-scale setting, these findings lay the groundwork for larger studies and the future implementation of DAs in routine pediatric care. Future research should focus on co-design approaches, long-term outcome evaluations, and the integration of DAs into multidisciplinary care frameworks to support family-centered and value-based decision-making in allergy treatment. Future work should involve large multisite trials to confirm its effectiveness, coupled with family co-design and age-specific adaptations.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
English translation of the decision aid.
[PDF File, 1388 KB - jopm_v18i1e77782_app1.pdf]

Multimedia Appendix 2
Semistructured interview guides (parent-child).
[DOCX File, 14 KB - jopm_v18i1e77782_app2.docx]

Multimedia Appendix 3
Deidentified parent-child excerpts by dyads A-D.
[DOCX File, 28 KB - jopm_v18i1e77782_app3.docx]

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Abbreviations

CSACI: Canadian Society of Allergy and Clinical Immunology
DA: decision aid
DCS: Decisional Conflict Scale
FA: food allergy
FAQLQ-PB: Food Allergy Quality-of-Life Questionnaire–Parental Burden
ODSF: Ottawa Decision-Support Framework
OIT: oral immunotherapy
PedsQL: Pediatric Quality-of-Life Inventory
QoL: quality-of-life
SDM: shared decision-making
STAI: State–Trait Anxiety Inventory

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Original Paper

Barriers and Facilitators of Digital Transformation in Health Care: Mixed Methods Study

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Abstract

Background: Digital transformation is now a fundamental component of health care systems worldwide. To develop effective digital health strategies, it is essential to examine physicians' perspectives on the barriers and facilitators of implementation, with particular attention to regional and cultural factors influencing technology adoption.

Objective: This study aims to identify and analyze key barriers and facilitators to the implementation of digital health technologies from physicians' perspectives in Russia.

Methods: A 2-phase nationwide mixed methods study was conducted involving 460 physicians from various specialties. The first phase comprised in-depth interviews with 10 physicians to develop a specialized questionnaire. The second phase involved a nationwide cross-sectional survey with 450 physicians using the developed questionnaire. Inclusion criteria were working in a Russian city with a population of more than 100,000, age 22 years and older, at least 3 years of specialty experience, and employment in public or private health care institutions. The analysis focused on 4 categories of digital health technologies: remote consultations, remote monitoring, digital diagnostic solutions, and clinical decision support systems.

Results: The main barriers identified were fear of making erroneous decisions (25% of physicians), technical difficulties (up to 25%), and legal insecurity (21% of physicians). Notably, the barrier profile varied depending on the type of technology. Key drivers for implementation included time saving (59% of physicians), practical benefits (55% of physicians), and legal security (54% of physicians). Additionally, a convenient training organization was a crucial motivator, with the availability of free training (53% of physicians) and provision of study leave (52% of physicians). These facilitators were consistent across all categories of digital solutions. Based on these findings, key recommendations for the implementation of digital transformation in medical organizations were formulated.

Conclusions: The findings highlight the need for comprehensive, technology-specific digital implementation strategies to improve health care digital transformation effectiveness, considering physician concerns about decision-making accuracy, technical challenges, and legal frameworks.

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KEYWORDS

digital transformation; physician barriers; technology acceptance; health care innovation; digital health; telemedicine; remote patient monitoring; clinical decision support systems; eHealth; mHealth

Introduction

Digital transformation has become an integral part of modern health care systems around the world [1]. Technologies, such as telemedicine, remote patient monitoring, artificial intelligence–based diagnostics, and clinical decision support systems (CDSS), are increasingly seen as essential tools to address current and future challenges in health care [2]. The

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COVID-19 pandemic, in particular, has accelerated the adoption of certain digital solutions in health care, demonstrating their potential to support care continuity and mitigate public health crises [3,4]. Back in 2020, the World Health Organization approved the development of the Global Strategy on Digital Health 2020-2025 at the 73rd World Health Assembly [5].

The willingness of health care professionals, especially physicians, to accept new technologies and actively use them is a determining factor in the successful integration of digital solutions in health care [1]. Physicians play a key role in the implementation of digital solutions, influencing both their use and acceptance of digitalization by patients [6]. Therefore, understanding the specific barriers to implementation and factors that facilitate it, from a physician's standpoint, is crucial for developing effective strategies for the implementation of digital solutions in health care [7]. At the same time, regional and cultural characteristics can have a critical impact on the typology of barriers and motivators in using various digital technologies.

This study aims to investigate the main barriers faced by physicians in using various digital technologies and to identify key drivers of health care digitalization in Russia.

Methods

Study Design

A 2-phase nationwide mixed methods study was conducted involving 460 physicians from various specialties.

First Stage

At the first stage, in-depth online interviews (up to 1.5 hours) were conducted with 10 Moscow physicians with experience in using digital technologies. Among interview participants were 8 outpatient and polyclinic physicians and 2 inpatient physicians; 8 respondents represented the public sector, and 2 represented private clinics.

The analysis of the interviews allowed identifying key factors that facilitate and hinder digital transformation in health care. Based on the data obtained, a new questionnaire was developed to assess the attitude of physicians to digital transformation in health care and their experience of using digital technologies (Digital Health Readiness and Barriers Questionnaire for Physicians).

Second Stage

At the second stage, an observational all-Russian study was conducted with 450 physicians using the questionnaire developed at the first stage.

To be included in the study, a physician had to meet the following criteria:

1. Work in a Russian city with a population of more than 100,000 people.
2. Age 22 years and older.
3. Work experience in the specialty for at least 3 years.
4. Work in public or private institutions (physicians working in departmental medical institutions were not allowed to participate).

To ensure an even and representative distribution of respondents, quotas were established for medical specialty and city of residence.

All respondents completed the online questionnaire developed in the first stage of the study. Completion of the questionnaire was voluntary and was processed anonymously and depersonalized.

This study analyzes the barriers to digital transformation in health care. The block includes 2 questions. The first one is devoted to the most significant obstacles to the implementation of digital technologies in practice. The physician is given 22 answer options; the respondent can mark up to 5 most relevant options. The full text of the question is provided in Multimedia Appendix 1.

For the ease of analysis, 22 statements were allocated into 5 domains—motivational, ability-related, process-related, physical (environmental factors), and social—reflecting the Motivation, Ability, Processing, Physical, and Social (MAPPS) framework grounded in behavioral theory. A comprehensive rationale and detailed description of each barrier group are provided in Multimedia Appendix 2.

The second question aimed to identify key factors that help overcome barriers to the implementation of digital technologies. Physicians were offered a list of 19 statements reflecting various advantages of using new digital solutions. Respondents assessed how likely it is that they would start using or use the relevant technologies more actively if the specified benefits were realized, using a 7-point scale: from 1 (definitely would not use or use more actively) to 7 (definitely would use or use more actively). The full text of the second question is provided in Multimedia Appendix 3.

The survey analyzed 4 categories of digital technologies (Table 1), with respondents separately noting the main barriers to the implementation of the relevant solutions for each category. This approach made it possible to identify the specifics and frequency of barriers depending on the type of digital technology, as well as to assess which barriers are most significant in each area of digital transformation in health care.

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Table 1. Categories of digital technologies.

Abbreviated name	Full wording used in the survey
Remote physician-patient or physician-physician consultations	• Remote (telemedicine) physician: patient consultations using audio or video communication • Remote (telemedicine) physician: physician consultations using audio or video communication (eg, for emergency cases, scheduled consultations, online consultations)
Remote patient monitoring	• Remote patient monitoring (eg, using medical sensors or an app to transmit one's readings remotely to the physician via an app)
Technologies for diagnostics	• Technologies for diagnostics (eg, computer vision to recognize X-rays, computed tomography scans, magnetic resonance imaging, and moles)
Clinical decision support systems	• Systems to support physicians in making medical decisions (analysis of patient medical records, anamnesis, symptoms, results). For example, Webiomed, TOP-3, Sapia, and Onqueta.

The survey was conducted online from February 24 to March 17, 2025. The sample frame was created by randomly sending invitation links to all physicians registered on the Ipsos Comcon platform "Healthcare Professionals." Emails containing a link to the survey were sent to 12,629 physicians; 1120 opened the link and viewed at least the first page and 450 physicians completed the survey. The survey response rate was 3.6%. Respondent recruitment was conducted using a quota sampling approach. A detailed description of the survey methodology, prepared in accordance with the CHERRIES (Checklist for Reporting Results of Internet E-Surveys), is provided in Multimedia Appendix 4.

Statistical Data Processing

Descriptive statistics of the analyzed group are presented as percentages for qualitative variables. For quantitative variables, mean values and SDs were calculated. The study data were weighted according to official statistics on the distribution of primary care physicians and specialists in Moscow, St. Petersburg, and other cities [8]. Percentage calculations and data processing were performed using IBM SPSS Statistics (version 27).

Ethical Considerations

Ethical Approval and Informed Consent

This study was approved by the Independent Ethics Committee of the Federal State Budget Scientific Institution "N.A. Semashko National Research Institute of Public Health" (protocol number 7, 2025). Written informed consent was obtained from all interview participants prior to conducting and audio recording the interviews. The study information materials provided comprehensive details regarding the research objectives, participant selection criteria, study procedures, time requirements, potential risks and benefits, participant rights and responsibilities, and data protection measures. Online survey respondents provided their consent by selecting the "Start" button following review of the introductory page, which contained information about survey content, estimated completion time, anonymity provisions, confidentiality protections, and research objectives. All participants were informed of their right to refuse participation or discontinue involvement in the research at any point without penalty. Informed consent was secured from all study participants. Participants in the online survey were offered a monetary incentive as compensation for their time and participation. Specifically, respondents were offered an electronic certificate worth 500 Russian rubles (US $6.44) for use at online hypermarkets. Interview participants did not receive monetary compensation.

Privacy and Confidentiality Protection

All survey responses were collected using anonymous data collection methods. Interview audio files and written transcripts underwent encryption protocols. Encrypted data access keys were maintained in a secure, password-protected local database with restricted access limited to MB, ES, and MZ only.

Results

Demographic Characteristics of the Sample

The survey on digital transformation in health care covered 450 physicians from 8 federal districts of Russia. Table 2 provides the characteristics of the study cohort of physicians.

The objective of the study was to obtain a result that would be representative of the digital transformation of physicians in Russia. It is obvious that the situation in large cities may differ from the results of the study in towns. According to official statistics, the share of physicians from Moscow and St. Petersburg (the 2 largest cities in the country) is 19% of all physicians in the Russian Federation [8]. The share of respondents practicing in Moscow and St. Petersburg was 28% (128/450) of the total sample, which indicates an insufficient representation of physicians from other regions and possible sample bias. To correct for this imbalance and ensure the representativeness of the data obtained, we applied poststratification weighting using official statistics on the regional distribution of physicians. The data below are given taking into account the weighting for the distribution of physicians by locality.

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Table 2. Clinical and demographic characteristics of doctors.

Characteristics	Values (N=450)
Gender, n (%)	
Men	57 (12.7)
Women	393 (87.3)
Age (years), mean (SD; range)	41.2 (9.57; 26-76)
Age (years), n (%)	
Up to 30	53 (11.8)
31-40	184 (40.9)
40-50	129 (28.7)
50+	84 (18.7)
Region of residence, n (%)	
Central Federal District	153 (34)
Northwestern Federal District	46 (10.2)
Southern Federal District	41 (9.1)
North Caucasian Federal District	4 (0.9)
Volga Federal District	115 (25.6)
Ural Federal District	30 (6.7)
Siberian Federal District	55 (12.2)
Far Eastern Federal District	6 (1.3)
City of residence, n (%)	
Moscow and St Petersburg	128 (28.4)
Other regions	322 (71.6)
Specialty, n (%)	
General practitioner or physician	110 (24.4)
Endocrinologist	71 (15.8)
Pediatrician	56 (12.4)
Gynecologist	45 (10)
Cardiologist	43 (9.6)
Neurologist	30 (6.7)
ENT[a]	17 (3.8)
Gastroenterologist	18 (4)
Surgeon	18 (4)
Pulmonologist	13 (2.9)
Ophthalmologist	8 (1.8)
Allergist	9 (2)
Urologist	9 (2)
Oncologist	1 (0.2)
Anesthesiologist-resuscitator	1 (0.2)
Functional diagnostics doctor	1 (0.2)
Average length of service (years), mean (SD; range)	15.6 (8.96; 3-45)
Scientific degree, n (%)	
None	422 (93.8)
Candidate of Sciences	26 (5.8)

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Characteristics	Values (N=450)
Doctor of Sciences	2 (0.4)
Type of institution, n (%)	
State	345 (76.7)
Municipal	228 (50.7)
Regional	94 (20.9)
Federal	23 (5.1)
Private	105 (23.3)
Type of admission, n (%)	
Outpatient	422 (93.8)
Inpatient	28 (6.2)

[a]ENT: ear, nose, and throat.

Key Barriers to Using Digital Technologies

Table 3 presents data on the frequency of various barriers that physicians encounter when implementing 4 digital technologies: remote consultations, remote patient monitoring, diagnostic technologies, and CDSS. The barriers were classified into 5 main groups: motivational, capability-related, process-related, physical, and social (MAPPS model). This classification was developed by Ipsos Comcon based on the behaviorist approach. For a detailed description and theoretical justification of barrier groups, see Multimedia Appendix 2.

For understanding the original distribution of responses, Multimedia Appendix 5 presents statistics corresponding to Table 3 based on the initial unweighted data, without adjustment for physician distribution. The results demonstrate that each type of technology is accompanied by a unique profile of barriers. For ease of perception, Table 4 shows the top 5 main barriers that physicians identified for each technology.

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Table 3. Identification of barriers to the implementation of digital technologies.

Barriers[a,b]	Remote consultation (%)	Remote monitoring (%)	Technologies for diagnostics (%)	Systems to support physicians in making medical decisions (%)
Motivation barriers[c]	42	39.2	37.2	45.7
I don't see any practical benefit from using this technology in my daily work.	5.3	5.5	5.7	5.1
I am concerned about data privacy issues when using this technology.	20.9	15.7	9.3	15.3
I am concerned about the problem of excessive control over my work when using this technology.	9.4	5.2	4.3	9.8
This technology reduces the importance of physician's work.	8.4	6.3	7.6	9.7
I don't trust the quality of this technology.	4.6	6	6.5	10.7
I am concerned about overdiagnosis when using this technology.	7.6	9.8	15.8	11.9
Capability-related barriers[c]	28.7	38.9	48.5	48
I don't have time to master this technology.	5.8	8.5	7.5	6.1
This technology is too complex to master.	1.4	2.5	4.2	5
I have no knowledge of specific products within this technology that could be used in my practice.	12.4	17.5	24.7	26
I don't have access to training courses to master this technology.	13.2	16.8	20.8	19.9
The technology requires personal investments to master it.	5.2	5.7	5.1	4.7
Process-related barriers[c]	49.7	53.7	40.8	39.8
I am not sure that this technology will work stably without delays and breakdowns.	25.3	29.2	18.9	18.2
I am afraid of making wrong decisions when using this technology.	22.2	26.4	26.8	22
Technology takes time without making work easier.	13.5	12.9	3.2	9
Environmental (physical) barriers[c]	44.4	39.4	45.4	47.5
I do not have technical base to master this technology (suitable equipment, software, communications).	20.5	24	31.6	26.7
Existing regulations do not include this technology or need to be revised.	20.5	13.4	12.5	15.3
This technology does not have qualified technical support.	14.8	11.3	10.4	13.3
Social barriers[c]	47.5	39.3	33.9	40.4
Management of my health care facility is not interested in using this technology.	13.9	15.1	14.3	20.7
My environment condemns the use of this technology.	1.1	0.9	0.6	1.5
I prefer to use other long-proven methods rather than this technology.	8.6	5.8	9.8	5.9
I feel a lack of legal security when using this technology.	29.8	21	14.9	17.5
None of the above.	14.2	13	13.6	11.1

[a]The data provided are weighted by the distribution of physicians across populated areas of the Russian Federation. Multimedia Appendix 5 provides unweighted data.

[b]The table shows the percentage of doctors who selected each answer. Each respondent could select up to 5 answers.

[c]The total for each category shows the percentage of doctors who selected at least one of the category barriers.

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Table 4. The top 5 main barriers to different types of digital technologies in health care.

Barriers to using digital technologies[a]	Values (%)
Barriers to remote consultations (top 5)	
Lack of legal protection	29.8
Doubts about stable operation of technology	25.3
Fears of making wrong decisions	22.2
Data privacy concerns	20.9
Lack of technical base	20.5
Barriers to remote monitoring (top 5)	
Doubts about stable operation of technology	29.2
Fear of making wrong decisions	26.4
Lack of technical base	24
Lack of legal security	21
Lack of knowledge about products	17.5
Barriers to technologies for diagnostics (top 5)	
Lack of technical base	31.6
Fear of making wrong decisions	26.8
Lack of knowledge about products	24.7
Lack of training courses	20.8
Fear of overdiagnosis	15.8
Barriers to systems to support physicians in making medical decisions (top 5)	
Lack of technical base	26.7
Lack of knowledge about products	26
Lack of interest from management	20.7
Lack of training courses	19.9
Lack of legal protection	17.5

[a]The data provided are weighted by the distribution of physicians across populated areas of the Russian Federation.

Remote Physician-Patient or Physician-Physician Consultations

The most common barriers for remote consultations are social barriers (47.5%) and process-related barriers (49.7%). The most frequently mentioned barriers include lack of legal protection (29.8%, the highest rate among all technologies), doubts about the stability of the technology (25.3%), and fears of making wrong decisions (22.2%). In addition, 20.9% of doctors expressed concerns about data privacy, which is the highest rate for this barrier among all technologies. Motivational barriers were encountered by 42% of doctors. It is the second most frequent value among all groups.

Thus, despite their relative prevalence and technical accessibility, remote consultations are often perceived by physicians as legally and organizationally vulnerable, especially in conditions of insufficient regulatory support and lack of confidence in data protection.

Remote Monitoring

For remote patient monitoring technologies, process-related barriers were dominant (53.7%), which was the highest value among all barrier categories. The most frequently noted barriers were system instability (29.2%) and concerns about decision-making errors (26.4%).

There was also a high proportion of physicians who indicated a lack of technical expertise to master this technology (24%), a feeling of legal insecurity (21%), and a lack of knowledge about specific products (17.5%).

Thus, physicians face challenges in integrating remote monitoring technologies into daily practice due to a wide range of concerns, but technical and methodological barriers related to reliability, safety, and the need for new professional skills come to the fore.

Technologies for Diagnostics

As barriers to implementation of diagnostic technologies, physicians most often indicated insufficient technical base (31.6%) and fear of making wrong decisions (26.8%) when using technology.

Technologies for diagnostics provided the highest values in terms of opportunity-related barriers (48.5%), particularly lack

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of product knowledge (24.7%) and lack of access to training resources (20.8%).

Also, 15.8% of respondents expressed fear of overdiagnosis**,** which is the highest among all technologies.

These results indicate that digital diagnostic solutions are perceived by physicians as technologically complex and not transparent enough, requiring serious support for implementation and methodological adaptation.

CDSS

CDSS turned out to be the least acceptable for respondents in terms of motivational barriers (45.7%) and environmental barriers (47.5%).

For this group of technologies, the most common problems were lack of technical base (26.7%), lack of knowledge about products (26%), and unavailability of training courses (19.9%).

Also, 20.7% of doctors indicated a lack of support from management of the health care facility (which is the highest indicator of this barrier among all technologies). This result demonstrates the importance of active participation and the initiative of management in integrating digital solutions into clinical practice.

An important issue for physicians remains legal security (17.5%) when using this group of technologies.

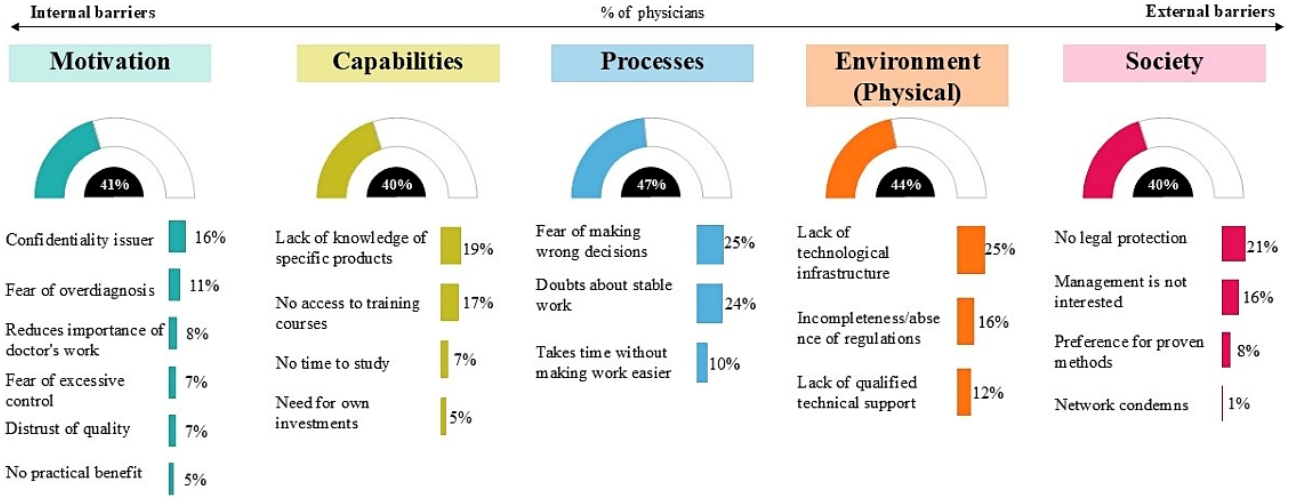
Physicians also noted a lack of trust in the quality of technology (10.7%), a feeling of excessive control over their professional activities (9.8%), and a decrease in the significance of the role of physicians (9.7%). Although these motivational barriers were selected by a relatively small number of respondents, they were most frequently identified for CDSS compared to other types of digital technologies, which characterizes the low level of trust of doctors in this type of technology.

Thus, CDSS is perceived by physicians as a problematic technology both in terms of technical infrastructure, organizational support, and professional trust.

Overall, the most common barriers to implementation of all digital solutions are technical and organizational difficulties, fear of making wrong decisions, and a sense of legal insecurity (Table 4). At the same time, the intensity of the expression of individual barriers varies depending on the type of technology: for example, for remote consultations, legal and regulatory barriers come to the fore, while for the other 3 types of digital technologies, technical difficulties play a key role. This emphasizes the need for differentiated implementation support strategies that take into account the specifics of each type of digital tool.

Figure 1 shows a generalized distribution of barriers that physicians face when implementing digital technologies in clinical practice (the total result for all types of technologies).

Figure 1. General distribution of barriers to the implementation of digital technologies in health care from the point of view of doctors. The graph shows the percentage of physicians who selected a particular answer option. For category data, the percentage of physicians who selected at least one of the category barriers is shown. The data presented are weighted by the distribution of doctors across populated areas of the Russian Federation.



Although the distribution of barriers was generally fairly even (from 40% to 47%), procedural difficulties came to the fore, noted by 47% of physicians. Most often, they indicated fear of making wrong decisions (25%) and doubts about the stable operation of digital systems (24%).

Among environmental barriers (44%), the leading one is the lack of technical base (25%), and among social barriers (40%), the first place is taken by the lack of legal security (21%).

A significant proportion are also capability-related barriers (40%), primarily a lack of knowledge about specific products (19%). Likewise, motivational barriers (41%) reflect physicians' internal doubts: primarily concerns about data privacy (16%).

Thus, the figure illustrates that barriers to implementation of digital technologies in health care are multifaceted and cover both the internal attitudes of doctors and external organizational and legal restrictions, which require comprehensive solutions at the level of the health care system.

Drivers of Digital Technologies Implementation in Health Care

Table 5 shows the top 5 main drivers that, in the opinion of physicians, can help overcome barriers to implementation of digital technologies (Multimedia Appendix 6 provides a complete table of the distribution of drivers for different types of technologies).

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Notably, while the barrier profile differed depending on the type of digital technology, the leading drivers were similar across all technology types.

Time-saving potential was consistently ranked first, with 56% to 62% of votes. Also, practical benefits were in the top 3 drivers for all technology types. This highlights that physicians are primarily interested in real functional efficiency and time savings in a busy practice environment.

For all types of technologies, legal security was included in the top 5 main criteria necessary for using the technology. This criterion was most significant for remote consultations (57.7%) and remote monitoring (54.6%).

Table 5. The top 5 main factors contributing to the introduction of digital technologies in health care, according to physicians.

Drivers of digital technologies implementation in health care[a,b]	Values (%)
Drivers to remote consultations (top 5)	
Technology will save time	62.2
Technology will deliver practical benefits in daily work	58.3
Legal protection when using this technology	57.7
Free or at the expense of the health care institution	55.8
Management will allow taking study leave	54.4
Drivers to remote monitoring (top 5)	
Technology will save time	58.1
Legal protection when using this technology	54.6
Technology will deliver practical benefits	54
Free or at the expense of the health care institution	53.2
Management will allow taking study leave	51.1
Drivers to technologies for diagnostics (top 5)	
Technology will save time	56
Free or at the expense of the health care institution	52.8
Technology will deliver practical benefits	52.2
Management will allow taking study leave	51.7
Legal protection when using this technology	51.4
Drivers to systems to support physicians in making medical decisions (top 5)	
Technology will save time	58.3
Technology will deliver practical benefits	54.5
Legal protection when using this technology	51.2
Free or at the expense of the health care institution	50.3
Interface will be accessible and understandable	49.4

[a]The data provided are weighted by the distribution of physicians across populated areas of the Russian Federation.

[b]Based on the answers to the question: "How likely is it that you would start using/more actively use the following technologies when implementing the ideas on a scale from 1 to 7?" The table shows the percentage of respondents who chose 7 points for this answer (a physician would definitely start using digital technology if the conditions specified in the statement were met).

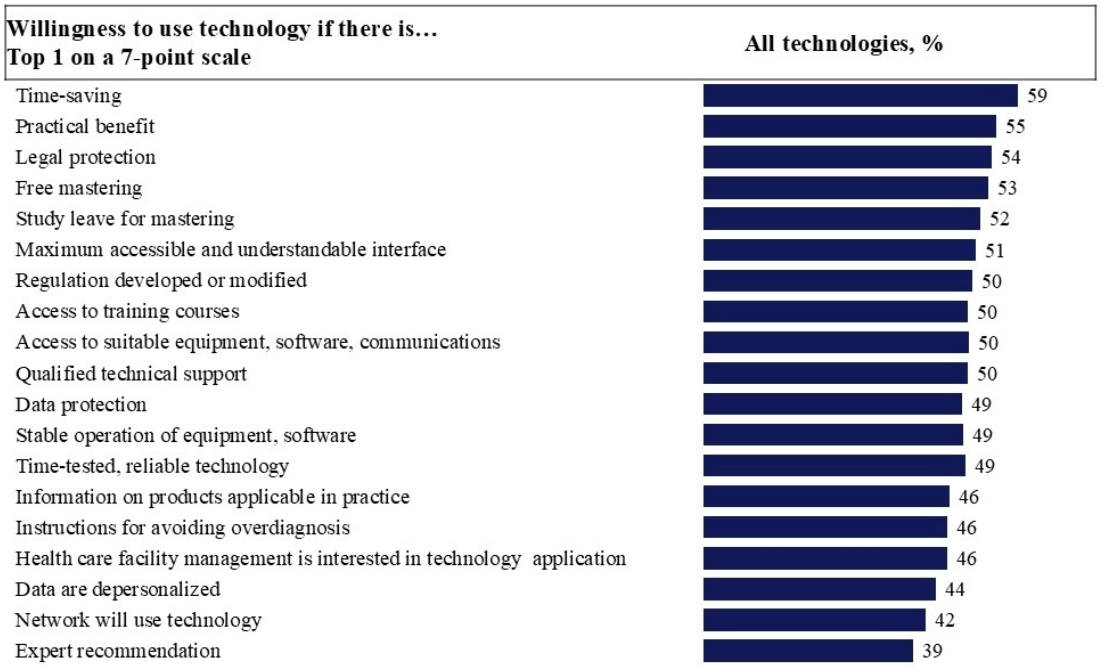
Another important block of incentives is related to the reduction of barriers to learning and the technical ease of using the technology: availability of free training, study leave, and a simple interface were also included in the top 5 factors. This indicates the need not only to implement technologies, but also to create a supportive learning environment, especially in conditions of time constraints for medical personnel. All drivers for different technologies are summarized in Figure 2.

The results highlight that physicians perceive digitalization primarily through the prism of daily efficiency, legal security, and organizational support.

The main driver for the implementation of all digital technologies is saving doctors' time. This is important to consider when implementing digital technologies in health care institutions.

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Figure 2. Key factors contributing to the implementation of digital technologies, according to physicians. The data presented are weighted by the distribution of doctors across populated areas of the Russian Federation. Based on the answer to the question: "How likely are you to start using or more actively use the following technologies when implementing ideas on a scale from 1 to 7? The figure shows the percentage of respondents who chose 7 points for this answer (a physician would definitely start using digital technology if the conditions specified in the statement were met).



Discussion

Barriers to Implementation of Digital Technologies in Health Care

In recent years, digitalization in health care has become an integral part of medical practice. However, the introduction of digital technologies is accompanied by a number of barriers that must be taken into account for the successful integration of innovations into clinical practice.

The study of 450 physicians in Russia found that key barriers to the implementation of digital technologies include technical difficulties, fear of making wrong medical decisions, and concerns about legal insecurity.

Lack of technical infrastructure (25%) and doubts about the stability of technology (24%) were the key barriers to the implementation of digital technologies. These data are relevant to that from the international studies, in particular, according to the largest umbrella meta-analysis of 108 systematic reviews [1], infrastructural and technical barriers to implementation of digital technologies in health care rank first in frequency worldwide.

Along with technical difficulties, fear of making wrong decisions (25%) based on the use of digital technologies was ranked first in this study. A number of studies also demonstrate that it is the fear of physicians to make a mistake when relying on digital tools that is an important barrier to the implementation of digital technologies. Thus, a survey of 1449 physicians by the American College of Physicians, conducted in 2019, showed that 29% of specialists see the risk of potential medical errors as one of the main obstacles to the implementation of telemedicine [9,10].

Another study showed that 42.1% of American doctors are concerned about a decrease in the quality of care provided when using telemedicine [11]. It is worth noting that this fear has certain grounds. Thus, in a study of medical malpractice cases related to the use of remote telephone consultations, the most common accusation was incorrect diagnosis (68%), and the most common form of damage was death (44%) [12]. Systematic review by Kim et al [13] found that IT issues in health care can significantly disrupt care processes and lead to errors in clinical decision-making, delays in treatment, and even harm to patients. In 53% of the included studies, IT-related issues were associated with actual or potential harm to patients, including deaths.

Thus, in addition to technical difficulties, it is the fear of physicians to make mistakes due to inaccuracies in digital systems that remains the key barrier to digitalization in health care. It can be overcome by improving the validation of algorithms, ensuring transparency of systems, and clear legal regulation in digital technology use.

The feeling of legal insecurity when using digital technologies, identified by 24% of Russian physicians, reflects one of the most significant and persistent problems in digital transformation in health care. This barrier manifests itself in the concerns of medical workers about the possible legal consequences of errors associated with the use of digital solutions, as well as in the unclear distribution of responsibility between a physician, an institution, and a technology developer [14,15].

Legal and regulatory risks are one of the main factors hindering the implementation of digital solutions in clinical practice [16]. In particular, it is noted that the existing legal framework is often not adapted to the specifics of digital technologies: there are no clear standards for medical data storage, transfer, and

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processing, as well as for determining liability in the event of errors or incidents related to digital tools [9,14,16]. This leads to the fact that physicians are forced to rely on general norms of professional duty and ethics, which increases uncertainty and reduces the willingness to use innovations [14].

Thus, the feeling of legal insecurity is not only a subjective fear, but also an objectively determined barrier associated with the insufficient development of the regulatory framework, absence of clear standards and mechanisms for distributing responsibility. To overcome this obstacle, it is necessary to develop and implement modern legal and ethical standards adapted to digital reality, as well as professional medical communities, to actively participate in the formation of regulatory policy [9,14,16].

Another important conclusion from the study is that a significant portion of physicians (16%) identified the lack of management support in the implementation of digital technologies as a key barrier. Specifically, for the CDSS, this factor was among the top 3 barriers and was noted by 20.7% of physicians. Organizational support and management interest are often considered important factors in the successful implementation of digital technologies in health care [17,18]. This study emphasizes the need for strategic management involvement and the development of leadership competencies for the successful implementation of digital technologies.

A literature review revealed that a significant number of studies have identified concerns among health care professionals that implementation of digital technologies will increase their workload, which is a significant barrier to digital decision-making [1,19-21]. This fear appears paradoxical, since many digital technologies are initially developed to optimize workflows, save time, and improve the efficiency of clinical decision-making [22-24]. However, this phenomenon requires serious attention from researchers and practitioners, since health care professionals' perception of a potential increase in workload remains a significant barrier to digital transformation.

In this study, the fear of losing time was also mentioned by physicians, although it did not come to the forefront. Only 10% of physicians identified "takes time and does not make work easier" barrier, and only 7% of physicians were not ready to spend time mastering the technology. It is also worth noting that according to this study, only 7% of physicians identified distrust of digital technologies as a barrier, and 5% a low level of practical benefit. This may indicate a high psychological readiness of Russian medical workers for digital transformation. Such differences emphasize the importance of taking into account national and cultural contexts when developing strategies for implementing digital solutions in health care.

In general, the spread of barriers among the 5 MAPPS categories was fairly uniform, ranging from 40% to 47% of respondents per category (Figure 1). This distribution highlights the need for a comprehensive and multilevel approach to addressing various obstacles to successfully advancing digital transformation in health care.

A more detailed analysis revealed that process-related and environmental barriers received somewhat higher ratings, 47% and 44%, respectively. These included fears of making errors, doubts about the stability of digital systems, and a lack of technical infrastructure with qualified support. Meanwhile, motivation, capability-related, and social barriers were noted by slightly fewer respondents, approximately 40%-41%. This pattern suggests a relatively high level of motivation among Russian physicians and a general readiness within the medical community to adopt digital technologies. At the same time, it underscores the critical need to enhance technical infrastructure and ensure the stable operation of digital tools with professional technical support.

The barriers were unevenly distributed among different technology groups. For example, for telemedicine technologies, a notably high percentage of physicians (47.5%) reported encountering social barriers, primarily linked to perceived legal insecurity. In contrast, for systems to support physicians in making medical decisions, process-related barriers (39.8%) and social barriers (40.4%) were minimal, whereas motivation barriers (45.7%) and capability-related barriers (48%) predominated. This divergence reflects the specific perceptions and challenges associated with implementing different digital solutions in clinical practice and underscores the necessity for a differentiated approach to their support and regulation.

The study findings emphasize the need for a comprehensive and tailored approach to overcoming barriers. This approach should consider the specific type of technology to determine the most effective implementation strategies.

Drivers of Digital Technologies Implementation in Health Care

In contrast to the diverse profile of barriers, the Russian study found remarkable consistency in the leading enablers of technology adoption across all 4 categories of digital technologies, pointing to universal motivators for physicians.

Physicians value digital solutions primarily for 2 specific advantages: time savings and real practical benefits. It is important for them that the technology makes work easier and speeds it up, rather than adding extra tasks [1,19,20]. If developers clearly show how much time the new system saves and how it fits into the routine process [25], physicians are willing to use it. Thus, it is important to demonstrate to physicians how the digital tool simplifies the routine and frees up time for the patient and other important matters.

Perceived legal security consistently ranked among the top 5 factors facilitating adoption for all types of technologies, being most significant for remote consultations (57.7%) and remote patient monitoring (54.6%). The lack of legal clarity is a significant barrier, and conversely, its presence acts as a powerful catalyst for the adoption of digital technologies. Physicians seek concrete assurances that they will not face undue professional or legal liability for potential errors, data breaches, or unintended consequences arising from the use of new, complex digital tools [9,14,16]. Thus, it is necessary not only to create a clear and transparent legal framework for the use of digital technologies in health care, but also to ensure that physicians are informed about the relevant legal norms and regulations in an accessible and understandable manner.

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"Free learning/at the expense of the health care institution" and "management will allow taking study leave" were among the top 5 factors of assistance for all types of technologies. This underlines the readiness to learn and the importance of competent organizational support for this process.

Unfortunately, the introduction of new technologies often requires physicians to master new skills without interrupting their clinical practice. Thus, this only increases their workload during the period of mastering the technology. This explains why, in a number of studies, the key barrier to implementation of digital technologies was the fear of increasing physicians' workload [1,19,20].

Our research shows that study leave and management-paid training make new technologies much more attractive to physicians.

Thus, the implementation of digital technologies in health care is a complex process of creating a supporting organizational ecosystem. Key factors in this process are the provision of technical infrastructure, legal transparency, training, and management support. The absence or weakness of any single component can undermine the entire digital transformation effort. True, sustainable transformation requires a coordinated, systemic approach in which all these elements are strategically aligned and continuously strengthened.

Limitations

This study has several limitations that should be considered when interpreting the findings. First, the study inclusion criteria required physicians to work in large urban centers in Russia, which inherently limits the generalizability of results to health care providers practicing in smaller towns or rural areas. The experiences and barriers faced by physicians in less populated or resource-constrained settings may differ significantly from those in larger urban centers.

Second, the reliance on online questionnaires might have introduced a selection bias, as physicians without reliable access to the necessary technology or internet connectivity were unable to participate.

Third, data collection was based on self-reported questionnaires, which are subject to inherent biases, including social desirability bias. Respondents may have underreported negative attitudes or challenges due to perceived social or professional expectations.

Despite these limitations, the study provides valuable insights into physician perspectives on digital technology adoption in health care within the sampled population. Future research should aim to include a more diverse sample and consider mixed data collection methods to minimize bias and enhance generalizability.

It is important to note that the process of health care digitalization depends not only on physicians but also significantly on patient readiness and engagement. Therefore, studying patient-related factors is crucial and represents a key focus for our future research endeavors.

Conclusions

The study showed that the key barriers to the introduction of digital technologies in health care in Russia are technical difficulties (lack of infrastructure, unstable operation of systems), fear of making wrong decisions based on digital data, and a feeling of legal insecurity.

Lack of knowledge about specific products, lack of management support, and limited training opportunities also play a significant role. The profile of barriers varies depending on the type of digital technology, which highlights the need for differentiated approaches to their implementation. At the same time, the leading drivers for physicians are time savings, practical benefits, legal protection, availability of free training, and organizational support. These motivators are universal for all categories of digital solutions and reflect doctors' desire to improve efficiency and reduce workload in a busy environment.

Based on the conducted research, we formulated key recommendations for the implementation of digital transformation in medical organizations.

1. Development of technical infrastructure: ensuring stable operation of digital systems, access to necessary equipment, and integration with existing work processes.
2. Improvement of the legal and regulatory framework: development of clear standards and mechanisms for sharing responsibility, and ensuring that physicians are clearly informed about current legal regulations.
3. Implementation of educational programmes: arranging free training and providing physicians with study leave to master new technologies, which will increase digital literacy and reduce resistance to change.
4. Strengthening of organizational support: involving management of medical institutions in digitalization processes, forming a culture of leadership and support for innovation.
5. Demonstration of practical value: demonstrating to clinicians how digital tools save time, simplify routine tasks, and improve the quality of care.
6. Considering specifics of technologies: developing implementation strategies taking into account the specifics of each category of digital solutions and the profile of relevant barriers.

The comprehensive implementation of these measures will increase the readiness of the medical community for digital transformation and ensure sustainable implementation of innovative solutions in health care.

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Data Availability

The datasets generated or analyzed during this study are not publicly available due to confidentiality and ethical restrictions protecting participant privacy, but are available from the corresponding author on reasonable request, in compliance with institutional and ethical guidelines.

Authors' Contributions

Conceptualization: MV (lead), MB (equal), MK (support), and EK (support)
Data curation: ES (lead) and MZ (equal)
Formal analysis: ES (lead), MZ (equal), and EK (support)
Funding acquisition: MV (lead) and PG (support)
Investigation: ES (lead) and MZ (equal)
Methodology: MB (lead) and PG (support)
Project administration: MV (lead) and MB (equal)
Resources: MB (lead) and MK (support)
Supervision: MV (lead) and MK (support)
Validation: MV (lead), MB (equal), MK (support), and PG (support)
Visualization: ES (lead) and MZ (equal)
Writing – original draft preparation: PG (lead) and EK (support)
Writing – review and editing: PG (lead) and EK (support)

Conflicts of Interest

Ipsos Comcon served solely as a coexecutor for data collection and analysis, funded by the Moscow School of Management Skolkovo under a collaboration agreement number 13790350-23.

Multimedia Appendix 1
Question 1. Different physicians mention different barriers to using digital technologies in healthcare. Are there any that are also relevant to you? Please select up to 5 answers. The physician is asked to answer a question on each of the four categories of digital technologies separately.
[DOCX File , 16 KB - jopm_v18i1e83551_app1.docx]

Multimedia Appendix 2
Justification for the division of barriers in accordance with the MAPPS model.
[DOCX File , 16 KB - jopm_v18i1e83551_app2.docx]

Multimedia Appendix 3
Question 2: A team of experts has already thought about some of the problems that arise when implementing digital technologies in the life of a physician. Now we will show you some ideas, please rate how likely it is that you would start using / use the following technologies more actively when implementing these ideas on a scale from 1 to 7, where 1 - definitely would not start using / use more actively, 7 - definitely would start using / use more actively. The physician is asked to answer a question on each of the four categories of digital technologies separately.
[DOCX File , 16 KB - jopm_v18i1e83551_app3.docx]

Multimedia Appendix 4
CHERRIES Checklist.
[DOCX File , 16 KB - jopm_v18i1e83551_app4.docx]

Multimedia Appendix 5
Identification of barriers to implementation of digital technologies.
[DOCX File , 14 KB - jopm_v18i1e83551_app5.docx]

Multimedia Appendix 6
Main drivers for overcoming barriers. The data are weighted by distribution of physicians by populated areas of the Russian Federation. The table shows the percentage of respondents who chose 7 points for this answer (physician would definitely start using digital technology if the conditions specified in the statement were met).
[DOCX File , 17 KB - jopm_v18i1e83551_app6.docx]

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Abbreviations

CDSS: clinical decision support system
CHERRIES: Checklist for Reporting Results of Internet E-Surveys
MAPPS: Motivation, Ability, Processing, Physical, and Social

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Evaluation of a Digital Intervention to Improve the Health Outcomes of Older Adults: Secondary Data Analysis

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Abstract

Background: The health of aging populations is among the top challenges facing global health systems. The use of mobile health (mHealth) approaches has been found to be effective in prompting changes and has been identified as a potentially valuable tool to enhance health behaviors among older adults.

Objective: This study sought to explore the efficacy and acceptability of a personalized mHealth app for older adults, focusing on well-being, mental and physical health, and relationship with food.

Methods: This secondary data analysis examined outcomes of real-world Holly Health users who enrolled between August 2022 and January 2023.

Results: Results showed that, after the intervention, self-confidence, energy, mindfulness, health mindset, and short- and long-term mindset all improved. Furthermore, the personalized mHealth app showed a good level of acceptability among the participants.

Conclusions: Engaging with this digital health intervention improved several aspects of physical and mental health, adding to existing evidence that effective and accessible tools are needed to promote healthy aging.

Trial Registration: OSF Registries osf.io/rbk36; https://osf.io/rbk36/overview

(J Particip Med 2026;18:e62748) doi:10.2196/62748

KEYWORDS

mobile health strategies; mHealth strategies; mobile health; mHealth; digital health; healthy aging; health outcomes; health behaviors

Introduction

The global aging population is increasing, with the World Health Organization predicting that the population aged over 60 years will double between 2015 and 2050 to an estimated 2.1 billion [1]. However, research suggests that increased life expectancy does not result in people having more years in “good health” [2]. Instead, as we age, we tend to experience a decline in mobility and mental health, along with an increase in coexisting health conditions such as cardiovascular diseases and other noncommunicable diseases (NCDs) [2-4]. “Healthy aging” refers to the ongoing development and maintenance of functional capabilities that promote well-being in older age [2] and encompasses positive health behaviors such as physical activity [5], eating healthily [6], and not smoking or having a moderate alcohol intake [7], which can reduce the incidence of NCDs when performed throughout the life span. Such behaviors also positively impact well-being in older age [8-10]. Given these benefits and the fact that NCDs are responsible for a large portion of morbidity, mortality, and health care expenditures in older age [11], more research is needed to determine how to promote positive health behaviors in an aging population.

Due to the rise in mobile phone and internet use, mobile health (mHealth) approaches are increasingly being used to deliver interventions [12]. They have been found to be effective in prompting changes across a range of health behaviors and in populations with a range of NCDs [13-15]. While much research has investigated mHealth interventions for younger age groups, there is evidence that they may also be a useful tool for older adults. Mobile phone ownership among this group is growing, with an estimated 78% of those aged over 55 years in the United Kingdom owning a smartphone [16]. A scoping review of mHealth interventions for adults aged over 60 years reported improvements in physical activity, chronic disease management,

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and medication adherence across studies, suggesting that this intervention type can be effective for older age groups [17]. However, effect sizes for the observed behavior changes tend to be small [18]. One way to maximize effectiveness is through personalization, whereby the intervention is dictated by the choices of the individual [19,20]. Personalized mHealth interventions are largely acceptable [21-23] and more effective for prompting behavior change (eg, increasing physical activity and reducing smoking) compared to nonpersonalized interventions [20,24,25]. This study aimed to evaluate a personalized mHealth app for older adults called Holly Health.

Holly Health targets 4 main health behaviors and constructs for older people (sleep, mental health, exercise, and relationship with food) through personalized features and content. The app incorporates elements of mindfulness therapy, cognitive behavioral therapy (CBT), and acceptance and commitment therapy (ACT). The app includes several features grounded in cognitive behavioral principles. First, the reflective chatbot provides cognitive restructuring prompts, encouraging users to identify unhelpful automatic thoughts (eg, all-or-nothing beliefs about health behaviors) and replace them with more adaptive alternatives. Second, behavioral activation techniques are embedded through graded habit recommendations and small, achievable goals designed to increase engagement in positively reinforcing activities. Third, self-monitoring is facilitated through check-ins and progress tracking, enabling users to notice patterns, triggers, and improvements over time. Fourth, psychoeducational content targets common maladaptive cognitions regarding food, exercise, or self-efficacy, supporting users in challenging rigid beliefs that can act as barriers to change. Finally, the structured goal-setting and problem-solving prompts mirror standard CBT frameworks by helping users break down difficulties, anticipate barriers, and plan coping responses. Features of the app include personalized goal setting, progress tracking (termed "self-monitoring"), habit recommendations, personalized nudges and reminders, and video content and exercises, all aimed at improving attitudes toward health behavior to promote behavior change. The app tailors these features for each user and continuously updates content based on their use of the app. This study aimed to explore the efficacy and acceptability of the Holly Health app for use in older adults, measuring changes in personal well-being, mental and physical health, and relationship with food and thoughts and opinions about the app

Methods

Ethical Considerations

This analysis was approved by the London South Bank University Research Ethics Committee (reference ETH2223-0097) and was preregistered on the Open Science Framework and updated on July 11, 2023. All participants provided informed consent, and data were anonymized prior to analysis. After completing the 12-week follow-up, participants were offered a £50 (US $68) voucher of their choice as thanks for taking part.

Recruitment

Participants were recruited via newsletters, in-person outreach, and posters distributed in local community centers, services, and charities in Lewisham and Southwark, as well as through social media advertisements. Interested individuals were directed to a study landing page and invited to complete a screening questionnaire. Eligibility criteria were age of 50 years or above, fluency in English, an email address, access to a phone or tablet with internet connectivity, and motivation to increase mobility or sustainably manage their weight. Individuals were excluded if they reported a major psychiatric disorder requiring treatment, major physical impairments, or visual impairments not correctable with contact lenses or glasses.

Eligible individuals were sent an information sheet and were asked to complete an onboarding questionnaire assessing current health and well-being habits to tailor program content. As this was a pilot study, no formal sample size calculation was conducted, and recruitment continued until a target sample of approximately 30 participants was reached. Participants enrolled on the Holly Health app between August 2022 and January 2023.

Intervention

Holly Health is a smartphone app that offers daily health and well-being coaching. It aims to help users prioritize, achieve, and sustain daily health habits across several domains, including exercise, sleep, mental health, and their relationship with food. The app incorporates elements of mindfulness therapy, CBT, and ACT. Features of the app include personalized habit recommendations; a chatbot for reflection exercises and tailored coaching; motivational nudges and reminders; and tailored content in the form of videos, articles, and exercises. The app and its recommendations (including habit reminders, articles, challenges, and reflective exercises) are tailored to each person, and the personalization adapts throughout the time the users engage with the service. Users were asked to use the app 3 to 4 times a week and were prompted to complete measures online at baseline and 8 and 12 weeks.

Outcome Measures

Overview

The schedule of measures can be found in Table 1.

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Table . Schedule of measures.

Outcome measure	Study stage		
	Baseline	Week 8	Week 12
ONS-4[a]	✓	✓	✓
FCQ[b]	✓	✓	
Health survey	✓	✓	✓
Retrospective questions	✓	✓	✓

[a]ONS-4: Office of National Statistics personal well-being questions.

[b]FCQ: Food Choice Questionnaire.

Office of National Statistics Personal Well-Being Questions

The Office of National Statistics personal well-being questions (ONS-4) measure subjective well-being. This measure consists of 4 scales developed to assess life satisfaction, worthwhileness, happiness, and anxiety. Each item is rated from 0 ("not at all") to 10 ("completely"). The Cronbach α was 0.83 in this study.

Food Choice Questionnaire

The Food Choice Questionnaire (FCQ) comprises 36 items that are designed to assess the health and nonhealth motives influencing an individual's food choices. This measure consists of 9 scales developed to assess health, mood, convenience, sensory appeal, natural content, price, weight control, familiarity, and ethical concerns as factors related to food choice.

Health Survey

The health survey is a tailor-made questionnaire developed by Holly Health and comprises 8 scales aimed at measuring different aspects of an individual's health: physical activity, self-confidence, relationship with food, energy levels, mindfulness, short- vs long-term mindset, health mindset, and self-kindness. This measure is not designed to provide an aggregate score but, rather, to illustrate different aspects of an individual's health. This questionnaire is provided in Multimedia Appendix 1.

Retrospective Use and User Experience Questions

At weeks 8 and 12, users were asked 4 questions regarding how often they used the Holly Health app and how useful they found it. These were summarized descriptively. At week 12, users were asked 2 questions about the acceptability of the app. These questions are provided in Multimedia Appendix 2.

Statistical Analysis

All analyses were exploratory. Formal hypothesis testing was restricted to primary outcomes (health survey self-confidence, energy, mindfulness, short- and long-term mindset, health mindset, and self-kindness subscales; FCQ; and ONS-4); other comparisons were treated as descriptive. Changes from baseline were assessed using paired *t* tests (2-tailed) for continuous variables and Wilcoxon signed-rank tests for ordinal or categorical domains. Effect sizes (Cohen *d* for *t* tests; *r* or *d* for the Wilcoxon signed-rank test) and 95% CIs were reported where available. Regression models examined baseline predictors of outcomes, and sensitivity analyses assessed moderation by app use frequency. Given the small sample size (N=34), analyses were underpowered, and the findings should be interpreted cautiously.

To evaluate the efficacy of the app in improving people's attitudes toward their health and food choices, changes in scores on the health survey and FCQ compared to baseline were assessed using repeated-measure *t* tests for all continuous data and the Wilcoxon signed-rank test of differences for all categorical data. Subscales 1 (physical activity), 2 (self-confidence), 4 (energy), 5 (mindfulness), 7 (health mindset), and 8 (self-kindness) on the health survey and the FCQ were coded as continuous data. Subscales 3 (relationship with food) and 6 (short- and long-term mindset) on the health survey were coded as categorical data. To assess whether users' attitudes toward their health and food choices predicted life satisfaction, logistical regressions on the ONS-4 were conducted at 8 and 12 weeks, predicted by scores on the health survey and FCQ (collected at baseline). A sensitivity analysis was undertaken on all continuous data by analyzing the number of times the app was used over the course of the trial as a moderator variable. This was achieved using the PROCESS macro by Hayes [26]. The sensitivity analysis was not conducted on categorical data. Finally, participants' responses to the retrospective questions (whether they reported using the app at least once a week and whether they reported that they had started to practice any of the habits automatically) were used to assess the acceptability of the app.

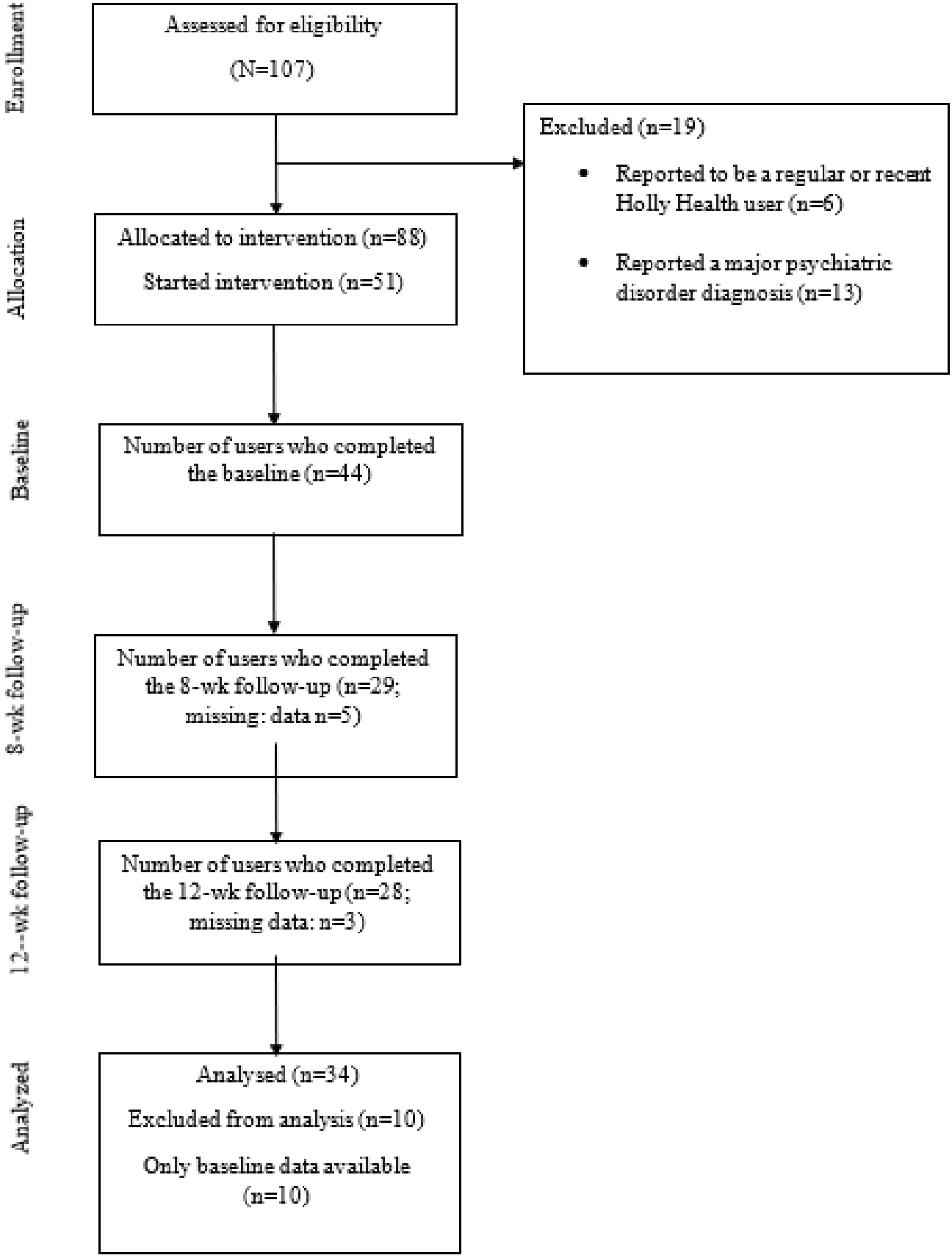
Results

Baseline Demographics

Participant flow is shown in Figure 1. Most users were women (28/36, 77.7%), aged between 50 and 59 years (18/36, 50%), and White (25/36, 69.4%) and reported having hypertension (11/36, 30.6%). Table 2 presents the sample demographics.

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Figure 1. ou maStudy flowchart.



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Table . User characteristics at baseline.

Variable	Participants (N=36)[a], n (%)
Gender	
Woman	28 (77.7)
Man	8 (22.3)
Age range (y)	
50-59	18 (50)
60-65	6 (16.7)
66-70	6 (16.7)
70-75	6 (16.7)
Race or ethnicity	
Asian British	3 (8.3)
Black, African, Caribbean, or Black British	5 (13.9)
Mixed or multiple ethnic groups	1 (2.8)
White	25 (69.4)
Other	1 (2.8)
Not disclosed	1 (2.8)
Medical condition	
Hypertension	11 (30.6)
Arthritis	10 (27.8)
Asthma	4 (11.1)
High cholesterol	11 (30.6)
Type 2 diabetes	6 (16.7)
Heart disease	1 (2.8)
Stroke	1 (2.8)
COPD[b]	1 (2.8)
Osteoporosis	1 (2.8)
Fibromyalgia	1 (2.8)
Cancer	1 (2.8)
Anxiety	10 (27.8)
Depression	7 (19.4)
Other	6 (16.7)
None reported	7 (22.2)

[a]Demographic characteristics are reported for the 36 participants who completed the baseline assessment and engaged with the intervention period. However, the final longitudinal analysis was conducted on 34 participants. Two participants were excluded from the final comparative analysis because, although they provided partial interval data, they did not meet the full data requirements for the cross-comparison across all primary time points (baseline to week 8/12).

[b]COPD: chronic obstructive pulmonary disease.

Evaluation Outcomes

Health Survey

Paired-sample *t* tests with Bonferroni correction showed that self-confidence scores were significantly higher at 12 weeks (mean 3.77, SD 0.77) than at baseline (mean 3.31, SD 1.09; P=.02; d=0.55). Energy scores were significantly higher at 12 weeks (mean 3.46, SD 1.03) than at baseline (mean 2.85, SD 1.12; P<.001; d=0.67). For mindfulness, scores at 8 weeks (mean 3.39, SD 1.20) were significantly higher than at baseline (mean 3.00, SD 1.06; P=.05; d=0.32). A Wilcoxon signed-rank test showed that short- vs long-term mindset scores were significantly higher at 8 weeks (mean 3.14, SD 1.22) than at baseline (mean 2.65, SD 1.25; z=–2.03; P=.04; d=0.38) and significantly higher at 12 weeks (mean 3.13, SD 1.28) than at baseline (z=–2.45; P=.01; d=0.44). Table 3 presents these findings.

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Table . Health survey (baseline, week 8, and week 12): paired comparisons.

Subscale	Time point	Participants, n	MD[a]	*t* test (*df; 95% CI*)	*z* score	*P* value	Effect size[b]
Physical activity	Baseline to 8 wk	29	−0.231	−1.223 (28; −0.616 to 0.154)	—[c]	.41	0.227
Physical activity	Baseline to 12 wk	31	−0.154	−1.606 (30; −0.619 to 0.312)	—	>.99	0.288
Physical activity	8 wk to 12 wk	26	0.077	0.811 (25; −0.166 to 0.320)	—	>.99	0.159
Self-confidence	Baseline to 8 wk	29	−0.269	−1.978 (28; −0.661 to 0.122)	—	.27	0.367
Self-confidence	Baseline to 12 wk	31	−0.462[d]	−3.053 (30; −0.870 to −0.053)	—	.02[d]	0.55
Self-confidence	8 wk to 12 wk	26	−0.192	−1.309 (25; −0.569 to 0.185)	—	.61	0.257
Energy	Baseline to 8 wk	29	−0.462	−3.266 (28; −0.787 to −0.136)	—	<.001	0.606
Energy	Baseline to 12 wk	31	−0.615[e]	−3.737 (30; −0.994 to −0.237)	—	<.001[e]	0.67
Energy	8 wk to 12 wk	26	−0.154	−1.162 (25; −0.493 to 0.186)	—	.77	0.228
Mindfulness	Baseline to 8 wk	29	−0.385[d]	−3.041 (28; −0.763 to −0.006)	—	.05[d]	0.32
Mindfulness	Baseline to 12 wk	31	−0.423	−1.827 (30; −0.995 to 0.149)	—	.21	0.328
Mindfulness	8 wk to 12 wk	26	−0.038	−0.171 (25; −0.149 to 0.149)	—	.21	0.033
Short- vs long-term mindset	Baseline to 8 wk	29	−0.491	— (−0.801 to −0.026)	–2.03	.04[d]	0.38
Short- vs long-term mindset	Baseline to 12 wk	31	−0.480	— (−1.042 to −0.119)	–2.45	.01[e]	0.44
Short- vs long-term mindset	8 wk to 12 wk	26	−0.01	— (−0.331 to 0.408)	0.00	.80	0.000
Self-kindness	Baseline to 8 wk	29	−0.385	−1.672 (28; −0.955 to 0.186)	—	.29	0.310
Self-kindness	Baseline to 12 wk	31	−0.154	−1.488 (30; −0.597 to 0.289)	—	>.99	0.267
Self-kindness	8 wk to 12 wk	26	0.231	1.443 (25; −0.179 to 0.641)	—	.48	0.283

[a]MD: mean difference.

[b]Cohen *d* for paired *t* tests and *r* for Wilcoxon signed-rank tests.

[c]Not applicable.

[d]*P*<.05.

[e]*P*<.01.

FCQ Results

Paired-sample *t* tests were conducted to compare FCQ scores between baseline and 8 weeks. A significant increase was found on the mood subscale, with higher scores at 8 weeks (mean 2.60, SD 0.78) than at baseline (mean 2.16, SD 0.60; t_{26}=–5.03; *P*<.001; *d*=–0.998). No other subscales showed significant changes. Table 4 presents these findings.

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Table . Food Choice Questionnaire (baseline vs week 8): paired-sample *t* tests.

Subscale	Participants, n	MD[a]	*t* test (*df*; 95% CI)	*P* value	Effect size (Cohen *d*)
Health	27	−0.048	−8.19 (26; −0.169 to 0.073)	.42	−0.163
Mood	27	−0.441[b]	−0.503[b] (26; −0.621 to −0.261)	<.001[b]	−0.998
Convenience	27	0.022	0.178 (26; −0.235 to 0.279)	.86	0.034
Sensory appeal	27	−0.10	−1.335 (26; −0.254 to 0.054)	.19	−0.282
Natural content	27	0.052	0.485 (26; −0.168 to 0.272)	.63	0.089
Price	27	0.026	0.268 (26; −0.173 to 0.225)	.79	0.050
Weight control	27	−0.015	−0.125 (26; −0.259 to 0.229)	.90	−0.040
Familiarity	27	0.004	0.027 (26; −0.282 to 0.290)	.98	0.000
Ethical concern	27	−0.015	−0.115 (26; −0.278 to 0.249)	.91	−0.037

[a]MD: mean difference.

[b]*P*<.01.

Regression Analyses

Hierarchical regressions were used to investigate which factors (scores on the health survey and FCQ at baseline) predicted scores on each of the ONS-4 scales (life satisfaction, worthwhileness, happiness, and anxiety) at 8 and 12 weeks. Scores on the health survey at baseline were found to be a significant predictor of life satisfaction, worthwhileness, and happiness scores on the ONS-4 at 8 weeks, accounting for 65%, 66%, and 60% of the variance, respectively. The regression coefficients are shown in Table 5. Similarly, scores on the health survey at baseline were also revealed as significant predictorof scores on the ONS-4 worthwhileness scale at 12 weeks, accounting for 51% of the variance. The regression models are shown in Table 6.

Regression analysis revealed that scores on the health survey and FCQ at baseline significantly predicted scores on the ONS-4 happiness scale at 12 weeks, accounting for 84% of the variance. Additionally, both scores on the health survey at baseline alone and scores on the health survey and FCQ at baseline combined were predictive of scores on the ONS-4 anxiety subscale at 12 weeks, accounting for 58% and 83% of the variance, respectively. These regression models are presented in Table 6.

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Table . Hierarchical multiple regression coefficients of Office of National Statistics personal well-being scales (ONS-4) as a function of scores on the health survey and Food Choice Questionnaire (FCQ) at baseline. β is the standardized regression coefficient from final hierarchical model (step 2). Step 1 included baseline health survey variables; step 2 added FCQ subscales.

Predictor		At 8 weeks		At 12 weeks	
		β	*P* value	β	*P* value
ONS-4 overall life satisfaction					
Health survey					
	Physical activity	−0.02	.95	−0.32	.24
	Self-confidence	0.31	.26	0.36	.23
	Relationship with food	−0.41	.13	−0.22	.44
	Energy	0.74	.03	0.34	.24
	Mindfulness	0.27	.32	0.01	.97
	Short- versus long-term mindset	0.16	.58	−0.01	.98
	Health mindset	−0.36	.34	0.14	.67
	Self-kindness	−0.26	.25	0.12	.62
FCQ					
	Health	0.28	.46	0.45	.15
	Mood	0.04	.89	−0.50	.13
	Convenience	0.35	.14	0.59	.02[a]
	Sensory appeal	0.09	.78	0.16	.59
	Natural content	0.14	.70	0.00	>.99
	Price	−0.09	.78	−0.36	.17
	Weight control	−0.28	.29	−0.04	.85
	Familiarity	−0.30	.32	−0.28	.30
	Ethical concern	−0.25	.32	−0.34	.14
ONS-4 overall worthwhileness					
Health survey					
	Physical activity	0.01	.95	−0.15	.61
	Self-confidence	0.51	.03[a]	0.26	.42
	Relationship with food	−0.22	.25	−0.11	.73
	Energy	0.63	.01[a]	0.45	.17
	Mindfulness	−0.01	.96	0.07	.84
	Short- versus long-term mindset	−0.13	.57	−0.24	.47
	Health mindset	0.02	.93	0.25	.50
	Self-kindness	−0.10	.58	0.11	.67
FCQ					
	Health	0.16	.72	0.24	.46
	Mood	0.10	.77	−0.21	.54
	Convenience	0.18	.52	0.16	.48
	Sensory appeal	−0.08	.84	0.07	.81
	Natural content	0.12	.79	0.25	.39

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Predictor			At 8 weeks		At 12 weeks	
			β	*P* value	β	*P* value
		Price	0.04	.93	−0.16	.57
		Weight control	−0.14	.65	0.09	.70
		Familiarity	−0.05	.90	−0.31	.29
		Ethical concern	−0.30	.33	−0.40	.12
ONS-4 overall happiness						
	Health survey					
		Physical activity	−0.13	.65	−0.62	.02
		Self-confidence	0.15	.64	−0.01	.97
		Relationship with food	−0.37	.24	−0.29	.25
		Energy	0.97	.0[a]2	0.43	.10
		Mindfulness	0.04	.91	0.24	.39
		Short- versus long-term mindset	0.09	.80	0.12	.65
		Health mindset	−0.15	.73	0.23	.44
		Self-kindness	−0.11	.67	−0.17	.41
	FCQ					
		Health	0.08	.87	0.74	.01
		Mood	0.04	.90	−0.26	.34
		Convenience	0.28	.31	0.44	.03
		Sensory appeal	0.19	.61	0.28	.27
		Natural content	0.28	.53	−0.17	.47
		Price	0.19	.62	−0.18	.41
		Weight control	−0.36	.26	−0.21	.27
		Familiarity	−0.22	.53	−0.10	.67
		Ethical concern	−0.16	.58	−0.63	.007
ONS-4 anxiety						
	Health survey					
		Physical activity	−0.26	.50	0.62	.02
		Self-confidence	−0.46	.28	−0.11	.67
		Relationship with food	0.03	.95	−0.36	.17
		Energy	−0.39	.39	−0.05	.85
		Mindfulness	−0.26	.54	−0.40	.17
		Short- versus long-term mindset	0.15	.73	−0.14	.61
		Health mindset	0.66	.27	0.01	.98
		Self-kindness	0.20	.57	0.11	.60
	FCQ					
		Health	−0.18	.76	−0.09	.73
		Mood	−0.39	.38	0.03	.90
		Convenience	0.04	.91	0.26	.18
		Sensory appeal	0.68	.18	−0.06	.82

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Predictor		At 8 weeks		At 12 weeks	
		β	*P* value	β	*P* value
	Natural content	−0.16	.78	−0.20	.41
	Price	−0.03	.95	−0.38	.11
	Weight control	−0.16	.69	0.35	.09
	Familiarity	−0.26	.58	−0.26	.29
	Ethical concern	0.00	>.99	−0.34	.11

[a]*P*<.05.

Table . Model fit and change statistics at 8 and 12 weeks for the hierarchical multiple regression analysis of Office of National Statistics personal well-being scales (ONS-4).

Predictor and time point	R^2	Adjusted R^2	ΔR^2	*F* change	*P* value
ONS-4 overall life satisfaction					
8 weeks	0.833	0.650	0.188	1.12	.43
12 weeks	0.781	0.457	0.324	1.81	.18
ONS-4 overall worthwhileness					
8 weeks	0.746	0.266	0.088	0.35	.94
12 weeks	0.740	0.512	0.228	1.09	.45
ONS-4 overall happiness					
8 weeks	0.762	0.311	0.163	0.68	.71
12 weeks	0.835	0.579	0.463	3.42	.03
ONS-4 anxiety					
8 weeks	0.595	−0.169	0.222	0.55	.81
12 weeks	0.825	0.554	0.247	1.72	.20

Sensitivity Analysis

A series of moderated multiple regressions were conducted to predict scores on all outcome measures at 12 weeks from baseline (or 8 weeks for the FCQ), with the number of times the app was used serving as a moderator variable. No interaction terms were statistically significant in the models.

Responses to the Retrospective Use and User Experience Questions

Most individuals used the Holly Health app at least once per week at both 8 and 12 weeks (27/34 79.4% and 30/34, 88.2%, respectively). Of those who reported using the Holly Health app at least once per week, most reported that they had started to practice some of the habits automatically without relying on the app to remind them at both 8 and 12 weeks (24/34, 70.6% and 28/34, 82.4%, respectively). Most respondents indicated that they found the Holly Health app useful at both 8 and 12 weeks (26/34, 76.5% and 27/34, 79.4%, respectively). At 8 weeks, most users (29/34, 85.3%) stated that they would like their local council to provide more services such as this one in the future. Finally, at 12 weeks, most users (47.1%) stated that they found the app to be a very appropriate tool for older adults to keep up with their healthy aging goals and that it would be extremely likely for them to recommend the app to other people with similar health and well-being goals to their own. Table 7 presents these findings.

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Table . Responses to retrospective questions.

Question and time point	Yes, n (%)	No, n (%)	No response, n (%)
Have you been using the Holly Health app at least once a week?			
Week 8	27 (79.4)	2 (5.9)	5 (14.7)
Week 12	30 (88.2)	1 (2.9)	3 (8.8)
Have you started to do any of your habits automatically?			
Week 8	24 (70.6)	3 (8.8)	7 (20.6)
Week 12	28 (82.4)	2 (5.9)	4 (11.8)
Overall, have you found Holly Health useful?			
Week 8	26 (76.5)	1 (2.9)	7 (20.6)
Week 12	27 (79.4)	3 (8.8)	4 (11.8)
In the future, would you like to see more services like this provided by your local council?			
Week 8	29 (85.3)	0 (0)	5 (14.7)

Discussion

This study presents a secondary data analysis of the Holly Health app. There were significant positive outcomes on the health survey over the trial duration. Specifically, the self-confidence, energy, mindfulness, health mindset, and short- and long-term mindset subscale scores were all higher after the intervention. Participants also rated mood as significantly more important on the FCQ at 8 weeks compared to baseline. Moreover, these effects were not influenced by the level of engagement with the app.

Importantly, the intervention showed a good level of acceptability among the participants. Most participants reported using the app at least once per week at both the 8- and 12-week time points. Participants also reported beginning to carry out their habits automatically at 8 and 12 weeks. Almost all respondents reported that they would like to see more similar services to this one provided by their local council. The findings suggest that older adults can achieve positive health outcomes through engaging with a health platform. The strong uptake observed may be attributed to several factors: the personalized nature of the app, which increases relevance and engagement; the recruitment strategy targeting individuals already motivated to improve their health; and the growing digital literacy among older adults, with 78% of those aged over 55 years owning smartphones in the United Kingdom [16].

The findings of this study are consistent with those of research indicating the potential for older adults to use mHealth interventions [17]. A systematic review identified that digital health interventions focused specifically on physical activity have been shown to improve balance and mobility and reduce falls in older adults [27]. Meanwhile, research suggests that older adults may engage with digital coaching programs at higher rates than their younger adult counterparts [28]. As such, these findings add to an emerging body of literature that suggests that older adults not only engage well with mHealth initiatives but can also experience positive health outcomes from doing so. A scoping review on digital health literacy in older adults indicates that many factors can influence it in this population [29]. This includes whether they already own a digital device and having more positive attitudes toward health knowledge and greater confidence in their ability to manage their health through their digital device [29].

To be eligible to take part in the study, participants were required to have access to a phone or tablet with internet access. Additionally, the fact that they would like to see similar services rolled out by their local council suggests that, among this sample at least, there is a clear interest in using digital devices to monitor one's health. Moreover, our results add to the literature suggesting that personalized content in particular is beneficial [24,25]. Qualitative research on perceptions of mHealth interventions highlights that users particularly value personalized and tailored content [30]. Similarly, research in the domain of weight loss indicates that tailored content is more effective than content that is either a moderate or poor fit for the user [31]. Thus, Holly Health's personalized features and content are beneficial for user experience, and future research should look into which elements of Holly Health offer the most benefit to its users.

The Holly Health app incorporates elements of behavior change theory, including self-determination theory, which posits that autonomy, competence, and relatedness are key to sustained behavior change. Features such as personalized goal setting and habit tracking may enhance users' sense of autonomy and competence. Additionally, CBT and ACT elements may help users reframe negative thoughts and increase psychological flexibility, contributing to improved well-being.

The health survey measures showed significant improvements after the intervention. Scores in domains such as self-confidence, energy, mindfulness, and short- and long-term mindset were all higher after the intervention as compared to before. Thus, after engaging in the intervention, participants were more likely to endorse the importance of longer-term outcomes as opposed to motivation dwindling when short-term goals did not yield immediate rewards. A study on physical activity in older adults identified that participants were likely to set goals related to maintaining physical activity and preventing aging decline. Thus, the authors concluded that apps that encourage goal setting

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are likely to give rise to stronger internal motivation, which may increase the intervention's effectiveness [32]. The findings of this study are in line with this, whereby participants were more likely to endorse a long-term mindset after engaging with the Holly Health app. This is important for ensuring that health behavior change is sustained. Participants also reported higher levels of mindfulness after engaging with the Holly Health intervention. Mindfulness refers to awareness of both one's internal states and one's surroundings [33]. Mindfulness stress reduction interventions have been shown to improve health-related behaviors [34] and improve quality of life and health behaviors among a sample of adults with hypertension [35]. As such, the significant increase in self-reported mindfulness in this study is a positive indicator that participants will be better able to engage in health behavior change after using the Holly Health app. In addition to statistical significance, effect size estimates (Cohen *d*) were calculated for all primary outcomes, which ranged from small to moderate. This suggests that, while the sample was underpowered, the observed changes could still be meaningful in a real-world context. Including effect sizes is especially important in feasibility studies because it helps show the potential impact of the intervention and informs sample size planning for future trials.

Participants' health survey and FCQ scores at baseline significantly predicted the ONS-4 happiness scale scores at 12 weeks, demonstrating the link among physical health, food choices, and well-being. This is consistent with research finding positive relationships among physical exercise, physical health, and well-being among adults in midlife [36]. As research indicates that diet quality is poor among older adults in the European Union and United States [37], the findings of this study suggest that engaging with a digital health intervention can help improve physical health and nutrition and may even have positive benefits beyond physical health. Given the importance of nutrition for healthy aging, the findings present promising initial evidence as to the potential for Holly Health to be effective in promoting healthy aging.

This study has several limitations. First, it was a proof-of-concept study focused on the acceptability and preliminary efficacy of the Holly Health app. Consequently, the sample size was small (N=34) and not statistically powered, which limits the strength and generalizability of the findings. Additionally, the pretest-posttest design lacked a control group, introducing potential bias and restricting confidence in attributing observed effects solely to the intervention—making it difficult to rule out alternative explanations such as regression to the mean [38]. Second, the sample was predominantly women (28/36, 77.7%) and largely comprised White individuals (25/36, 69.4%). Gender imbalances are common in digital health research as women often show higher rates of participation and engagement—possibly due to greater interest in health apps and wellness interventions. However, this imbalance may still influence outcomes and limits generalizability. Future research should recruit gender-balanced and ethnically diverse samples to explore subgroup differences in engagement and efficacy. Moreover, the volunteer sampling method likely attracted adults already motivated to improve their health, introducing self-selection bias that may have inflated engagement and outcome measures [39]. Future studies should use more diverse recruitment strategies to capture a broader range of health motivation levels. The study also included only short-term follow-up at 8 and 12 weeks, limiting insights into the sustainability of behavior change and health outcomes. Future research should incorporate longer follow-up periods (eg, 6 to 12 months) to evaluate the maintenance of effects and long-term health outcomes. Finally, the study used some study-specific measures (eg, the health survey and retrospective questions) that have not been prevalidated. While these were tailored for exploratory purposes, their reliability and validity are unestablished, warranting caution in interpretation. Nevertheless, many items were derived from validated instruments such as the ONS-4, enhancing partial validity [40]. Future research should incorporate fully validated instruments to improve the comparability and robustness of the findings.

In summary, while this study demonstrated that the Holly Health app is effective in improving health outcomes in a sample of older adults and showed good acceptability, these findings should be interpreted with caution due to methodological limitations. Nonetheless, the results underscore the potential of personalized digital health interventions to empower older adults in self-managing their health. The strong engagement and reported improvements in self-confidence, energy, and mindfulness suggest that such tools can play a transformative role in promoting healthy aging. Future research should build on these findings through robust, controlled trials and validated measures to confirm efficacy and explore long-term impacts across diverse populations.

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Authors' Contributions

Formal analysis: JC
Methodology: JC, GB, DF
Supervision: DF

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Visualization: JC
Writing—original draft: JC, GB, LH
Writing—review and editing: JC, GB, LH, DF

Conflicts of Interest

LH is supported by the Medical Research Council [MR/W006677/1]. All other authors have no conflict to declare.

Multimedia Appendix 1
Holly Health survey.
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Multimedia Appendix 2
Frequency of use and acceptability measures.
[DOCX File, 16 KB - jopm_v18i1e62748_app2.docx]

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Abbreviations

ACT: acceptance and commitment therapy
CBT: cognitive behavioral therapy
FCQ: Food Choice Questionnaire
mHealth: mobile health
NCD: noncommunicable disease
ONS-4: Office of National Statistics personal well-being questions

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Visualizing the Maternal Health Journey for Learning Health Systems: Mixed Methods Combined Experience Approach

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Abstract

Background: The United States faces a persistent maternal mortality crisis, with rates far higher than those in other high-income nations. The mortality rate among Black women is more than 3 times that among White women. Traditional data visualizations, such as bar and line charts, often emphasize aggregate outcomes, masking inequities and failing to reflect patient-level experiences.

Objective: This study aimed to address the gaps by taking a systems view and developing a Visualized Combined Experience (VCE) diagram, which is an innovative tool that integrates persona-based storytelling with data visualization to provide a more comprehensive understanding of maternal health outcomes. Specifically, the following research questions were explored: (1) How can the VCE diagram approach be applied to illustrate maternal mortality disparities in the United States? (2) To what extent does this integrated visualization technique reveal connections between individual patient experiences and population-level health outcomes that traditional visualization methods do not? (3) How can the VCE diagram inform a learning health system (LHS)?

Methods: This mixed methods study used publicly available quantitative data from the US Centers for Disease Control and Prevention and adapted qualitative data from the ProPublica award-winning investigative series *"Lost Mothers"* to construct the VCE diagram through a seven-step process involving the following elements: (1) composite persona derived from publicly available narratives, (2) journey map illustrating patient experiences and health system touchpoints, (3) emotive elements of the patient, (4) Sankey diagram of population-level maternal mortality outcomes, (5) "closer look" inset to unmask disparities obscured in aggregate data, (6) evaluation, and (7) data integration.

Results: The VCE diagram revealed critical connections between individual experiences and population-level disparities. When examining mortality rates per 1000 births, Black women had a high rate of 51.2, compared with 16.8 for White women, 14.3 for Hispanic women, and 10.2 for Asian women. The relationship between diagnostic delay and population-level mortality was revealed, with the "closer look" inset demonstrating how disparities can be obscured in aggregate data. The VCE diagram supported a more efficient and empathetic understanding of maternal health outcomes.

Conclusions: The VCE diagram bridges micro-level patient experiences with macro-level population data, holding promise to enhance service evaluation, delivery, and design, and improve health care outcomes. The VCE diagram provides a replicable framework for data visualization that highlights systemic disparities often hidden in aggregate data. Moreover, the availability of structured human experience and service outcome data can provide robust context-specific and situational data to foster a culture of organizational learning and continuous improvement via an LHS. The LHS's knowledge translation loops provide a conduit to improve patient experiences and reduce morbidity and mortality across populations and health systems. Future work will include usability testing across diverse audiences to assess interpretability and refine applications in LHSs.

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KEYWORDS

maternal mortality; patient journey map; journey map; persona; data visualization; health disparities; social determinants of health; Sankey diagram; health care inequities; visualized combined experience diagram; learning health system; systems thinking; systems approach; systems view; human-centered; patient outcomes; maternal health

Introduction

Current Landscape of Maternal Mortality

The United States has the highest maternal mortality rate among high-income countries, with the US Centers for Disease Control and Prevention (CDC) reporting that more than 80% of deaths are considered preventable [1-8]. In their 2023 vital statistics report, the CDC reported a 40% increase in maternal deaths from 861 to 1205 and reported a mortality rate of 69.9 deaths per 100,000 live births for Black women, which was 2.6 times the rate for White women (26.6) and Hispanic women (28.0), with no reported data for Asian women that year [9-11]. Following this, in their 2024 report, the CDC reported that maternal mortality decreased from 32.9 to 22.3 deaths per 100,000 live births; however, mortality differed by race, with 13.2 deaths per 100,000 live births for Asian women, 16.9 for Hispanic women, 19.0 for White women, and 49.5 for Black women [12]. Lastly, in their 2025 report, the CDC reported that the maternal mortality rate per 100,000 live births decreased significantly among White women (14.5), Hispanic women (12.4), and Asian women (10.7), but increased among Black women (50.0) [3]. Though the report stated that the mortality increase in Black women was not statistically significant, it was the only race group that showed an increase from 49.5 (in the previous year) to 50.0 deaths per 100,000 live births in 2023 [3,11,12]. These differences persist across income and education levels, reflecting systemic inequities [8,11,13-16].

Symptoms, Causes, and Impacts of Maternal Morbidity and Mortality

Accordingly, the five most prominent causes of maternal mortality are as follows: (1) infections, (2) complications from delivery, (3) severe bleeding, (4) hypertension, and (5) unsafe abortion [17-19]. Statistically, cardiovascular diseases and hypertensive disorders of pregnancy (before and after) are more prominent in Black women than in White women (during and after pregnancy) and are the leading cause of death [14,20,21]. As hypertensive disorders of pregnancy (eg, pre-eclampsia and eclampsia) simultaneously affect the fetus and mother, their therapeutic management and pathology are uniquely challenging [22]. Pre-eclampsia (historically referred to as “toxemia of pregnancy” [23]) is a complex multisystem disease, diagnosed by sudden-onset hypertension (>20 weeks of gestation) and at least one other associated complication (eg, proteinuria [protein found in the urine] [24], uteroplacental dysfunction [eg, uterus or placenta dysfunction], and maternal organ dysfunction) [22,25]. When left untreated, pre-eclampsia can rapidly progress, leading to serious and long-lasting complications for both the mother (eg, diabetes, cardiovascular disease, increased risk of stroke, and reduced life expectancy) and the fetus (eg, neurodevelopmental disability, perinatal death, preterm birth, and metabolic or cardiovascular disease), which can result in death [22,25,26]. In pre-eclampsia, the mother’s high blood pressure reduces the blood supply to the fetus, which may result in reduced oxygen and fewer nutrients [27].

Eclampsia, another life-threatening pregnancy disorder, poses the highest risk during the first postpartum week; however, it can occur before, during, or after labor and is frequently characterized by the sudden onset of seizures or coma [27,28]. While pre-eclampsia often precedes it, eclampsia adds complexity, as it can be asymptomatic or show sudden symptoms (eg, visual disturbances, altered mental states, and severe headaches), which require immediate medical intervention to safeguard the mother and fetus [27,28]. Hypertensive disorders of pregnancy, especially pre-eclampsia and eclampsia, are leading causes of maternal mortality and disproportionately affect Black women [14,20-22]. Although generally treatable, these conditions can rapidly progress to severe complications, such as “HELLP syndrome” (ie, hemolysis, elevated liver enzymes, and low platelet count), pulmonary edema, and stroke, with rare but fatal outcomes even in hospital settings [25,28-30]. Our focus on eclampsia reflects its complex trajectory and the systemic delays in recognition and treatment that contribute to preventable deaths.

Population Health Data and Social Determinants of Health

Data have revealed that Black women are dying from pregnancy-related complications disproportionally compared with other races in the United States [3,9,10,12,31]. Nonmedical factors, such as social determinants of health (SDOH), could be contributing to increased maternal mortality and morbidity across the United States [32-38]. The World Health Organization (WHO) defines SDOH as “the conditions in which people are born, grow, live, work, and age” and contextualizes them as “significant drivers of disease risk and susceptibility within clinical care and public health systems” [19,34,39]. Broadly, SDOH can be categorized into five separate but interrelated domains: (1) economic stability, (2) education access and quality, (3) health care access and quality, (4) neighborhood and built environment (eg, buildings, parks or green spaces, water systems, and energy infrastructure [40]), and (5) social and community context [41]. Despite their importance, SDOH factors are frequently overlooked, unidentified, and poorly documented [35,42,43]. When data are collected, they are often not available in a structured format, making it difficult to aggregate, analyze, and share with other care providers. Until recently, these factors were rarely captured in electronic health records, and thus, their utility in root cause analysis of health disparities was hindered by data quality and availability [42].

Disparities, Medical Provider Shortages, and Health System Implications

Notably, regardless of income, education level, or socioeconomic status, Black women are 3 times more likely to die from pregnancy-related complications when compared with White women in the United States [8,11,13-16,36,38,44,45].

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Furthermore, maternal outcome disparities can reflect broader systemic issues within society and have profound implications for public health. Racial disparities can also exist within and between hospitals, further stratifying the experience of patients and complicating access to quality health care services [5,46]. The most current available data from the CDC, delineating maternal mortality by state, revealed that some US states exhibited higher reported maternal mortality rates than others [37,47,48]. Between the years 2018 and 2021, maternal mortality rates per 100,000 live births were the highest in the following US states: Arkansas (43.5), Mississippi (43.0), Tennessee (41.7), Alabama (41.4), Louisiana (39.0), Kentucky (38.4), Georgia (33.9), and South Carolina (32.7) [37,47,48]. Compounding this problem, the shortage of health care workers is a growing issue not only in the United States but also around the globe [49,50]. The WHO has reported that by 2030, there will be a global shortage of almost 14 million health care professionals (eg, physicians, nurses, and midwives) [51]. Moreover, as difficulties in talent recruitment and retention continue, challenges in meeting "supply" (ie, health care providers) and "demand" (ie, patient volumes) will be exacerbated [49,51,52]. Further, with hospital bed shortages anticipated to reach dangerous thresholds as early as 2032, the situation can become more devastating [53]. US health systems are additionally facing scarcities, specifically in maternity service providers, with 13 obstetrician-gynecologists (OB-GYNs) and only 16 midwife providers per 1000 live births [5,54,55]. Adding complexity, many providers report burnout and job dissatisfaction, with OB-GYNs in particular having the highest litigation rates across specialties [5,50,54,55]. Further, exacerbating the health care crisis, the decommissioning of hospitals in rural and urban centers has been accelerating over the past 30 years, with 136 rural closures between 2010 and 2021 alone [56-59]. The cessation of hospital service operations has unquantifiable consequences for impacted communities, with delays in medical care associated with increased transport times, elevated neighboring hospital and emergency department (ED) patient volumes, and increased morbidity and mortality due to a lack of time-sensitive medical or surgical interventions [56-61]. While this study focuses on the United States, this concerning trend is also prevalent globally and has grave implications for patients and health care providers alike (eg, poor health outcomes, increased mortality rates, hospital closures, medical workforce burnout, moral injury, and compassion fatigue) [49-52].

Data continue to demonstrate the severity of environmental factors that cause risks to human health, and in particular, pregnancy-related mortality and other time-sensitive urgent health care scenarios. Moreover, some researchers posit that a person's geographic location (eg, city, county, state, and zip code) could be a more powerful indicator of their projected health outcomes than their genetic code [32,33,37]. Others argue that "a person's biggest risk factor isn't [their] personal preferences or medical needs...but which door [they walk] through" and infer that inconsistencies in medical service provision and capacity also exist [48]. Thus, disparities can not only be indicative of broader health system failures but also reflect the cumulative impact that SDOH present to the health trajectory of marginalized populations. Thus, participatory and system thinking approaches that foster active collaboration and partnerships between patients and health care stakeholders may have merit in assisting with the root cause analysis of poor patient outcomes [35,36,62,63]. Moreover, participatory models of care delivery by their essence increase communication among health care professionals (eg, physicians, nurses, and caregivers), increase patient empowerment, and improve shared decision-making [64,65]. Additionally, participatory approaches hold promise institutionally to improve not only the effectiveness of clinical handovers but also the health system itself [62,64,65]. Understanding the lived and living experiences of the holistic circle of care (eg, patients, caregivers, nurses, and physicians) and human-centered system perspectives are vital and must be expediently adopted by the broader health care collective [66]. Thus, the adoption of the learning health system (LHS) concept is paramount for targeted and scalable transformational change, and the strategic utilization of human experience data can be a conduit for sustained quality improvement and evaluation [66,67]. As LHSs are systems in which informatics, culture, science, and knowledge translation are aligned for innovation and continuous improvement, their benefits lie in their seamless capacity to embed best practices and human experiences into the care process [18,66-69]. By definition, LHSs present opportunities to align multiple stakeholders, integrated systems, human experiences, real-world data, and external evidence through the application of knowledge [18,66-68,70,71]. As such, human-centered contextually driven data, as experienced by patients, providers, and health care stakeholders, hold promise to yield rich precision-level data (eg, process improvement, diagnostic, clinical, and operational data), which can inform LHSs to improve care and health care outcomes [66].

Objectives

This study aimed to address the gaps by adopting a system view and developing a Visualized Combined Experience (VCE) diagram that integrates population-level data with persona-based storytelling to assess the interconnected nuances that can lead to disparities in maternal health care outcomes. Specifically, this study seeks to investigate the following research questions:

1. How can the VCE diagram approach be applied to illustrate maternal mortality disparities in the United States?
2. To what extent does this integrated visualization technique reveal connections between individual patient experiences and population-level health outcomes that traditional visualization methods do not?
3. How can the VCE diagram inform an LHS?

Methods

Study Design and Framework

Overview

This study is part of a broader investigative series that uses nontraditional data visualization techniques to interpret publicly available population health data, illustrating the human aspects of big data and how the data may be convergently displayed to effectively inform the health care sector [35]. Specifically, this study used a mixed-methods approach [72,73] to create a VCE

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diagram integrating qualitative patient narratives with quantitative population health data. This methodology was used, as it provides a deeper, more comprehensive understanding of the drivers and facilitators of maternal mortality in the United States than either approach (ie, quantitative and qualitative) could have achieved independently [72,73].

Phase 1

Phase 1 of this series began with an inquiry into the trends of COVID-19 [35] mortalities across race groups (eg, Asian, Black, Hispanic, Native Indian, and White) and resulted in the creation of a novel methodology for COVID-19 mortality analysis [35]. As such, the VCE diagram consisting of a persona, an Experience Journey Map, and a Sankey diagram was designed to illustrate the varied patient outcomes and trajectories, using preliminary COVID-19 data from the Centers for Medicare & Medicaid Services in the United States [35,74], and the patient narrative data were derived from lived experiences of African American men in the United States who died from COVID-19 [75].

Phase 2

Phase 2 (this study) refined the phase 1 methodology [35] and applied it to a different health care scenario, specifically to determine maternal health outcomes across race groups (eg, Asian, Black, Hispanic, and White) across the United States. Next, the VCE diagram was developed, integrating the persona and Experience Journey Map to provide a holistic perspective.

Quantitative Data

Publicly available maternal mortality data were obtained from the CDC National Vital Statistics System's Vital Statistics Rapid Release (VSRR) dataset, entitled "provisional maternal death counts and rates" [3,31]. The reporting period was monthly, with values for each race group summed to provide a single figure for each member in the respective race categories. After calculating the values, a new data table was created to detail each group's totals and the proportion of maternal deaths during the aggregate 2023 reporting period. This dataset was selected because it contained the latest official statistics on maternal mortality in the United States (ie, 2023), as published in the National Center for Health Statistics 2025 report [3,31]. Maternal death in the dataset was defined according to the WHO's classification as follows: "the death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and site of pregnancy, from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes" [76].

Qualitative Data

The qualitative data for the persona and Experience Journey Map were synthesized from cases documented from the Goldsmiths Prized ProPublica *"Lost Mothers"* series [7,77]. The *"Lost Mothers"* investigative journalism project was selected as a data source, as it provided detailed narratives of maternal health experiences from all 50 states, Washington DC, and Puerto Rico [7,77,78]. The series explored why the United States, compared with other countries in the developed world, has the highest per capita health care expenditure but the worst maternal outcomes. It also depicted the intimate stories, lived experiences, and health outcomes of Black mothers across US continuums of care [7,77].

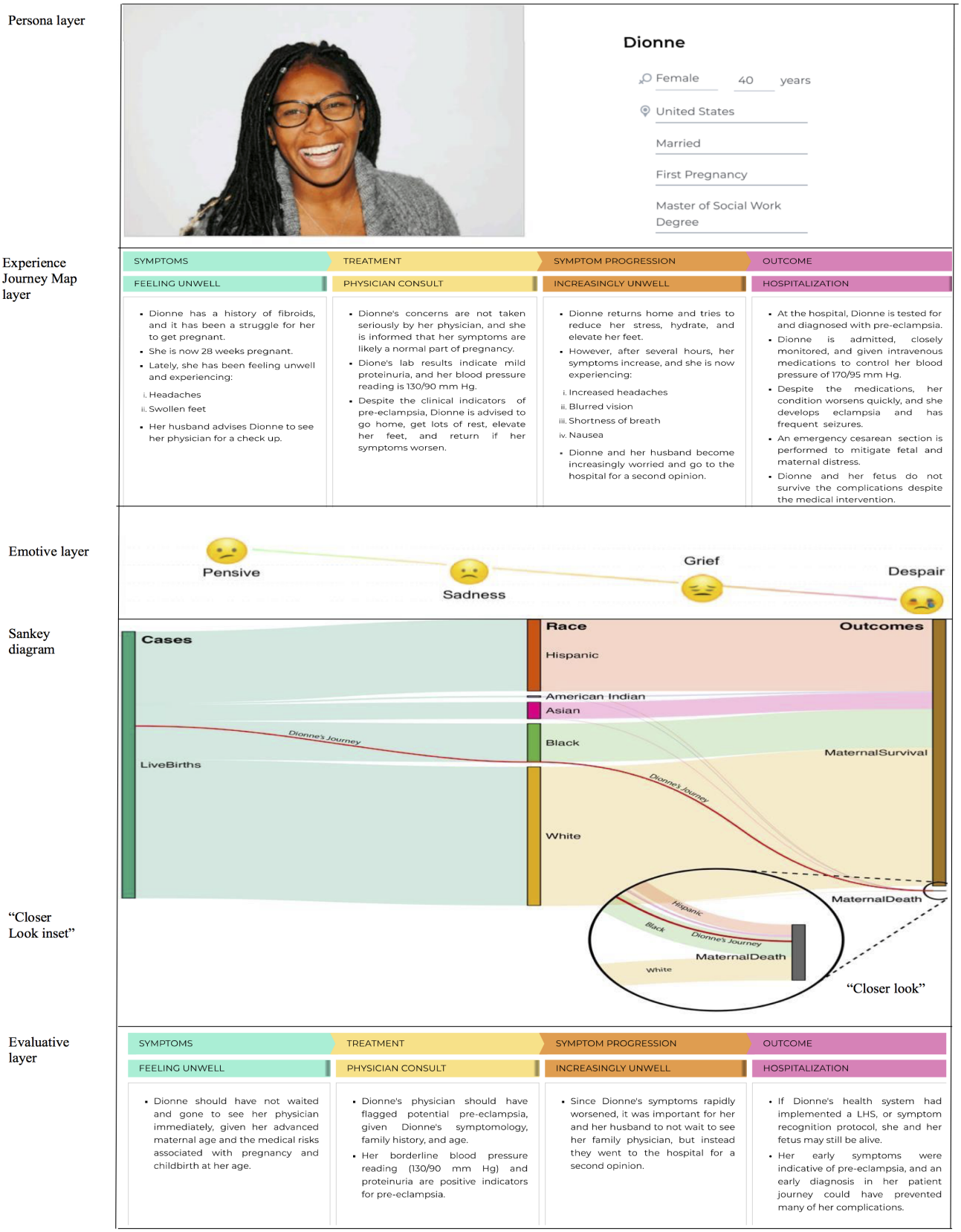
VCE Diagram Development Cycle

Overview

The VCE diagram has 7 sequential segments (Figure 1), with each corresponding to a layer of the final visualization. The VCE diagram development cycle consists of the following seven steps: (1) persona development, (2) Experience Journey Map development, (3) emotive development, (4) Sankey diagram development, (5) deeper dive - second Sankey diagram development, (6) evaluation, and (7) data integration.

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Figure 1. Visualized Combined Experience diagram illustrating Dionne's trajectory compared with the maternal health outcomes of other population groups. LHS: learning health system.



Step 1: Persona Development Segment

The persona development segment is the first step of the VCE development cycle. The persona layer is vital as it establishes the contextual background of the analysis and humanizes the numeric health statistics [35,66]. The persona "Dionne" was developed using a structured approach to represent experiences that some Black women in maternal health care settings in the United States may face. The development process included a relational analysis of the narratives and patient experiences

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depicted in ProPublica's *"Lost Mothers"* series [7,77]. The analysis identified recurring themes across the maternal health trajectories of Black women; the extraction of demographic information, medical conditions, and health care interactions; and the synthesis of a composite persona incorporating key elements from multiple narratives [7,77]. The persona visualization was developed using a combination of software (UXPressia and Microsoft PowerPoint).

Step 2: Experience Journey Map Development Segment

The Experience Journey Map development segment, which is the second layer of the VCE diagram, provides a visual narrative of Dionne's patient experience as she navigates the care continuum in search of different modalities of care for her symptoms [35,66,79,80]. It was developed to visualize Dionne's interactions with the health care system across four key phases: (1) symptoms, (2) treatment, (3) symptom progression, and (4) outcomes. Dionne's actions (ie, what she did, scheduling appointments, and seeking care) were documented in each phase of her journey. Additionally, the touchpoints (ie, interactions with health care providers and systems) and emotional responses (ie, her feelings during each interaction) were also depicted in the schematic. The Experience Journey Map visualization was developed using Adobe Acrobat Reader, UXPressia, Microsoft PowerPoint, and Microsoft Word software.

Step 3: Emotive Development Segment

The emotive development segment is the third layer of the VCE diagram. It illustrates Dionne's emotional spectrum across the four phases of her patient journey: (1) symptoms, (2) treatment, (3) symptom progression, and (4) outcomes. The richness and complexity of Dionne's emotions are illustrated in the context of each phase of her patient journey experience (ie, the Experience Journey Map) to provide a balanced and intuitive representation of patient emotions. The visualized emotions in this layer were inspired by the sentimental narratives depicted in the ProPublica series [7,77] and created using Adobe Acrobat Reader, UXPressia, Microsoft PowerPoint, and Microsoft Word software solutions.

Step 4: Sankey Diagram Development Segment

Sankey diagrams were selected as a visualization tool, as these diagrams provide an intuitive way to represent proportional flows and disparities that are otherwise hidden in aggregate data. Unlike traditional bar or line charts, which often present mortality rates in isolation, Sankey diagrams emphasize the relative magnitude of outcomes between groups through visually weighted flows, making disparities immediately apparent. Studies in health and policy communication suggest that flow-based visualizations can enhance the comprehension of proportional relationships and inequities when accompanied by clear annotations and guiding narratives [81,82]. For policymakers (eg, local and national governments, international bodies, and public agencies), who must often make rapid decisions based on complex data, Sankey diagrams can reduce cognitive load by simultaneously displaying both absolute counts and proportional differences across populations, enabling quicker recognition of systemic inequities. When paired with persona narratives and journey maps, Sankey diagrams serve as a bridge between statistical abstraction and human experience, reinforcing both empathy and data-driven insight. Traditional visualizations, such as stacked bar charts and small multiples, are effective for summarizing quantitative rates across groups [83], but they often strip away the lived experiences that contextualize those disparities. These methods can reveal numeric differences, yet they fail to illustrate how individual patient trajectories connect to population-level inequities, leaving critical drivers of maternal mortality abstract and impersonal. The VCE diagram directly addresses this gap by linking micro-level narratives to macro-level outcomes, aligning with our research questions that seek to both humanize maternal mortality data and expose structural inequities that are otherwise masked.

Both Sankey diagrams were created with a JavaScript library, Data-Driven Documents (D3), using publicly available population data from the VSRR dataset of the National Center for Health Statistics of the CDC, which reported the incidence of maternal death [31,35,84]. Specifically, the Sankey diagrams were populated by the "provisional maternal death counts and rates" dataset, which provided the incidence of maternal death during childbirth (categorized for age and race). Next, the data were filtered by row, race group, and year of death. Within the dataset, the reporting period was monthly, with values (monthly) for each race group summed to provide a single figure for each member in the respective race categories. After calculating the values, a new data table was then created to detail the totals in each group and the proportion of maternal deaths during the aggregate 2023 reporting period. Following this, the aggregate data table was processed through the D3 software visualization library [84] to render the initial Sankey diagram.

Step 5: Deeper Dive - Second Sankey Diagram Development Segment

A second Sankey diagram was created, given that the proportion of maternal death was small when compared with the proportional data of maternal survival across all racial populations and the disparities between groups were not visible in the original Sankey diagram. The creation of the second Sankey diagram involved the same diagrammatic curation methods and the same dataset as in step 4. However, maternal death was expressed in a per-thousand ratio as depicted by a magnified inset with flows labeled with race groupings where space permitted. In lieu of demonstrating a second comprehensive diagrammatic representation, a "closer look" inset was embedded within the VCE diagram for esthetics and effective visual impact.

Step 6: Evaluative Segment (Patient Choice, Service Delivery Bottlenecks, and Care Gaps)

The evaluative segment, which is the sixth layer of this comprehensive visualization, provides insights into probable situations that could have been improved to avoid patient disposition. It provides a system assessment of the top journey map quandrant through an analysis of the aforementioned 5 layers: persona development, Experience Journey Map development, emotive development, Sankey diagram development, and second Sankey diagram development. This evaluation assesses the various components contributing to

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Dionne's health care outcomes and compares her individualistic patient circumstance across the health care interactions in seeking care. The evaluative layer then provides the best practice suggestions for enhancing patient satisfaction, refining service design, and addressing specific patient circumstances, with suggestions toward a more positive human experience and improved health care outcomes for Dionne's situational narrative and specific patient circumstances.

Step 7: Data Integration Segment - Creation of the VCE Diagram

The last step of the VCE development cycle involves the combination of the stratified data elements: (1) persona, (2) Experience Journey Map, (3) emotive layer, (4) Sankey diagram, (5) second Sankey diagram, and (6) evaluation. To illustrate the micro and macro perspectives chronologically, the VCE diagram was created initially with the micro perspective (ie, the persona and journey map), followed by an application of Sankey diagrams to illustrate the macro perspectives. The persona is positioned first to establish context, the journey map is positioned in the middle to illustrate the individual patient experience, and the Sankey diagram is positioned at the bottom to show population-level outcomes. A combination of software tools was used for the final integration and layout of the segments, including Adobe Acrobat Reader, UXPressia, Microsoft PowerPoint, and Microsoft Word. A red line was added to connect Dionne's journey outcome with the corresponding flow in the Sankey diagram, visually linking the individual experience to population-level data. Annotations were added to highlight key insights and guide the interpretation of the visualization. This design choice was made to personify the statistical data and promote an empathetic understanding of maternal mortality disparities across the United States. The final evaluation layer provides the best practice suggestions from the data and the scenario contexts to improve service delivery and patient outcomes.

Evaluation Approach

While formal evaluation of the VCE diagram's effectiveness is planned for phase 3 of this investigative series, a preliminary internal assessment of the visualization was conducted against established information visualization principles [85-87] and health care data visualization best practices [88-90]. This assessment focused on clarity, information density, visual hierarchy, and narrative coherence. We evaluated how effectively the visualization communicated both the individual narrative and population-level disparities and the connections between these 2 levels of analysis.

Ethical Considerations

This study used publicly available data and published narratives, with no direct involvement of human participants, and thus, it was exempt from ethics review. As an additional safeguard, ethical aspects were considered in representing maternal experiences to ensure a respectful portrayal of maternal mortality cases. Special attention was paid to accurately represent the structural and systemic factors contributing to racial disparities in maternal health outcomes while avoiding potential stereotypes or oversimplifications of complex health care interactions.

Results

Overview

This study showed a novel application of the VCE diagram (Figure 1), which exposed hidden disparities across race groups in the United States. Specifically, Dionne's unique patient journey was illustrated across the maternal health care continuum. By illustrating the human experience, the VCE diagram personified the CDC's maternal mortality dataset [31], and its application yielded a layered visualization (Figure 1), which integrated individual patient experience with population-level maternal mortality data, revealing three key findings: (1) the presence of significant disparities in maternal mortality rates across racial groups, (2) the presence of critical gaps in care delivery during the pre-eclampsia diagnostic phase, and (3) the masking effect of aggregated data on racial disparities. This study underscores the complexity of aggregating, cleaning, collecting, and interpreting health care data. While the overview presented in the original analysis stratified the data by race group, it did not demonstrate a true categorical representation of race data inequities; thus, the "closer look" secondary analysis was used to clarify the disparities within the dataset (Figure 1).

Interpreting the Diagrammatic Representation

The completed VCE diagram was designed to be read from top to bottom, allowing readers to understand an individual's experience before seeing how it relates to broader population patterns. This interpretation should begin at the micro perspectives (persona and journey map) and move toward the macro perspectives (Sankey diagram). The micro perspectives (ie, persona and journey map) provide insights into the individual (ie, Dionne) and her situational factors, health status, and experience across the care continuum. Following this, the macro perspectives (ie, Sankey diagram) layer is presented and used as a macro lens to augment the previous visualization, which incorporates a holistic presentation and positions Dionne's experience (illustrated by the red line in Figure 1) in relation to the maternal health outcomes of other race groups in the United States. This structure provides a comprehensive view of maternal mortality by connecting individual experiences to population-level outcomes.

VCE Segment Analysis and Application

Overview

The seven segment analysis stages are as follows: (1) persona development, (2) Experience Journey Map development, (3) emotive development, (4) Sankey diagram development, (5) deeper dive - second Sankey diagram development, (6) evaluation, and (7) data integration.

Step 1: Persona Development Segment - Introducing Dionne

Dionne is a 40-year-old woman with a Master of Social Work degree who works with disadvantaged children. Dionne is married to a general surgeon and loves children, but has never been able to conceive. The couple's high levels of education and wealth, and affluent socioeconomic status provide them

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with superior access to medical care and specialized consultations. Dionne has been diagnosed with fibroids (ie, benign growths found inside the uterus), a uterine condition prevalent in women of reproductive age who are of African descent [7,77,91,92]. The fibroids have caused Dionne painful (often debilitating) menses since menarche [7,77,91,92]. Fibroids, especially if large, can impact fertility, and this is the reason Dionne has been unable to conceive [7,77,91,92]. While Dionne became resigned that she may never become a mother, she was surprised 6 months ago with a positive pregnancy test. Dionne is now in her third trimester (just over 28 weeks of gestation) and has been experiencing frequent headaches and swollen feet. She assumes that these symptoms are a normal part of pregnancy, but her husband has convinced her to schedule a visit with her physician to get the symptoms checked [7,77,93].

Step 2: Experience Journey Map Development Segment - Dionne's Journey

Dionne's complicated journey and individual narrative have been simplified for this study via the Experience Journey Map across four phases: (1) symptoms, (2) treatment, (3) symptom progression, and (4) outcomes (Figure 1). Collectively, the 4 phases provide an illustrative application of the experiences that Dionne goes through across her patient journey in seeking medical care to alleviate her symptoms and safeguard her pregnancy.

Symptoms: Feeling Unwell

The micro perspectives provide insights into Dionne's patient experience [7,91-93]. At about 28 weeks of gestation, she has recurring headaches, slight nausea, and progressive pedal edema, which should raise suspicion for pre-eclampsia [22,25,77,93-95]. However, this is Dionne's first pregnancy, and she assumes that these are just "normal" symptoms and is reluctant to see her family physician. After much apprehension and discussion with her husband, she eventually calls her physician's office to book an appointment. During the call, the medical office assistant (MOA) informs Dionne that she will need to go to her local laboratory and provide a urine sample for analysis. The MOA reiterates that this must be done prior to her appointment with her physician and informs Dionne that she will email her requisition forms later that day, which she can present at the laboratory. Dionne checks her email the next day, prints the forms from her home computer, and goes to the laboratory.

Treatment: Physician Consultation

Dionne mentions her symptoms, concerns, and assumptions to her physician, who validates her assumption that her swollen feet are likely a "normal" part of pregnancy. Her physician also checks her blood pressure and reviews her urinalysis results. Dionne's blood pressure reading of 130/90 mm Hg is a borderline blood pressure reading, and her laboratory results demonstrate mild proteinuria. Despite these warning signs for pre-eclampsia, Dionne is advised to go home, manage stress, elevate her feet, get lots of rest, and book another appointment if her symptoms worsen [7,24,77,93].

Symptom Progression: Feeling Increasingly Unwell

Dionne returns home, tries to reduce her stress, and elevates her feet. However, after several hours, her symptoms progress, with increasing nausea, blurred vision, and headaches, and she is now becoming increasingly short of breath [14,77,96]. Dionne's husband is concerned about the intensity of her symptoms and cautions her that their baby's safety may be at risk. He encourages her to seek a second opinion. Dionne calls her mother, who agrees with her husband's perspective, and they promptly go to the hospital for a second opinion.

Outcomes: Hospitalization

Following a long wait in the hospital's ED, Dionne's symptoms get significantly worse. At this point, she is struggling to breathe and feels faint. Eventually, she is seen by the attending physician. Her husband articulates that Dionne has just seen her family physician, but they are concerned that her symptoms are progressing and are worried about her mild proteinuria diagnosis and elevated blood pressure (130/90 mm Hg). The attending physician takes their concerns seriously, given that Dionne's husband is a physician as well, and immediately checks her blood pressure and tests her for pre-eclampsia. By this time, Dionne's blood pressure has elevated to 170/95 mm Hg, and the attending physician then officially diagnoses her with pre-eclampsia.

Outcomes: Mortality

During her admission, Dionne and her fetus are closely monitored, and she is given intravenous antihypertensives to lower her blood pressure, but there is no success [25,77,93]. Despite medications, Dionne develops eclampsia and has seizures. An emergency cesarean section is performed to mitigate fetal and maternal distress and further complications. However, unfortunately, both Dionne and her fetus do not survive despite the emergency intervention [27,28].

Step 3: Emotive Layer Development Segment - Dionne's Emotional Journey

Illustrating Dionne's emotions during each phase of her patient journey (Figure 1) provides valuable and insightful information, which is often overlooked due to the transactional and time-constrained nature of care delivery. The emotive layer provides context for the feelings associated with each time Dionne interacts with the health system in seeking care. This segment facilitates intuitive visual representation and immediately communicates whether the experience was positive or negative at each touchpoint. As a 40-year-old, first-time mother with a high-risk and unexpected pregnancy, her visualized emotions have included pensiveness, sadness, grief, and despair across the 4 phases of her emotive journey.

Symptoms: Feeling Unwell - Pensive

The starting point of Dionne's emotional journey is established. She is pensive as she and her husband are engaged in deep thought to understand the root cause of her symptoms.

Treatment: Physician Consultation - Sadness

Dionne returns home from her medical appointment but feels sad as she does not feel that her concerns were heard or adequately addressed by her physician. Prior to the consult, she

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had been resting and elevating her feet, but it did not help with the swelling or her headaches. Dionne has a bad gut feeling that something is seriously wrong and worries about the safety of her baby, but she tries to remain calm and trust the medical advice she has just been given.

Symptom Progression: Feeling Increasingly Unwell - Grief

After several hours and much anxiety, Dionne's husband and her mother convince her to go to the hospital for a second opinion. Since her previous physician consultation, Dionne struggles to cognitively process that something could be wrong with the pregnancy, and her feelings, behaviors, emotions, and experiences range from denial and isolation to anger, bargaining, depression, and acceptance [62,97]. Furthermore, Dionne struggles with losing hope that she will survive and has intense anticipatory grief that her baby will die [62,97]. She is very angry that her family physician did not take her concerns seriously and is inconvenienced to have to go to the hospital. Along with her cyclic internal emotive struggle, her symptoms (eg, headaches, shortness of breath, swelling, and blurred vision) are increasing in severity.

Outcomes: Hospitalization - Despair

Dionne is diagnosed with pre-eclampsia, which progresses to eclampsia. Between the terrifying seizures, she cries uncontrollably, gripped by agony, fear, and despair, unsure if she and her baby will survive.

Step 4: Sankey Diagram Development Segment - Dionne's Journey Compared to the Population

The first population-level Sankey diagram revealed quantitative disparities in maternal mortality rates across racial and ethnic groups. When accounting for the population density of each racial group in the United States (Hispanic, 19.1%; Asian, 6.3%; Black, 13.6%; and White, 75.0%) [98], the maternal mortality rates per 100,000 births were as follows: Hispanic women, 14.3; American Indian women, 45.3; Asian women, 10.2; Black women, 51.2; and White women, 16.8 [31]. These rates demonstrated that Black women had the highest maternal mortality rate among all race groups analyzed [31].

Step 5: Deeper Dive

A secondary analysis was conducted, and an additional Sanky diagram (ie, "closer look" inset) was created to underscore the complexity of aggregating, cleaning, collecting, and interpreting data [90,99]. While the overview presented in the original Sankey diagram analysis stratified the data by racial group, it did not demonstrate a true categorical representation of the racial data inequities. As such, the "closer look" inset revealed that in the aggregate view of the initial Sankey diagram, racial disparities were visually obscured owing to the small proportion of maternal deaths relative to the total number of births. When visualized at an appropriate scale (per 1000 births), the magnitude of disparity became clearly apparent, providing methodological insights into how conventional data display can mask significant disparities.

Step 6: Evaluative Segment (Patient Choice, Service Delivery Bottlenecks, and Care Gaps)

As demonstrated in Figure 1, we provide hypothetical solutions and probable action paths that Dionne could have taken to potentially improve her health care outcomes across the following four key phases: (1) symptoms, (2) treatment, (3) symptom progression, and (4) outcomes. In the symptom phase, Dionne should not have waited and should have consulted her physician immediately, given her advanced maternal age, her pre-existing conditions, and the medical risks associated with childbirth at her age. Next, in the treatment phase, Dionne's physician should have flagged potential pre-eclampsia, given Dionne's symptomology, family history, and age. Moreover, her borderline blood pressure reading (130/90 mm Hg) and proteinuria could be considered positive indicators for pre-eclampsia and should have been further investigated. Following this, in the symptom progression phase, since Dionne's symptoms rapidly worsened, it was prudent for her and her husband to not wait to see her physician and instead seek immediate medical care at the hospital. Lastly, in the outcome phase, Dionne's health system should have implemented a symptom recognition protocol and ultimately an LHS, which might have saved her and her fetus. Her early symptoms were indicative of pre-eclampsia, and an early diagnosis in her patient journey could have prevented many of her complications.

Step 7: Data Integration Segment - Dionne's Holistic Journey

The integrated VCE diagram demonstrated connections between individual experience and population-level outcomes that traditional visualization methods typically do not account for. The red trajectory line (Figure 1) connecting Dionne's journey outcome to the corresponding flow in the Sankey diagram showed that her experience represented a systemic pattern affecting Black women in the US health care system and that this was not an isolated case. The combined visualization identified specific clinical decision points (ie, dismissal of early pre-eclampsia symptoms and delayed diagnosis) that could contribute to the population-level disparity observed in the Sankey diagram layer. Most notably, the VCE diagram revealed that individual-level factors (eg, high socioeconomic status, education, and health care access) did not mitigate the disparity observed at the population level, suggesting that SDOH alone cannot explain the disparities in maternal mortality.

Discussion

Principal Findings

The VCE diagram (Figure 1) combines multiple perspectives and data points into a cohesive visualization and efficiently illustrates stratified maternal outcomes within the United States. This study used data [31] from the CDC to illustrate the trends in maternal mortality across the US population. Maternal mortality is unacceptably high across all race groups; however, when considering the population density of each group, disproportions exist. Regarding the first research question ("How can the VCE diagram approach be applied to illustrate maternal

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mortality disparities in the United States?"), it was revealed that the VCE visualization facilitates a holistic assessment of relevant health care stakeholders involved in Dionne's journey and outlines the gaps in care delivery and the pain points she experienced when seeking health care services. Regarding the second research question ("To what extent does this integrated visualization technique reveal connections between individual patient experiences and population-level health outcomes that traditional visualization methods do not?"), it was revealed that this innovative methodological approach provides a more nuanced and comprehensive understanding of the complex, intersecting factors contributing to maternal mortality disparities. By constructing a multidimensional visual representation that simultaneously contextualizes and maps an individual patient's health care journey in parallel with population-level demographic outcomes, the VCE diagram highlights systemic health care challenges that conventional visualization methods systematically overlook. Unlike standard epidemiological charts that typically present aggregated data through decontextualized line graphs or bar charts, the VCE diagram bridges the epistemological divide between statistical abstraction and human narrative. Similarly, while patient journey maps have emerged as a valuable tool in service design, they are underutilized in health care and frequently lack a substantive connection to broader population-level health trends [35,66,67,79,80]. The proposed approach innovatively integrates individual patient trajectories with demographic mortality patterns through a sophisticated Sankey diagrammatic representation. The VCE diagram offers a holistic analytical framework that transcends traditional disciplinary boundaries by synthesizing multilayered data visualization techniques. This approach not only renders visible the often invisible mechanisms of health care disparities but also provides a powerful methodological tool for understanding the complex interactions between individual experiences and systemic health inequities. The study also revealed many unique features, including but not limited to implications of bias and SDOH, streamlining health care service delivery, and implications for the health care workforce, including policymakers, health systems, advocacy groups, and researchers.

Implications of Bias and SDOH

The VCE diagram provides a methodological bridge between quantitative disparity metrics and the qualitative experiences of care that contribute to these disparities, particularly the documented pattern of symptom dismissal experienced disproportionately by Black women (Figure 1). Our findings underscore that maternal mortality variations between racial and ethnic groups cannot be explained by biological factors alone. Most studies have demonstrated that a significant proportion of maternal morbidity and mortality cases are preventable, making health care equity and efficiency imperative [5,19,32,46,48,77,93,100,101]. Both implicit bias (ie, unconscious mental processes leading to associations and reactions) and explicit bias (ie, conscious beliefs and attitudes) permeate health care systems through institutionalized practices, clinical decision-making, and clinician-to-patient communication [102-105].

Historical context further complicates this issue, as many foundational advances in obstetric and gynecologic procedures are embedded in discriminatory practices [106-111], race‐based medicine, and research practices with a questionable ethical basis [105,107,109,112-116]. Medical textbook codification and approaches, such as the Caldwell-Moloy pelvic classification system and the Vaginal Birth After Cesarean (VBAC) calculator, continue to influence gynecological practice despite evidence that obstetric pelvises vary in complex ways, which are not effectively captured by artificial typologies [1,117-122]. Moreover, beliefs and practices regarding biological differences in pain perception and blood coagulation across race groups should be re-examined with modern scientific rigor and evaluated by evidence-based human-centered patient outcome research [110,111,123]. Complicating matters, historical biases can also manifest in contemporary disparities, including higher rates of unplanned cesarian births among Black and Hispanic women, with treatment response associations including but not limited to increased risks for hemorrhage, surgical complications, and postpartum infections [2,37,48,118,122,124,125]. To make matters worse, due to many variables and SDOH factors, women with pre-existing mental health issues (eg, anxiety, depression, and post-traumatic stress disorder [126]) from marginalized groups are also vulnerable to receiving poorer care, and consequently, they could experience more distress during childbirth, resulting in worse health care outcomes [127]. Childbirth is a transformative experience for women, not only physically but also psychologically, and their memories of it are indelible [127,128]. The VCE diagram illustrates how these biases translate into clinical encounters where symptoms, such as headaches, visual disturbances, high blood pressure, and edema (clear signs of pre-eclampsia), may unintentionally be dismissed [8,14,44,45,77,96].

Streamlining Health Care Service Delivery

The VCE approach can help address inconsistencies in medical education and health care service delivery by clearly representing how individual patient journeys connect to population-level data. Black women in the United States face the highest maternal mortality rates across racial groups [8,11,13,15,16,36,38,45,96], underscoring that access to health care alone is insufficient without addressing biases in care delivery. Addressing maternal mortality comprehensively requires acknowledging these disparities as manifestations of structural discrimination, socioeconomic inequities, and inadequate health care infrastructure. High maternal mortality rates are associated with broader health system weaknesses, which also impact other aspects of care, such as chronic disease management, reproductive health services, and preventive care. Furthermore, it involves addressing the underlying SDOH contributing to unequal health outcomes. By addressing these root causes, health care interventions can promote more sustainable, cost-efficient health system practices, where all individuals have the opportunity to thrive with high-quality maternal care, regardless of race, socioeconomic status, or geographic location. Thus, addressing maternal mortality comprehensively is not just a health priority but also a social imperative. The VCE diagram demonstrates that even for women

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with optimal socioeconomic factors, racial disparities persist, suggesting that structural racism and bias in clinical encounters play significant roles. By visualizing these connections, the VCE diagram gives stakeholders a more comprehensive understanding of intervention points beyond individual clinical encounters.

Implications for the Health Care Workforce

Overview

The VCE diagram offers significant benefits that extend beyond enhancing public understanding of maternal mortality data. By presenting data in a visually intuitive format, the VCE diagram serves as a powerful tool for various stakeholders who play critical roles in addressing health care outcomes, such as policymakers, health systems, health care providers and administrators, advocacy groups, and researchers.

Policymakers

For policymakers, the VCE diagram provides a compelling human-centered visual representation of complex data that traditional presentations (eg, statistical tables and text-heavy reports) often fail to convey succinctly or effectively. The combination of personas, journey maps, and Sankey diagrams visually dramatizes inequalities within the health care system, offering an accessible narrative that can drive policy change and identify organizational barriers to care [35,66]. By simplifying the interpretation of data, the VCE diagram enables policymakers to quickly grasp the scope and scale of maternal mortality issues across different demographic groups. This immediate understanding is crucial for effective decision-making and resource allocation. The holistic visualization (Figure 1) provides a clear delineation of health care disparities that can inform targeted interventions and quality improvement initiatives. Moreover, the VCE diagram could serve as a vital tool in legislative advocacy, helping to rally support for policies aimed at reducing maternal mortality and improving health care outcomes.

Health Systems

The rapid pace of technological advancement further complicates health systems and their ability to effectively utilize, interpret, and codify population-level data. The consistent influx of new diversified health information systems and health information technologies, along with their data, often hinders their utility and effectiveness in health systems. Technological heterogeneity often perpetuates institutional data siloes across health systems, with interoperability not being possible. This issue is further complicated by the mechanisms by which health care data are collected, synthesized, and aggregated, inhibiting scalability and comparability of macro-level analysis [35,129]. Health systems struggle to not only remain current with evolving medical research and clinical practices but also manage and process the staggering variety and volume of health care data [90,129]. To combat these challenges, health systems could implement regular reviews of maternal care journeys using the VCE diagram methodology to identify critical intervention points, particularly focusing on the transition between prenatal visits and acute care for conditions like pre-eclampsia.

Health Care Providers and Administrators

Health care providers and administrators (eg, physicians, nurses, midwives, doulas, and health care executives) can utilize the VCE diagram as an educational tool to enhance their awareness and understanding of health care outcomes across patient populations. By visualizing patient experiences across different metrics (ie, race, age, and location), providers can recognize patterns of care that may unintentionally perpetuate disparities. Integrating the VCE approach into professional medical training curricula and continuing medical education could propagate the importance of contextual understanding in health care delivery, leading to more empathetic, human-centered care [62,66].

Advocacy Groups

Advocacy groups could leverage the VCE diagram as a persuasive communication tool by illustrating personal stories alongside systemic patterns of inequality. The stratified visualization provides the micro-level context of an individual's circumstances and emotional well-being throughout their health care journey. The macro-level health care outcomes create powerful narratives that contextualize population health data. The combined visual narratives (Figure 1) could serve as a potent tool to emotionally engage audiences, mobilize communities, and influence health care reform. Beyond advocacy, the information gleaned from the VCE diagram can also be applied in different contexts to facilitate information exchange and public education to build skills and create awareness. By making complex health data visible and easy to understand, individuals are better equipped to lead local initiatives. Moreover, this transparency can allow communities to take accountability for their own well-being as independent data stewards and advocates.

Researchers

For researchers, the VCE diagram offers a novel methodological approach for analyzing and presenting data on maternal health. Integrating qualitative elements, such as personas and journey maps, with quantitative data (ie, stratified mortality rates depicted in the Sankey diagram) allows for a more holistic understanding of maternal mortality. Researchers can use this combined approach to explore correlations between SDOH and maternal outcomes, generating new insights that may not be evident through traditional data analysis or display methods alone. By presenting data in a format that is both accessible and informative, the VCE diagram encourages dialogue and knowledge exchange among researchers, ultimately fostering a more comprehensive approach to understanding and addressing maternal health disparities. This approach facilitates interdisciplinary collaboration by providing a common visual language that bridges gaps among health care, sociology, clinical medicine, and health informatics.

Applying the VCE Diagram to Inform an LHS

Lastly, regarding the third research question ("How can the VCE diagram inform an LHS?"), it was revealed that the VCE diagram efficiently illustrates the interpretive complexities of working with large publicly available datasets and reveals that data integrity depends on accurate, timely, and structured processes for curation, cleaning, and aggregation [99,130].

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Technological advancement has introduced diversified digital and analytic tools that leverage artificial intelligence (AI) to synthesize data with far greater granularity than was previously possible [131]. The integration of AI technologies, such as machine learning, large language models, natural language processing, and neural networks, into health care underscores the need for accurate, unbiased datasets and registries to avoid propagating existing bias gleaned from historic data [103,132,133]. Figure 1 illustrates the criticality of understanding SDOH and their complex relationships with health care outcomes. It has also highlighted the importance of data-informed decision-making, the relevance of accountability in data curation and practices, and the importance of valuing the lived experiences and perspectives of patients and their families [35,131].

LHSs provide a platform to facilitate knowledge creation, translation, and mobilization of the continuous data and analytics gleaned from health care operations, clinical practice, and patient experiences [67,71,134]. This constant influx of new data could catalyze data-informed decision-making, real-time data synthesis for predictive analytics, and patient outcome simulation to foster continuous organizational learning [66,67,71]. Additionally, quality improvement initiatives and targeted interventions could also manifest, which hold promise to improve patient outcomes and reduce morbidity and mortality [66,67,71]. This continuous supply of data could assist in crafting human-centered care delivery [50,66] that meets the needs and goals of health care stakeholders, including but not limited to the following: policymakers, health systems, health care providers and administrators, advocacy groups, researchers, patients, and formal and informal caregivers. Moreover, the VCE diagram (Figure 1) provides six interrelated data streams to inform an LHS: (1) persona, (2) Experience Journey Map, (3) emotive information, (4) Sankey diagram of population data, (5) closer look inset, and (6) evaluation data. Together, these components demonstrate health inequities while challenging popular beliefs, for instance, showing that low socioeconomic status is not necessarily a determinant of mortality in Black women [15,32,38].

Incorporating SDOH data into LHSs could foster improvements to patient engagement, enabling them to have an active role in shared decision-making as stewards of their own health (should they desire to do so), and it would provide more targeted data for care providers as they would have better insights into the social circumstances of their patients [66,135]. Furthermore, integrating SDOH data into LHSs could cultivate personalized and tailored service provision, which could allow health care providers to circumvent biases inherent in maternal care (eg, the Caldwell-Moloy classification and VBAC calculator) [66,135]. Incorporating human-experience data into LHS activities and initiatives holds endless promise to improve health care outcomes, patient and provider satisfaction, and medical intervention efficacy [35,66,67]. The VCE diagram (Figure 1) illustrates multiple data streams in aggregate, and thus, if used in real-world settings, it could assist in targeted medical diagnostics and catalyze holistic and continuous improvement through simultaneous data analysis and synthesis. Moreover, the data gleaned could inform LHSs and service design, increasing health system scalability and efficiency [136].

Future Work

A key area for future work is formal user testing to evaluate how different audiences, such as the general public, clinicians, and policymakers, interpret the VCE diagram. While the design was assessed against established visualization principles, the extent of its accessibility and usability across diverse stakeholders remains untested. Clarifying the most appropriate target audiences and assessing their engagement with the VCE diagram will be essential to validate its utility and guide its application in practice.

Limitations

While the Dionne persona illustrates important aspects of the maternal experience, a single persona cannot capture the true diversity of the patient experience. This study was limited by the quality and accuracy of publicly available maternal mortality data from the CDC, and it is acknowledged that data may fluctuate due to reporting issues on death certificates [12]. Additionally, the VCE diagram used static data from a specific period, which may not reflect current maternal mortality ratios, and the quality of comparisons depends on how the CDC data were classified, coded, and sourced. Additionally, while the study focused on pre-eclampsia among Black women, the authors acknowledge that this condition affects women across all racial groups, and this study intended to not only identify maternal health disparities but also demonstrate how aggregate data can be misinterpreted in different contexts.

Conclusion

This study demonstrates the novel mixed methodological contribution of the VCE diagram as an innovative human-centered method to integrate qualitative patient narratives with quantitative population-level maternal health data. By combining personas, journey maps, and Sankey diagrams, the VCE diagram offers a structured framework that reveals disparities often obscured by conventional visualization methods. While the current work illustrates its potential to enhance the understanding of maternal mortality, further research is needed to evaluate its interpretability among diverse audiences and its effectiveness as a decision-support tool. Future studies will explore how the VCE diagram can be applied to other clinical domains and tested within LHS contexts. In this way, the VCE diagram serves as not only a novel mixed-methods tool but also a foundation for advancing human-centered approaches to presenting health care data and visualizing health care outcomes.

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Authors' Contributions

ALJ conceptualized the study and design, created the first draft, and led the writing of the manuscript. ALJ and YQ refined the study design and manuscript structure. ALJ, SRM, and HM assessed and selected the dataset. SRM conducted the data synthesis and created the Sankey diagrams. ALJ designed and developed the Visualized Combined Experience (VCE) diagram. BO and MCT validated the medical perspectives of the VCE diagram scenarios. All authors contributed to the writing and editing of the paper and approved the publication of the final version.

Conflicts of Interest

ALJ is a board member of the Society of Participatory Medicine Inc. The other authors declare no conflicts of interest.

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Abbreviations

AI: artificial intelligence
CDC: Centers for Disease Control and Prevention
ED: emergency department
LHS: learning health system
MOA: medical office assistant
OB-GYN: obstetrician-gynecologist
SDOH: social determinants of health
VBAC: Vaginal Birth After Cesarean
VCE: Visualized Combined Experience
VSRR: Vital Statistics Rapid Release
WHO: World Health Organization

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Theorizing How Context Influences School-Based Interventions That Support Children's Weight Management: Co-Producing a Refined Logic Model

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Abstract

Background: Schools can play an important role in supporting child weight management, with evidence suggesting that school-based interventions can be effective, albeit with substantial variation. Part of this variation could reflect the different contexts in which interventions are implemented. Our previous work found that co-production of research and adopting a complex systems model of evidence can be transformative for understanding this context. However, less is known about how co-production helps prioritize elements for exploration or how we should assess the value of co-production in research development. This study addresses these gaps by co-producing a refined logic model (a graphical representation of a theory) of the contextual influencers on school-based weight management to support public health research and policymaking.

Objective: This study aimed to (1) identify critical contextual features to consider when planning school-based weight management interventions targeting the intersection of physical activity, healthy eating, and mental well-being; (2) understand the difference that we, as co-producers, make when working together; and (3) identify learning about the process of producing and refining a logic model.

Methods: Through collaborative workshops, we refined an existing theoretical framework identifying contextual influences. We critically reviewed existing frameworks for evaluating co-production, creating a new evaluation approach for our collaborative practices, complemented by surveys and workshop feedback.

Results: Six criteria were identified and applied to refine the original logic model, significantly reducing complexity. The revised model prioritized systemic and policy factors, emphasizing environmental structuring rather than individual behaviors, and incorporated a stronger emphasis on life course factors. We used a tool and process developed specifically for this project, which may have broader utility for other research projects, to understand the value of working together. Many of us recognized that the impacts of the project and working together were unexpected and, for some of us, transformational. Nevertheless, we did identify some factors that could support co-production in future. These included the need for clearer initial discussions on positionalities, role expectations, and autonomy.

Conclusions: Our refined model aligns with broader calls to shift away from narratives centered on personal responsibility in children's health. This research further demonstrates the practical value and feasibility of co-produced theoretical frameworks, effectively reshaping the focus of research from the outset and challenging established assumptions.

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KEYWORDS

logic model; prioritisation; co-production; children's health; social determinants of health

Introduction

Schools as a Site of Public Health Action

Children spend approximately a fifth of their waking hours in schools, highlighting the potential of schools as sites that can support children's health through implementing public health interventions [1]. Reviews across a diversity of topics demonstrate the role that schools can play in supporting children to lead healthier lives [1-4], including the role that schools have in supporting children's weight management [1,2].

In England, schools play an important role in monitoring the weight status of children, with the annual mandated National Child Measurement Program collecting weight and height data to calculate the BMI of children aged 4 - 5 years and 10 - 11

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years [5]. This measurement program can also serve as a form of intervention to support children's weight management, with parents being provided with feedback about their children that is designed to help them to correctly recognize their children's weight status and may stimulate some parents to seek out support [2,6]. More broadly, schools can support children's weight management through the delivery of universal preventative interventions to promote healthy diets and physical activity, as well as multicomponent lifestyle weight management interventions that support children identified as overweight or obese [7]. While meta-analytic evidence points to schools having an overall positive influence in helping prevent childhood overweight and obesity [8] and supporting weight management [9], estimates point toward high levels of largely unexplained heterogeneity in the success of interventions. Part of this unexplained variation may be attributable to differences in the school context itself, as well as the contexts within which schools are nested. Moreover, despite substantial investment, levels of childhood overweight and obesity in England have broadly stabilized, with over a fifth of children aged 4 - 5 years categorized as being overweight or obese and over a third of children aged 10 - 11 years [10].

Although children's weight management is an area where a large evidence base examining the effectiveness of different strategies exists [11,12], there are indications that policymakers tasked with commissioning children's weight management services do not engage with evidence on the effectiveness of interventions prior to commissioning services [13]. Previous research has indicated that there are missed opportunities for evidence to inform public health decision-making, with public health decision-makers working in local settings expressing an unmet need for contextually sensitive evidence that better reflects the complexity of policymaking decisions [14,15].

This study is part of a larger program that aims to address critical limitations in the way in which evidence is generated to support public health decision-making. Here we report on the development of a co-produced theory about the context surrounding school-based weight management interventions. The focus on context and complexity is congruent with the recognition that school-based interventions supporting childhood weight management take place within systems characterized by multiple factors interacting at different ecological levels [16,17]. Our previous research has also indicated that practitioners and those with lived experience perceive that focusing solely on BMI within the field of children's weight management, as has been the case within the evidence [8,9], is insufficient to understanding the impacts of interventions and is potentially stigmatizing [18]. Instead, greater prominence should be given to the broader markers that reflect children's behaviors and capacity regarding weight management [18]. While anthropometric measures such as BMI have a vital role in decision-making and remain fundamental to assessing child growth, there are concerns that the exclusive focus on clinical measures of health could lead children—particularly those with weight management issues—to experience harmful levels of stigma [19]. Therefore, in addition to the focus on the "whole system" of contextual factors, we also theorize how these contextual factors shape the "whole outcome" that is frequently addressed within children's lifestyle weight management interventions, namely children's physical activity, healthy eating, and mental well-being.

Incorporating Complexity and Co-Production in the Way We Create Evidence

The recognition that childhood obesity appears to be largely intractable has prompted the exploration of different approaches around how we think about evidence for children's weight management. Two key movements of interest here include strategies that apply a systems-based approach to understanding the drivers of (childhood) obesity and approaches that attempt to prioritize people's lived and professional experience in the conceptualization of complex public health issues and the identification of actions that should be taken.

Evidence that adopts a "complex systems model" recognizes that poor health and health inequalities, such as those observed in the case of childhood obesity, are generated through the interactions of a multitude of interdependent elements within a "system" [20]. For example, children's weight may be influenced by the actions of teachers or school curricula, which are themselves influenced by the sociopolitical "ecosystem" surrounding children, such as government policies or the actions of large corporations. Taking a complex systems perspective not only involves identifying or theorizing the multifarious individual components included within a system, but also entails recognizing that the emerging health outcomes generated by a system cannot be directly predicted from the elements within it [20]. In the context of childhood health, children and their families have volition, their perceptions, values, and feelings can be unpredictable, and the places in which they live are dynamic.

Alongside calls for an evidence base that reflects the complexity of public health interventions and phenomena is the increasing recognition that academic lenses and perceptions alone are insufficient for unpacking and understanding the complexity of public health issues [21]. There is a growing body of literature demonstrating the value of incorporating people's lived experience into the design of policies and interventions [22,23]. Co-production is one of a spectrum of approaches to involving the public and patients in the design of research, interventions, and services. The distinctive feature of co-production is the intended formation of equitable partnership with patients, the public, and/or practitioners [24]. Co-production is underpinned by common values (eg, a commitment to challenge the status quo, to being equitable, and to incorporating a diversity of perspectives) and involves working toward a common goal [21,25]. It should be of mutual benefit to researchers and co-producers and seek to reduce traditional power differentials between researchers and research users and beneficiaries [26]. These characteristics can differentiate it from other forms of public participation where, for example, public partners are consulted but have minimal influence over research decisions.

Co-production has been described as adept at capturing the complexity of real-world perspectives and as a research method that "embraces life rather than bracketing it out, neutralizing or controlling it" [27]. While it has been used to design complex public health interventions, there are fewer examples where

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co-production has been used to theorize complex phenomena. Co-production may be particularly valuable in challenging existing conventions and could help to steer researchers from perpetuating stigmatizing ways of conceptualizing health outcomes. The research we describe here explores how co-production can help us make sense of how health is experienced and how health inequalities form.

Building on Previous Attempts to Conceptualize Complex Public Health Phenomena and Understand the Role of Co-Production

Previous attempts at understanding the complexity of public phenomena have encountered obstacles. Notably, the Foresight obesity systems map visually sets out the drivers of (adult) obesity through identifying 108 features and 300 connections between the features to depict the factors influencing "energy imbalance" [28]. Although this represented an innovation in the theorizing of obesity, among several critiques leveled at the model were questions about its practical application in supporting theorizing and decision-making, as well as the lack of public involvement in its development [18]. The map depicted a complex system around (adult) obesity but was created through expert and commercial input alone.

Our own preliminary work in this area, where we set out to create a complex system model of the context surrounding school-based weight management interventions, partially addressed some of these critiques through ensuring that the perceptions of parents, teachers, people with lived experience of issues with weight management, public health practitioners, general practitioners, and researchers all occupied a central position in the theorizing. The resulting theory took the form of a logic model, a graphical representation of the different factors and their putative links that influence childhood health. It was created using a co-production and focused on contextual factors that could influence school-based interventions to improve childhood health. This original model included 144 factors organized according to 10 "domains" (types of factors) and across 8 "ecological levels" (see Textbox 1 for more detail on this model). The 144 factors were identified through a series of co-produced workshops and categorized into 10 domains based on common themes and relationships.

Textbox 1. A description of our starting point—an existing theory of childhood health—the "CEPHI (Co-production of Evidence for Public Health Interventions)" model.

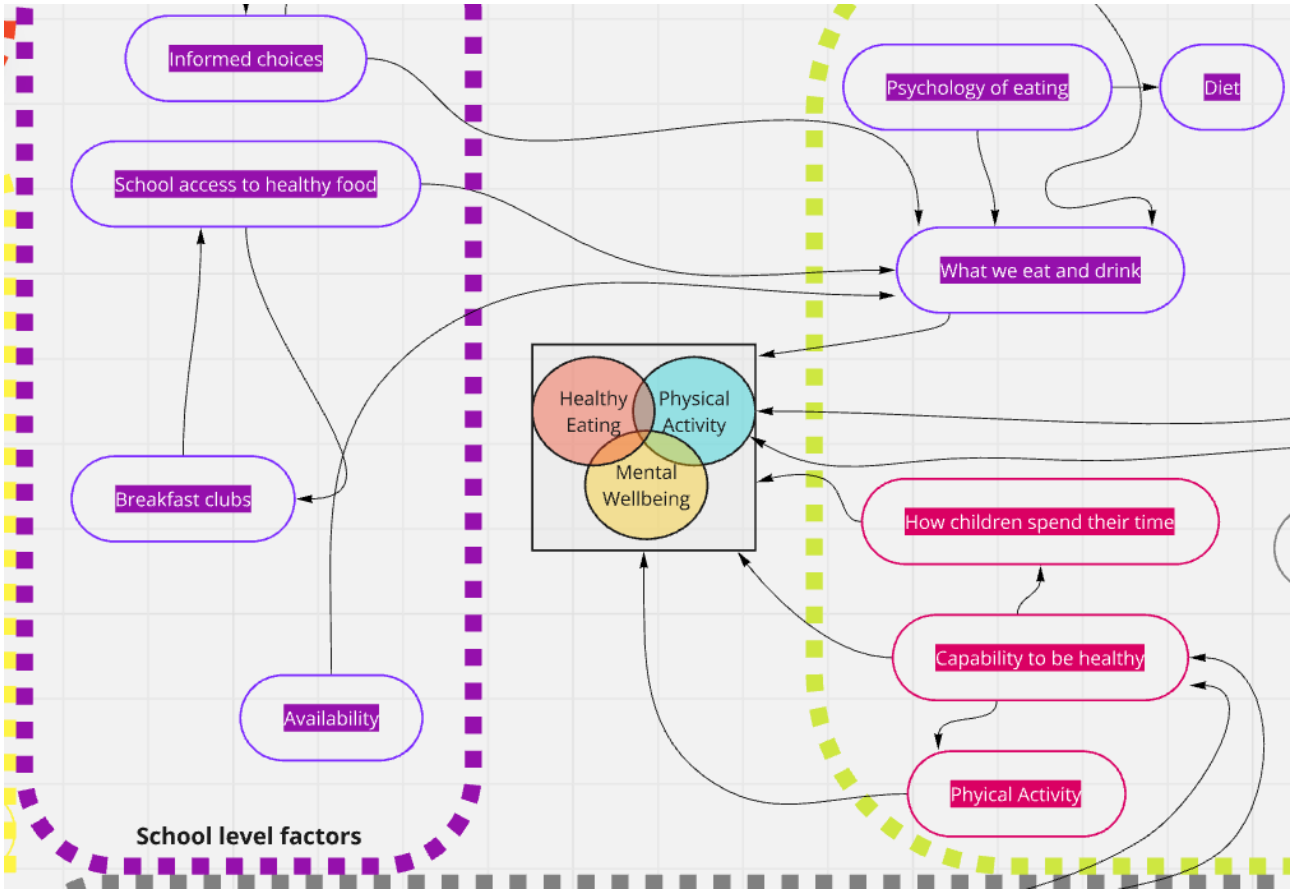
Our earlier work illuminated the way in which overweight and obesity are conceptualized by stakeholders as markers of a broader set of health challenges facing children and their parents around healthy eating, physical activity, and mental health. Within this project, we co-produced a systems-based logic model [29].

The intention of the original co-produced logic model was to identify contextual features of interest and how they interact to influence school-based interventions. Local authority decision-makers were identified as a key group who could benefit from the model, and it was thus designed with these decision-makers in mind. The model was co-produced with individuals possessing contextually relevant lived and professional experience across a series of workshops. Co-producing this initial model involved up to 13 co-producers located outside the university-based research team, in addition to another 6 university-based co-producers.

The original logic model consists of almost 150 factors and subfactors that were viewed by co-producers and researchers as important contextual influencers of school-based weight management interventions (with the outcome reflecting the intersection of healthy eating, physical activity, and mental well-being; Figure 1). These factors were split across 10 domains, which represented broad categories of "topics": media, infrastructure and environment, food, developmental, school, psychological, biological and medical, activity, economic, and "other." Factors were also split across several ecological levels that influence children's health from the individual through to a broad cultural level. The model was created using the software Miro (Miro), where one could shift between an overview of the model (snapshot shown in Figure 1) and more detailed depictions of factors and subfactors within each domain.

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Figure 1. Snapshot of part of the Co-production of Evidence for Public Health Interventions (CEPHI) logic model.



This array of factors provided a theoretical basis for examining the "whole system" and had an emphasis on socioeconomic and sociopolitical factors [18]. Among the co-production team, this emphasis was viewed as important in shifting the narrative away from one where personal responsibility had previously dominated discourse. Through co-producing the model, the focus of the theorizing switched from a narrow focus on BMI to a more holistic understanding of the components of weight management, namely the intersection of healthy eating, physical activity, and good mental well-being. This "whole outcome" focus also underpins the present research.

Despite the advances that this newer model was perceived to hold over existing models in the literature, the model and the process of its construction raised further analytical concerns. First, questions were raised about the complexity of the model and its practical utility. While depicting almost 150 factors and their relationships appeared to represent a comprehensive theory, the model provided little indication around the relative importance of these factors and where policymakers and practitioners should prioritize their work. Second, we were unsure of how to evaluate the success of the co-production and the extent to which our work had upheld the values of co-production.

The work that is reported here sets out to address these challenges through: (1) co-producing a "whole systems" and "whole outcomes" theory that prioritizes the contextual factors thought to be most influential on children's levels of healthy eating, physical activity, and mental well-being and (2) developing and piloting an approach to evaluating the success of the co-production. In particular, through building on an existing logic model and refining its contents, the aim of the work is to understand the value of co-production in helping researchers make sense of complex public health issues.

Aims and Research Questions

This study aims to contribute to developing evidence that better reflects the complexity of the social world, the experiences of people, and the types of questions that arise in public health decision-making [20,30]. Theorizing the features of systems that promote and inhibit health benefits from the perspectives of a wider range of co-producers. However, identifying the optimum ways in which people can come together not only to identify the multifarious features of a system, but also to make decisions about their relative importance, is unclear. Moreover, the optimal way of identifying how and if co-production works in practice and from the perspectives of all co-producers has not been established. This study examines these challenges, and our work was guided by the following research questions:

1. What do we, as a team of co-producers, theorize are the most important contextual features for policymakers, practitioners, and other stakeholders to consider when planning school-based weight management interventions?
2. How can we, as a team of co-producers, understand the difference we make when working together?
3. How did we perceive the way we worked together and what did we learn about the process of producing and refining a theoretical model?

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Methods

Overall Approaches

Overview

This research involved the following approaches:

- To address research question 1, we co-produced a refined theory through a series of workshops and activities to understand the contextual influencers that could help inform the design of policies, interventions, and research, and support the interpretation of evidence on school-based weight management interventions (led by DK and RCE).
- To address research question 2, we undertook a critical review of existing tools to understand their features and developed a new approach to understanding the depth of co-production (led by MK).
- To address research question 3, we evaluated our practice and identified lessons to support future co-production drawing on survey-based and workshop-based approaches (led by LR and VB).

This study is part of a larger study (underway at the time of this writing), and a protocol for the full study is available on the National Institute of Health Research's Funding and Awards database (see NIHR161485) and registered on the Research Registry (unique identifying number: researchregistry10035). In addition, a protocol for the study addressing research question 2, which took the form of a methodological substudy, is available on the Evidence for Policy and Practice Information (EPPI) Centre website.

The logic model included the emphasis on a "whole outcomes" approach to weight management (the intersection of healthy eating, physical activity, and mental health) that was important to co-producers from different backgrounds. It also is a "whole systems" model that includes considerations from different socioecological contexts, from broad cultural factors to family-level factors [31].

However, while the existing model represents the views of stakeholders, it is also large, complex, and was viewed as unwieldy by some stakeholders (see partial snapshot in Figure 1). The model occupies an uneasy balance between representing some contextual factors of importance (although not all) and can be understood as a partial representation of the complexity of child health with respect to weight management; at the same time, the model is nuanced and complex and does not have a clear starting point for supporting decision-making.

Methods for Co-Producing a Refined Theory

Reworking the Co-production of Evidence for Public Health Interventions (CEPHI) logic model involved a series of co-produced workshops in which the initial model was to be refined and involved a core team of 6 members. This core team was comprised of 3 researchers from University College London (UCL) and 3 co-producers based outside UCL (AOME, DK, RCE, PTN, SC, and SS). All co-producers had different blends of relevant lived, living, professional, and practice experience. The co-producers outside UCL were recruited through an open call, and screening conversations were conducted to ensure their availability and commitment to the project. Recruitment happened through UCL's Co-production Collective, a diverse community of people from a variety of backgrounds who come together to learn, connect, and champion co-production. Joining the workshops was a co-production expert from UCL's Co-Production Collective who was also an integral team member (VB). Two of the UCL researchers were involved in the creation of the original logic model (AOME and DK).

From April to November 2024, the team engaged in a series of eleven online workshops (totaling 17.5 hours) to refine the existing WOWS logic model for child health. To integrate a greater range of perspectives, we also sought wider stakeholder feedback on an initial draft of the refined model in Autumn 2024 (led by TE). To support our co-production, all co-producers received training in co-production during the first workshop. This training involved familiarizing the co-producers with the values and principles of co-production, clarifying expectations around ways of working and communication, and establishing a shared agreement to guide the collaborative process. The team also co-produced a shared agreement, which helped to clarify expectations around ways of working and communication.

Co-production workshops adopted a semistructured format. UCL-based researchers (DK and RCE) would prepare a loose agenda in advance and act as chair, taking notes and ensuring the workshops progressed. Workshops typically began with a brief presentation from UCL researchers, which would be followed by open discussion. The small size of the team meant that all co-producers typically had the opportunity to feed into each point raised in the discussion. Most workshops were recorded, and following the workshops, EPPI Centre researchers circulated summaries of action points and/or decisions made. All co-producers were encouraged to contribute any additional thoughts or questions between workshops.

Throughout the project, we aimed to enact the values of co-production identified through previous research and by the Co-Production Collective [21,25].

Methods for the Development of a Tool to Support Evaluation of Co-Production

This work aimed to:

1. Identify tools and resources that are available to assist in evaluating co-production and understand their features
2. Use the evidence in (1) to inform the co-production of a tool to evaluate co-production of the WOWS project

These aims were met through undertaking a brief review of the most widely applied tools for evaluating co-production. We recognized that tools used to support, report, and evaluate other forms of patient and public involvement may also be useful to consider and included these as appropriate in the review. This brief review itself was not co-produced, although MK, who led this strand, worked closely with the core co-production team and informed their decision-making in developing the evaluation tool. Further details of how the tool was developed are also available elsewhere [32].

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Methods for Evaluating Our Practice in Co-Production

Overview

The third strand of this project involved trialing the new tool and approach for evaluating co-production. This new tool had not been trialed previously, and there were no set guidelines for how it should be administered. This stage of the work involved:

1. Testing the tool itself, developing the approach for administration, and reflecting on this new approach to evaluating co-production, as well as
2. Generating substantive data on how well we perceived that we had worked together and how much the research (in this case, the logic model) reflected all of our input.

LR reviewed the evaluation tool and developed the process for implementing the tool. VB mediated between the core co-production team and LR. LR remained external to the co-production team. LR became a co-evaluator toward the end of the project, analyzing and preparing the data to share with co-producers, observing the final workshop, and leading a reflective workshop.

The evaluation was structured across stages:

Stage 1: Individual Summaries and Feedback

All team members started by completing the evaluation tool and LR created individual summaries of our responses. These summaries provided a personalized account of our experiences and perceptions. Each summary included a visual display of our ratings, significant changes in ways of working, and personal reflections on the co-production journey.

Stage 2: Individual Sense Check

Each co-producer was then given the opportunity to review their individual summary during this phase. This allowed all members to confirm agreement with the content and make any necessary amendments. Team members could highlight any omissions or request the removal of information they preferred not to disclose.

Stage 3: Collective Sense-Making

Amended summaries were then integrated into one summary document by LR and shared across the core co-production team prior to a collective sense-making session. This session was critical as it moved the evaluation from individual reflections to developing a collective understanding. Collective sense-making involved a group discussion where key themes and learnings were identified, starting with a visual representation of all individual ratings and working to create a common narrative around how we worked together. A record of this session was then produced and reviewed by the co-production team, a summary of which is reported here.

Ethical Considerations

This research was conducted following the UK Health Research Authority's research ethics framework. Ethical approval for the co-production evaluation (REC2046) and stakeholder engagement (REC2053) was granted from the UCL Institute of Education Research Ethics Committee. Informed consent was collected from all co-producers involved in the evaluation of the co-production (but not the stakeholder engagement, as there were no research participants). The consent process was co-produced and was in the form of a shared agreement to which all co-producers signed up. This agreement included that co-producers had the right to withdraw at any time, provisions around anonymity and the right to withdraw direct quotes from being published, and that the decision to be named on the final paper was voluntary. Ethical approval for the creation of the logic model was not needed, as this was conceptual work and there was no research data involved.

Results

Describing the Process of Working Together

As a group, we developed criteria around how to prioritize elements of the existing logic model. We started by reviewing the literature on prioritization in public health decision-making, which provided a sense of general categories of criteria that are often applied [33,34]. A few options were presented to the wider team, who were also encouraged to identify additional criteria. After detailed discussion, we decided on a set of 6 questions that were used as a reference when prioritizing the factors and subfactors:

1. Is the feature or pathway likely to impact a large number of children?
2. Does the feature or pathway impact disadvantaged children disproportionately?
3. Is the feature or pathway actionable through local interventions?
4. Could focusing on the feature or pathway stigmatize children and families?
5. Is this a factor that is important because of your experience or the experiences of those you know?
6. Is this a factor that appears most logical to you?

We co-produced a detailed strategy on how to apply these criteria to rank the most and least important features (see Multimedia Appendix 1). We then applied these criteria to each domain to determine if and how the factor and subfactors should be retained and produced an initial draft of the refined model. In addition to the ranking questions, space was also provided within the Qualtrics (Qualtrics) form for us to name any factors we felt were missing, describe the rationale behind our ranking decisions, and name a factor we felt should definitely be retained in the revised model. This latter question was added to ensure that underrepresented perspectives were not lost by only taking the majority view.

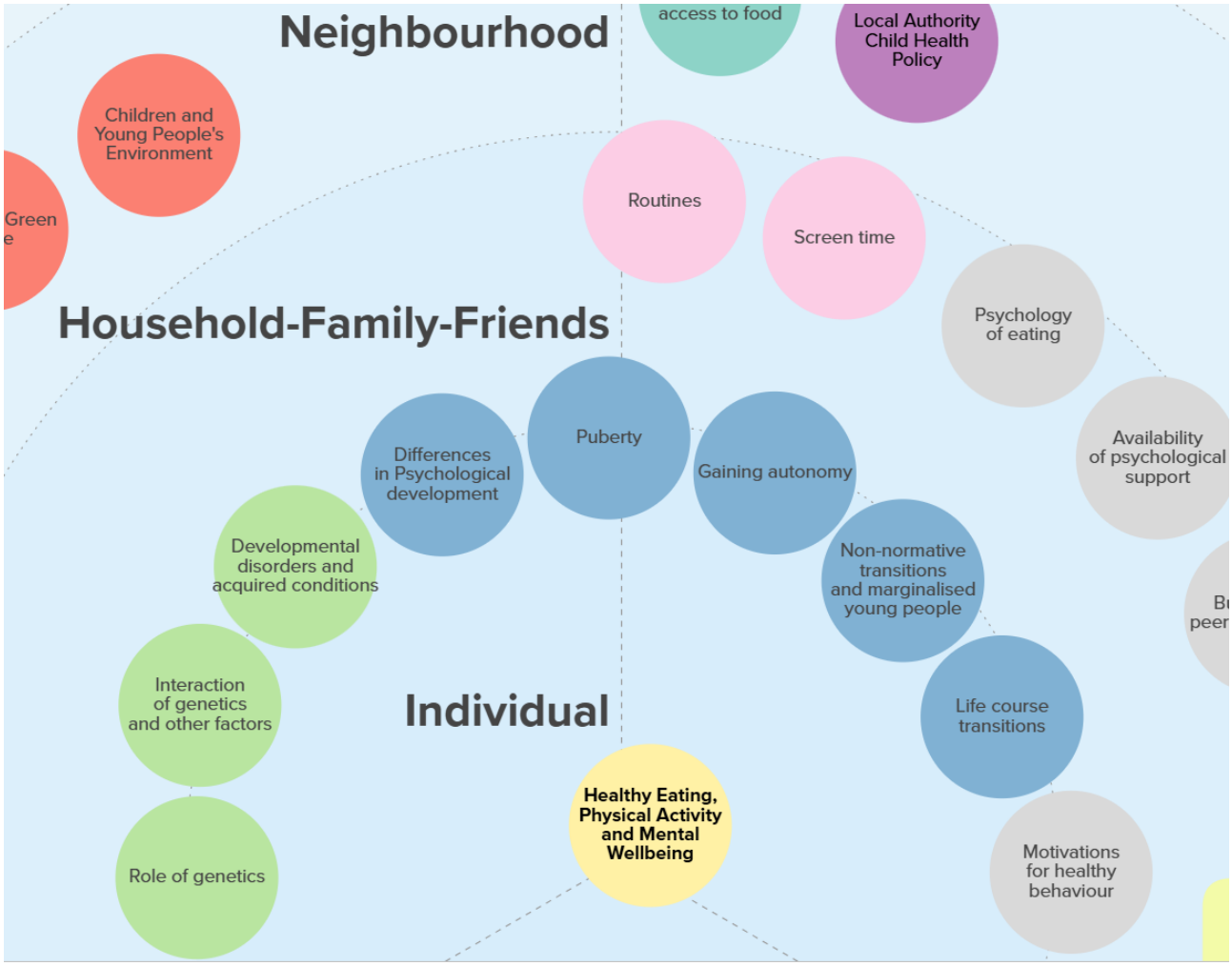
Visualizing the Updated Logic Model

Following the refinement of factors and subfactors in the logic model, EPPI Centre researchers explored how the model could be visualized to be engaging, usable, and accessible. It was decided based on expertise and feedback from the co-producing team that we would use the website Kumu. We drew on the social-ecological model to depict the ecological levels as concentric half circles. The circles broadened from the individual level in the center through sociopolitical and economic levels at the outer edges (Figure 2). The domains were identified through color coding of the factors, which were placed within their corresponding ecological level. Clicking on a factor would bring up a box on the side of the screen containing a detailed

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description. We chose not to distinguish between factors and subfactors in the updated model.

Figure 2. Snapshot of the first draft of the refined logic model in Kumu.



The refined model was discussed among the co-production team, which provided the opportunity for feedback on both the final list of included factors and subfactors and the visualization. These discussions identified that the omission of the views of children and young people was a weakness, as well as the absence of a wider set of perspectives. It was agreed to explore stakeholder engagement to address these gaps.

Stakeholder Engagement

Overview

As part of our earlier workshops, we identified several relevant voices and perspectives that were missing from within our team. To incorporate these wider perspectives within the model, we invited external stakeholders with lived, professional, and academic expertise to provide feedback on the refined model. We did this in three ways: (1) a blog, (2) engagement with undergraduate students, and (3) further purposive engagement with young people (led by TE).

Blog

We wrote a blog (see Multimedia Appendix 2) on the EPPI Centre website explaining the purpose and context of the logic model and requesting anonymous feedback through a free-text box on the blog [35]. We indicated that we were particularly interested in feedback relating to the following questions:

- Which factors are missing?
- Which factors need a better description?
- How holistic is the model?
- How accessible is the model?

We publicized the blog that included a request for feedback through a range of channels, including X (X Corp), LinkedIn (Microsoft Corp), and through email lists.

Engagement With Undergraduate Students

As part of a seminar activity for a public health undergraduate module, students were tasked with exploring and discussing the model. We obtained verbal feedback from 2 groups of approximately 15 undergraduate public health students.

Purposive Engagement

To ensure that we obtained input from a broader spectrum of young people, one of the wider teams (TE) engaged in informal conversations with young people aged 16 - 24 years, discussing the contents of the model and asking for suggestions for improvement.

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A final workshop with the co-production team allowed us to reflect on the results of the stakeholder engagement (see Multimedia Appendix 3) and consider if/how suggestions could be incorporated.

What Do We, as a Team of Co-Producers, Theorize Are the Most Important Contextual Features for Policymakers, Practitioners, and Other Stakeholders to Consider When Planning School-Based Interventions for Improving Children's Health?

The new logic model, a snapshot of which is reproduced below (Figure 3) and which can be explored in full here [36], provides a working theory of the 52 factors that influence the whole outcome of healthy eating, physical activity, and mental well-being among children. Across 7 socioecological levels, plus an eighth denoted as "cross-cutting demographic factors," the model illuminates the factors theorized to influence the outcome and which can either be the subject of an intervention (eg, breakfast clubs) or which may influence the transferability of an intervention effect (eg, features of the economic system including capitalism).

Figure 3. Snapshot of the final draft of the refined logic model.



Greater weight is given to the factors that could be considered broader systemic and policy factors that do not focus on changing individual behaviors but are, nevertheless, theorized to influence population health through structuring the environment for health decisions. This greater weight is reflected both in the number of factors, for example, 18 factors are included in the "economic" and "sociopolitical" layers versus 15 factors in the "individual" and "household, family, and friends" layer, as well as the size of the factors (larger in the outer semicircles than the inner semicircles; see Figure 3). These features reflect the narrative of discussions that took place within co-production workshops, which rejected a focus solely on personal or parental responsibility and instead involved greater acknowledgment of the influence of socioeconomic and sociopolitical contextual factors. This means that factors in the food domain, for example, only start to appear at the neighborhood level through the "availability and geographic access to food," and that previous factors such as the level of energy drink consumption (which had been included within the "individual" level) have been deprioritized and may instead be reflected in policy-level factors such as the "regulation of the food industry." In this sense, the model theorizes that important contextual influencers of children's health occur "upstream" at the economic, sociopolitical, and cultural community and social media levels. This is commensurate with classic public health theorizing about the importance of both the social determinants of health and upstream interventions.

The model also helps to identify elements of the context within schools themselves that influence weight management behaviors. For example, these included conscious and unconscious bias and stigmatizing behaviors in the school environment (stigma) and the extent to which schools engage with all children. With respect to the latter, one of our team members reflected that "engagement with [all] children was a particularly sensible choice for me because of the ripple effects that success with this population would have on a generation of minority children and families."

Our new model also incorporates a greater focus on the life course and development, acknowledging that childhood is a time of flux and shaped by complex interactions between genetics and environment. These factors, rather than behavioral

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factors, are now represented at the individual level. We also theorize that these transitions—their timing, meaning, and nature—differ by individual characteristics, although they have historically been viewed solely through the lens and norms of nonmarginalized (ie, socially included) people. More broadly, the model acknowledges that the influence of all the factors across the levels is moderated by "cross-cutting demographic factors" including ethnicity, sex, and gender identity.

What Has Changed in the New Model and How Will It Be Used

The new model offers a more streamlined theory of the system to consider when planning school-based weight management interventions. It has reduced the number of factors included from 144 to 52 (see Table 1) and gives greater weight to factors that are influential outside the individual and household levels. While the influence of upstream factors was acknowledged in the original theorizing, this has been further emphasized in this iteration.

Table . An overview of the contents of the different domains within the logic model (see text for further information).

Domain name	Number of factors (previous total number of factors and subfactors in brackets)	Number of levels in which the domain is represented (previous number in brackets)
Psychological	9 (25)	4 (5)
Infrastructure and environment	4 (7)	2 (3)
Media	4 (5)	1 (1)
Biological and medical	3 (4)	1 (1)
Activity	3 (14)	1 (6)
Schools	6 (12)	1 (2)
Developmental	5 (3)	1 (1)
Economic	5 (13)	1 (3)
Food	9 (39)	4 (7)
Policy (previously other)	4 (22)	3
All domains	52 (144)	8 (including cross-cutting trends; no change)

Each factor now includes text to support its inclusion, mainly sourced from the co-production discussions (and supplemented where needed), to aid in clarity. Some of the nomenclature has changed, alongside the visualization of the model. Stakeholder engagement informed the way we conceptualized demographic factors so that they were represented as moderating factors at all levels.

Finally, one key change between this model and the previous is the absence of connections between the factors that had indicated the putative causal chains. This omission is deliberate, as the associations between the factors will be investigated and evidenced in later planned work, as well as interventions that could be implemented. However, the size and design of the model do convey the direction of expected effects, with factors at the economic and sociopolitical level viewed as catalysts that influence how factors in layers that are situated closer to the individual are experienced.

How Can We, as a Team of Co-Producers, Understand the Difference We Make When Working Together?

A more detailed account of the results of the brief review is published elsewhere [32]. Here we focus on the main themes emerging from the review and how these informed the development of elements of the tool developed to evaluate co-production. Based on the analysis of 16 papers and 5 tools, the review identified that existing guidance and resources were more oriented toward supporting the conduct of co-production, embedding it within practice, and reporting co-production, rather than evaluating process or change. Nevertheless, tools and frameworks provided important signals on what could be included when designing a tool to support evaluating co-production, including the need to capture power dynamics, role expectations, and if co-producers felt valued [32]. The themes were used to develop a first iteration of a tool, designed as a self-completion survey, for evaluating the process and influence of co-production. The tool was discussed within co-production workshops and developed further. A third iteration of the tool was used to evaluate the process and influence of co-production in developing the logic model. The full tool, which we refer to through Synthesizing Through Reflection And Participatory Sense-making (STRAPS), is reproduced in [32], and some of the results are presented below.

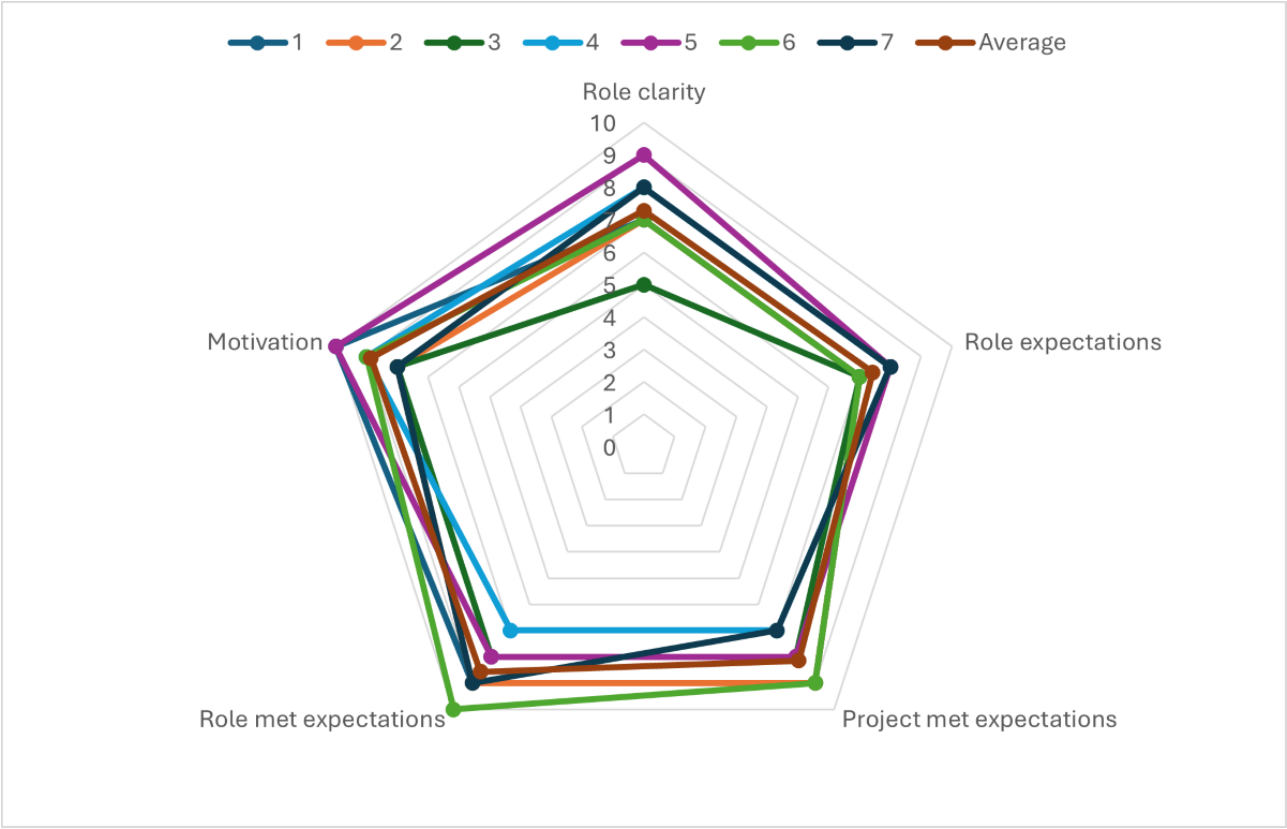
How Did We Perceive the Way We Worked Together and What Did We Learn About the Process of Producing and Refining a Theoretical Model?

The radar chart in Figure 4 shows ratings for items relating to the role expectations, role clarity, and motivation. Scores close to the middle of the chart may indicate a lack of clarity about the role or project or that expectations of the project or role have not been met. For motivation, scores closer to "0" indicate low motivation, and those closer to the edge indicate high motivation (extremely motivated). Role expectations and role clarity showed some variation, with some of us feeling hesitation on what our role was and the expectations on us when the project started. This may also reflect that co-production is a relatively new way of working. Open-ended questions suggested that

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clarity of role improved over time through the process of working out "what to do and how to do it." Motivation was high for many of us, and some of us described how working together helped to sustain our motivation. As one of us also reflected, the purpose and end goal of the research itself was also a motivating factor, "the realization that this logic model could inform policy which could then be seen in cafeterias around the country, perhaps in local supermarkets, and neighborhood parks was humbling." A number of challenges were also raised. These included that a lack of clarity around the role meant we were unclear about how much of our personal or lived experience to contribute to the decisions being made. Another challenge surrounded some of the bureaucratic hurdles we faced (particularly around ethics; see also limitations), which meant that some of the time that we should have taken understanding the processes of co-producing the model itself was instead diverted to understanding and navigating obstacles to the research.

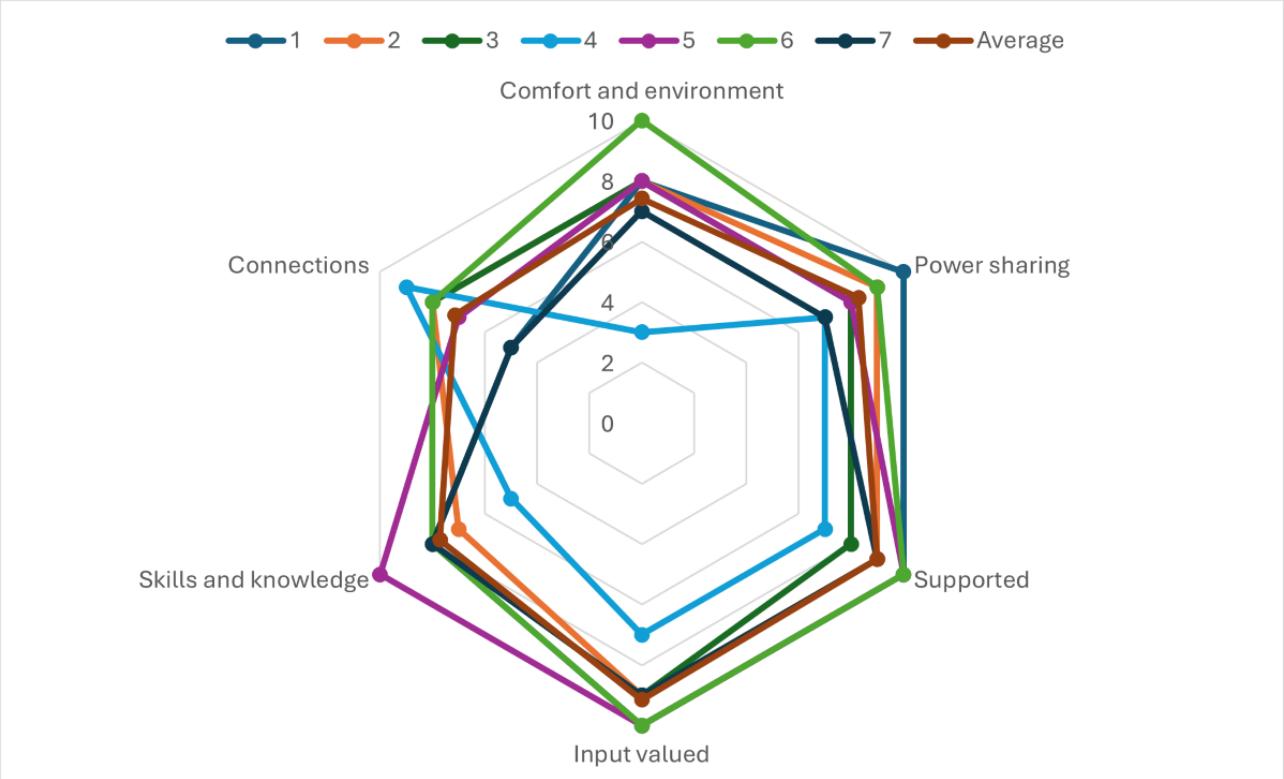
Figure 4. Radar chart showing all team members and average ratings for factors related to role, expectations, and motivation.



We had highly varied scores when it came to assessing the comfort and environment for co-production (Figure 5). Two of the factors that appeared to undermine how comfortable we felt included were (1) uncertainty about how our contributions would "land" with our fellow co-producers and (2) the challenges of working online. Most of us reflected that our contributions were valued and respected and that we developed an "unspoken consensus on equal participation and making all co-producers' contributions visible." For some of us, this was something that evolved over time as we observed that our contributions were valued and as we built relationships, creating something of a virtuous cycle. Not all of us agreed on all points, although "even where there wasn't consensus there was always validation and acknowledgment of different opinions and a genuine attempt to explore those further." In addition, it was noted that together we put into place a process for decision-making to prevent minority issues from being voted out by majority view. However, while we adopted an approach where "nothing was predetermined" and all views were considered, some of us observed that sometimes more scaffolding to support decision-making would have been helpful. Finally, although we felt that while we had developed a good "working" relationship, we had missed opportunities to "speak about ourselves in a way that could build a connection beyond our synchronous workshop time."

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Figure 5. Radar chart showing all team members and average ratings for factors related to co-production processes and outcomes.



What Were Our Reflections as We Made Sense of Things Together?

Much of our conversation explored the challenge of understanding our positionality (our potential biases and benefits) and thinking about how we share our understanding, views, and experiences.

We acknowledged that social anxieties generally, as well as social preferences, norms, or cultural influences and expectations (eg, not doing small talk, working or living in a different country), have an influence on the way we interact with each other and how we felt at the end of a co-production workshop. Some of us felt that we might want to share more about ourselves in co-production activities in the future, while others of us felt that the process in this project had given us confidence to share personal stories and recognize that "the people around you are not there to judge you, they are, if at all, they can help you, and if nothing else, they can listen." We recognized that the impacts of the project and working together were unexpected and, for some of us, transformational. This experience helped us to feel more relaxed when communicating with others and encouraged us to think about our relationships more broadly.

We noted the need to overcome pragmatic challenges that could facilitate future exercises and, particularly, some of the difficulties those of us outside UCL faced in claiming compensation for our time. An unresolved challenge we also recognized was the productive tensions that arise in co-production spaces, for example, where academic knowledge conflicts with lived experiences. We questioned how this type of tension can be navigated in the future so that nothing is overlooked and people still feel valued. Some of the places where we did identify some factors that could support co-production in the future were around (1) allowing time for an informal update at the start of meetings that could be personal; (2) considering the possibility of meeting in person, perhaps at the beginning of co-production; (3) building in more discussion at the beginning of co-production around positionalities; and (4) developing and/or communicating role expectations and levels of autonomy more clearly at the beginning of projects.

How Did the Tool and Evaluation Process Help Our Learning?

We reflected that having more continuous and reflective learning during the project would allow us to implement changes (if any are needed). This can also be seen as part of relationship building, power sharing, and "being human." However, we also acknowledge that the experience and perceived benefits of co-production are not linear, and in our earlier evaluations, we acknowledged that some of us experienced periods where we felt disconnect or a lack of clarity, which were subsequently resolved. We reflected that the process for administering the tool developed by LR and VB worked well, and most of us liked seeing our collective reflections from our individual reports as a prompt to help us during collective sensemaking. However, we noted that this may not always be the case, and there may not be the same level of comfort in sharing experiences in future projects.

All of our reflections were about the way we created the logic model and not around the logic model itself. This is perhaps further testament to the value of the tool in measuring the process of co-production, but there may be an opportunity to further tease out the perceived value of co-production in the future.

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Discussion

Summary of Findings

This study aimed to co-produce a logic model that could be used to plan future research. This model would explore which factors influence children's healthy eating, physical activity, and mental well-being (our whole outcome), with a focus on weight management and school-based interventions. We used a preexisting logic model that had itself been co-produced [18] and aimed here to co-develop this further through establishing a collaboration between co-producers based within and outside UCL. The existing model, while rich and nuanced, was complex and challenging to use to support research and policy in this form. As part of a project taking a "whole outcomes whole systems" approach to evidence, we aimed to explore how further co-production could identify which features should be prioritized in future investigations. The next stages of the research involve us first evidencing the putative pathways through secondary data analysis, and then exploring which interventions may be promising in supporting the promotion of childhood health.

Given that this is a co-produced model, we also wanted to understand how well we had worked together. While we acknowledge that our brief review was not comprehensive (or intended to be), we also observed that many of the available tools, frameworks, and guidelines support users on how to understand and undertake co-production in very specific contexts. Other tools, such as Guidance for Reporting Involvement of Patients and the Public Version 2 (GRIPP2; GRIPP2 Study Group) [37], support the reporting of public involvement in research. Similarly, a number of other tools have been developed to help to evaluate and understand the impact of public involvement more broadly in research [38-40]. However, a gap identified here was in tools that could be used to evaluate the process of co-producing research. While we acknowledge clear overlaps between co-production and other forms of involvement, of particular significance for our needs was the inclusion of questions around power and relational dynamics. The tool proposed and piloted here represents a contribution to addressing this gap for our future projects in the evidence synthesis London Alliance for the Co-production of Evidence Synthesis group. We also questioned whether there was more opportunity to evaluate the difference that co-production makes to the research itself using this kind of approach.

A key output of this research is the generation of a logic model that is the product of a number of different co-producers coming together to identify factors and later prioritize these factors. While created through the input of co-producers with multiple roles and identities, the theorized model embodies a number of the arguments set out earlier around the need to account for complex systems and the need to examine health outcomes holistically. In addition, the model also mirrors calls in the literature to avoid drawing closely on narratives of personal responsibility [41], which perpetuate cultures of stigma around weight and weight management [42], and instead highlight the need to (1) focus more closely on upstream factors and the social determinants of health [43] and the need to (2) consider developmental and demographic characteristics when planning policies and interpreting evidence [44]. Our work illustrates that these are not simply lofty ideals; instead, they are how many people see the world and how they want academics and those in power to see the world. The contribution of the theory developed here is the rejection of these stigmatizing modes of evidence production, although we acknowledge that this theory has not been evidenced at this point.

Strengths and Limitations

There is emerging familiarity among researchers around the transformative nature of co-production, although there exists uncertainty on how to embed co-production as "normal" research practice [25]. Some of this uncertainty is reflected in the observations made here, for example, the absence of a clear tool to evaluate co-production. However, some of this is also reflected in the limitations we encountered in co-producing this study, including navigating ethical structures. Co-producers of research are not research participants, and conflating co-producers with research participants, for example, by requiring their consent to become researchers, undermines the very endeavor of co-production as a transformative way of working aimed at disrupting traditional power hierarchies in research production. We encountered a number of time delays navigating our own ethical structures, including a requirement to obtain ethical approval for stakeholder engagement, involving the publication of a blog and soliciting anonymous feedback on the logic model. By extension, this could mean that any dissemination activity needs ethical approval. Anxiety around public involvement not only causes delays but also reinforces power hierarchies between those deemed to have the capacity to become researchers and those deemed to lack capacity. While we acknowledge safeguards are needed for vulnerable groups, we question if imposition of a blanket policy could risk undermining future co-production. Certainly, our experience here speaks to the dissonance between institutional ethical review processes and the nuanced realities of undertaking co-produced research [45].

We also note that co-production blurs the distinction between "method" and "result," particularly as was the case here where the methods themselves are co-produced. Here, the method for prioritizing factors in the logic model was co-produced, as indeed was our whole way of working. This means that we emphasize in our reporting what was decided and how, as might be the case with a process evaluation [46].

UCL co-producers had envisaged up to 6 co-production workshops would take place at the outset, but in practice, the number of co-production workshops and off-line working outside of meetings exceeded this. Such observations could lend support to the concerns leveled elsewhere, which emphasize that the resources that it takes to co-produce research outweigh the benefits [47]. In response, we would emphasize that co-production can take a number of different models [21], and in this study, additional resources brought about significant benefits due to the way prioritization in the model was structured. At its essence, co-production involves academic researchers and those outside academic research working together and agreeing on which decisions will be taken by whom

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and how. Our chosen model here was to co-produce all decisions, including the number of workshops. On reflection, UCL co-producers acknowledge that this was a highly conceptual project, and the actual number of workshops was commensurate with the challenge of the task. We also reflected that had the project been co-produced from the outset, including co-producing the scope and timelines, then this complexity may have been identified earlier on and been reflected in a greater number of planned workshops.

Two other possible limitations are also worthy of highlighting. The first reflects the number of co-producers, which was lower than had been originally planned. Although stakeholder involvement widened the breadth of perspectives, and the original model had been co-produced with a much larger number of co-producers, this remains a possible limitation. The second is that the model itself does not contain any clearly distinguished causal chains, as might be expected, and even required, to fulfill the criteria of being a "logic model." While this is a potential limitation, we note that the size and design of the model do convey the direction of expected effects, and that several logic models only give a vague description of the direction of expected effects at the outset of research. Furthermore, these chains are expected to be evidenced further during the course of the project and later work packages.

Conclusions

As we reflected in the evaluation, this project was highly conceptual and involved co-producing a logic model, which is increasingly recommended within research and evidence syntheses [48]. The work reported here is further testament that this type of practical theorizing can be done with a variety of co-producers, which contributes to changing the focus of the research and challenges the lens of researchers at the outset.

In co-producing this research, our evaluation tool helped us to realize the challenge of bringing our multiple identities to research. The evaluation results also showed that developing clarity around how to work together, our roles in teams, and forming trusting relationships evolved during the project. As was reflected at one point in this work, "being inclusive takes time," although the clarity that the new logic model brings to supporting the later stages of the research and its potential contribution to informing debates on narratives of personal responsibility in health [49] demonstrates the value of working inclusively through co-production.

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Data Availability

The interactive logic model is freely available online [36]. This study did not involve the handling of any personal information. The co-production evaluations and transcripts from the reflective session are not publicly available as this would compromise the anonymity of the team members.

Authors' Contributions

Conceptualization: DK, RCE, AOME
Methodology: DK, RCE, MK, PTN, SS, SC, LR, VB, TE, AOME
Formal analysis: DK, RCE, MK, PTN, SS, SC, LR, VB, TE, AOME
Investigation: DK, RCE, MK, PTN, SS, SC, LR, VB, TE, AOME
Data curation: DK, RCE, MK, PTN, SS, SC, LR, VB, TE, AOME
Visualization: DK, RCE, AOME
Supervision: DK, RCE, AOME
Project administration: DK, RCE, AOME
Funding acquisition: DK, AOME
Writing – original draft: DK, RCE, AOME
Writing – review & editing: DK, RCE, MK, PTN, SS, SC, LR, VB, TE, AOME
We would like to acknowledge the contributions of members of the LACES Advisory Group and a Voluntary Research Assistant.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Details of the prioritization approach.
[DOCX File, 24 KB - jopm_v18i1e80309_app1.docx]

Multimedia Appendix 2
Blog to elicit stakeholder feedback.

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[DOCX File, 25 KB - jopm_v18i1e80309_app2.docx]

Multimedia Appendix 3
Summary of stakeholder feedback and response.
[DOCX File, 25 KB - jopm_v18i1e80309_app3.docx]

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Abbreviations

CEPHI: Co-production of Evidence for Public Health Interventions
EPPI: Evidence for Policy and Practice Information
GRIPP2: Guidance for Reporting Involvement of Patients and the Public Version 2
STRAPS: Synthesizing Through Reflection And Participatory Sense-making
UCL: University College London

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Integrating Data Visualizations Into Digital Mental Health Care for Adults With Anxiety and Depression: Participatory Design and Case Study

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Abstract

Background: Digital phenotyping offers unprecedented opportunities for capturing real-time mental health data through smartphones, yet translating this data into clinically actionable insights remains challenging. While smartphones can generate nearly one million data points per patient per day, health care systems have struggled to incorporate even basic ecological momentary assessment data into routine care workflows.

Objective: This paper presents a model for clinician-facing data visualizations that can be shared with patients to increase understanding of mental health symptoms and enhance shared decision-making. We describe (1) a participatory design process through which visualizations were cocreated with clinicians; (2) integration of these visualizations into a Digital Navigator-supported (DN) workflow; and (3) a case example illustrating how data visualizations can enhance patient insight and support treatment adjustments.

Methods: This work was conducted within the Digital Clinic program at Beth Israel Deaconess Medical Center. Fifteen clinicians and 3 clinical supervisors participated in a participatory design process to develop visualizations meeting clinical workflow needs. Data visualizations were integrated into weekly DN sessions following a 3-phase model (guide, refinement, and autonomy) based on self-determination theory.

Results: Six visualization types were developed: gauge charts for engagement behaviors, symptom trajectory graphs, correlation matrices linking passive and active data, sleep visualizations, polar/radar charts for multidimensional assessment, and passive-active data integration graphs. A clinical case demonstrates how these visualizations, when delivered through structured DN facilitation, supported patient engagement, behavioral insight, and autonomous self-management across an 8-week treatment program.

Conclusions: Thoughtfully designed data visualizations, when developed collaboratively with clinicians and delivered through structured support, can transform digital phenotyping from a technical capability into a practical tool for enhancing engagement, promoting behavioral insight, and supporting self-management in digital mental health care. Future research should examine how this approach affects therapeutic alliance and clinical outcomes across diverse patient populations.

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KEYWORDS

data visualization; digital phenotyping; patient engagement; mental health; digital mental health; digital navigator

Introduction

Patient engagement is essential to delivering effective health care. Despite many digital health tools offering impressive efficacy data, their real-world effectiveness has been less impressive due to low real-world engagement [1]. While there are many pathways to improve engagement, extensive efforts in better design, patient cocreation, and gamification have yielded only modest improvements [2]. Another pathway, data sharing, has been less explored. In this paper, we examine how data visualization can drive clinical engagement with digital health tools.

Data sharing in the era of digital health holds untapped potential. The widespread availability of smartphones, owned by over 90% of Americans and 50% of the global population, has created unprecedented opportunities for capturing real-time health data [3,4]. Through digital phenotyping, the process of quantifying human behavior using personal smartphone data, clinicians can access rich information, including sleep patterns, physical activity, mobility routines, screen time, and self-reported

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symptoms through ecological momentary assessments (EMAs). Numerous reviews highlight that such data can inform preventive, predictive, and more responsive care across the spectrum of mental illnesses [5,6].

However, this data richness presents a formidable barrier to clinical integration and shared decision-making. Modern smartphones can generate nearly one million data points per patient per day when continuously sampling GPS and accelerometer data at standard frequencies [7]. Health care systems have already struggled to incorporate even basic EMA survey data into routine care workflows, and the volume and complexity of passive sensor data amplify these challenges [8]. Bringmann et al [8] developed ESMvis, one of the few tools created to display individual experience sampling method (ESM) data for clinical use. Their work highlights both the promise and the challenge of turning detailed, real-time data into formats that clinicians can quickly understand during short appointments [8]. More broadly, research shows several barriers to using ESM in routine care: limited clinician time, uncertainty about how to interpret fluctuating moment-to-moment data, and a lack of clear workflows for reviewing results [9-11]. Qualitative studies also find that while patients appreciate the self-reflection encouraged by ESM, they often want structured guidance to help them understand their data [11]. Likewise, clinicians report preferring clear, actionable summaries rather than raw data streams. Emerging evidence suggests that both clinicians and patients are receptive to digital phenotyping data when supported by clear, interpretable formats. A 2022 survey of UK clinicians found openness to incorporating digital phenotyping data when interpretation support was available [12], and related research indicates clinicians want actionable information summarized from raw behavioral data rather than unprocessed outputs [13]. Similarly, patients express willingness to share personal data if they trust the recipients and can derive meaningful insights from what they share [14].

To address this challenge, our team at the Digital Clinic at Beth Israel Deaconess Medical Center (BIDMC) has developed data visualizations that translate complex digital phenotyping data into clinically interpretable formats, supported by a structured workflow for their use in care [15,16]. Central to our model is the Digital Navigator (DN), a trained member of the care team who supports technology-enabled care and guides patients through the interpretation of visual data reports in structured weekly sessions [17]. Unlike models where patients access data independently, this approach ensures that visualizations function as communication tools that support collaborative decision-making rather than standalone interventions. This workflow positions the DN as a guide who helps patients progress toward autonomy in understanding their own data.

This structure mirrors the broader Digital Clinic model, in which digital tools, such as the mindLAMP smartphone application and weekly data reports, support reflection, shared understanding, and care coordination, while clinical treatment is delivered through clinician-led psychotherapy and skills-based interventions [18].

In this paper, we present a model for clinician-facing visualizations that can be shared with patients and targeted to their specific conditions to increase both patient and provider understanding of mental health symptoms and enhance shared decision-making around disease management. We illustrate (1) a participatory design process through which visualizations were cocreated with clinicians to meet clinical workflow needs, (2) integration of these visualizations into a DN-supported workflow, and (3) a detailed case example illustrating how data visualizations, when paired with structured facilitation, can enhance patient insight, contextualize symptom fluctuations, and support real-time treatment adjustments.

The visualizations depicted here are currently in use in both research and clinical settings within the Digital Clinic program [18,19]. The aim of this paper is to describe a replicable model for integrating clinician-informed data visualizations into a DN-supported clinical workflow for digital mental health care. Specifically, we aim to (1) document the participatory design process through which visualizations were developed, (2) describe how these visualizations are embedded within structured DN sessions, and (3) illustrate through a detailed clinical case example how this approach can enhance patient engagement, promote behavioral insight, and support the development of autonomous self-management skills.

Methods

Ethical Considerations

This work was conducted as a quality improvement initiative within the Digital Psychiatry Clinic program at BIDMC. The project was reviewed by the BIDMC Institutional Review Board and determined to be a quality improvement activity, not human subjects research, and therefore exempt from Institutional Review Board oversight (Protocol # 2022D000016). The case example presented was deidentified, and identifying details have been modified to protect patient privacy. No compensation was provided as part of this work.

All data visualizations were generated using Python-based tools applied to data stored within institutional infrastructure, with processing supported by Cortex, an open-source pipeline developed by the Division of Digital Psychiatry specifically for mindLAMP-based studies. Phenotyping data include passive metrics (such as entropy, home duration, screen duration, and step count) and self-reported survey responses collected at daily and weekly frequencies. Passive signals are aggregated and deidentified so that precise locations and raw GPS traces are not stored or displayed to clinicians. In the current implementation, all identifiable clinical and digital phenotyping data remain under the control of BIDMC and are not shared with external third parties for commercial use.

Participants and Clinical Context

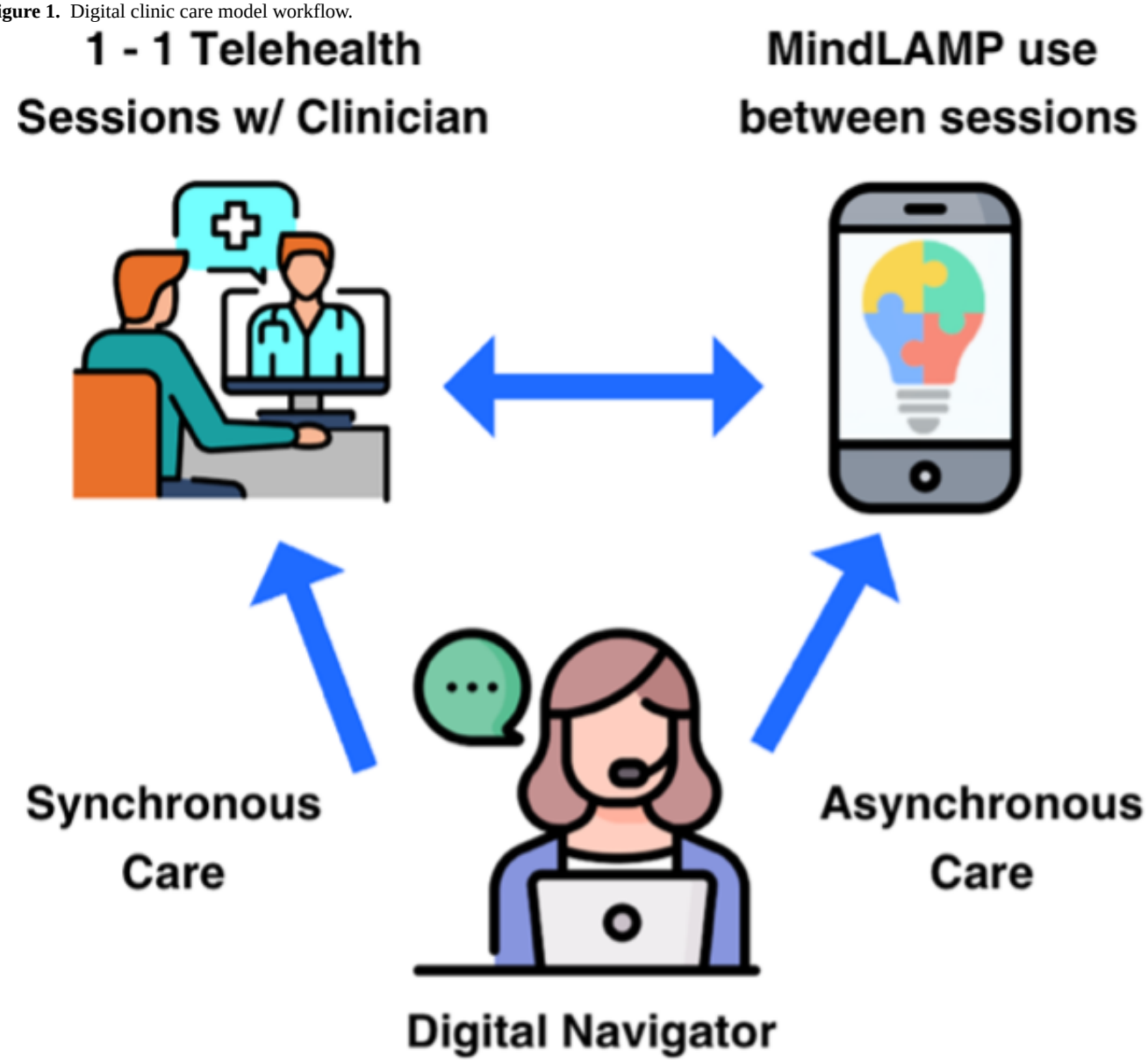
This work was conducted within the Digital Clinic program at the Division of Digital Psychiatry at BIDMC, an affiliated teaching hospital of Harvard Medical School. The Digital Clinic provides an 8-week, evidence-based virtual treatment program for adults primarily diagnosed with mild to moderate anxiety or depression [20]. The program consists of (1) the mindLAMP smartphone application, which collects EMAs, passive behavioral data, and sensor-derived activity metrics; (2) weekly

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clinician sessions focused on psychotherapy or skills-based interventions; and (3) weekly meetings with a DN, who supports patient engagement with the digital tools and assists with interpretation of the visualized data.

Patients complete the Patient Health Questionnaire-9 (PHQ-9) and Generalized Anxiety Disorder-7 (GAD-7) on a weekly basis through the mindLAMP application. In addition, patients respond to brief daily EMA surveys administered once per day via push notification, comprising 3 single-item Likert-scale ratings that assess daily anxiety, daily mood, and daily difficulty functioning. Passive data collection occurs continuously through the smartphone's built-in sensors, including GPS (from which entropy, hometime, and distance metrics are derived), accelerometer (used to estimate step count and sleep), and screen state (used to estimate screen time and, in combination with accelerometer data, sleep duration) [21]. At intake, midpoint (wk 4), and completion (wk 8), patients also complete a broader assessment battery that includes measures of emotional self-awareness, perceived social support, self-efficacy, motivation, and digital literacy. Figure 1 shows a schematic of the digital clinic team and tools.

Figure 1. Digital clinic care model workflow.



The Digital Navigator Role and Implementation

DNs are research assistants or clinical research coordinators with at least a bachelor's degree who serve as technology and engagement support members of the care team. Training includes learning the mindLAMP app and its reports, practicing motivational interviewing, and completing supervised practice sessions [22]. Weekly meetings with clinicians and supervisors support case discussion and skill development. DNs are also trained to recognize and escalate situations requiring clinical attention, such as worsening symptoms or safety concerns.

DNs work alongside but separately from clinician-led therapy, meeting patients for weekly 30-minute virtual sessions to review data reports, resolve technical issues, and support data comprehension. After each session, they document key observations and data patterns in a shared note for the treating clinician, enabling efficient information transfer without additional data review time. DNs do not provide psychotherapy

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or make clinical decisions; their role is to support data engagement and clinical communication. This aligns with the broader framework by Wisniewski and Torous, which presents DNs as a scalable role adaptable to various professional backgrounds [22].

For conflict resolution and clinical oversight, weekly case reviews with supervising clinicians address ambiguous data patterns or engagement concerns. When disagreement or uncertainty arises, DNs follow the supervising clinician's recommendations regarding safety planning or treatment adjustments. Discrepancies between patient statements and DN inferences are clarified during sessions, with the patient's interpretation documented in their chart.

DNs also act as advocates for patient preferences. If a patient feels overwhelmed by certain data streams, the DN offers to pause specific data collection while continuing therapy and communicates this to the clinician. Individual visualization components (eg, sleep or mobility graphs) can be removed from the report to align with patient comfort while preserving clinical usefulness.

The mindLAMP application includes free-text journaling for patients to record reflections, and relevant excerpts can be incorporated into weekly reports. During sessions, visualization interpretations (eg, "my anxiety tends to increase on d with high screen time") are developed collaboratively and documented as the patient's own statements. This supports the coproduction of meaning: visual patterns are presented, jointly interpreted, and recorded, reflecting the patient's perspective. When disagreements arise, DNs prioritize the patient's account and adjust their documentation accordingly.

Lack of engagement is operationalized as 0% completion of daily surveys or exercises over the preceding week. The DN explores potential barriers (eg, difficulty locating surveys, forgotten assignments, reduced motivation) and collaboratively proposes solutions. If a patient misses both DN and clinician sessions in one week, the DN emails to inquire and offer rescheduling; clinicians are alerted after every missed appointment. Currently, the program does not use automated notifications or messaging for nonadherence; all outreach and monitoring are conducted manually by DNs and clinicians. DNs review weekly PHQ-9 and GAD-7 scores and typically notify the clinician when an increase of approximately 3 or more points is observed. All changes in symptom scores are documented in the patient's note, but larger increases prompt same-day communication from the DN to the clinician so that potential treatment adjustments can be considered at the next scheduled visit.

Visualization Needs Assessment and Design

To ensure visualizations would meet clinical workflow needs, 15 clinicians (bachelor's degree or higher) and 3 clinical supervisors (PhD-level) from the Digital Clinic participated in a participatory design process. This work built off of prior published papers [21,22] that established foundational principles for patient-centered digital health tools. All participants routinely review mindLAMP-generated reports and integrate digital phenotyping insights into therapeutic work.

The process consisted of 4 iterative cycles over approximately 3 months. Each cycle included a structured group feedback session reviewing draft visualizations for clinical relevance, interpretability, and workflow burden. Participants provided feedback on clarity, usefulness for DN and clinician-patient discussions, and data quality concerns. Decisions were reached through consensus, with disagreements resolved by prioritizing the majority clinical perspective while documenting alternatives. Between cycles, the team refined prototypes based on the preceding feedback.

Through structured discussions, clinicians identified priority visualization needs:

1. Engagement behaviors (survey completion patterns and exercise adherence)
2. Symptom-severity trajectories for depression, anxiety, and difficulty functioning at weekly and daily levels
3. Correlation matrices linking passive digital phenotyping features and EMA responses
4. Sleep duration and patterns
5. Polar charts displaying intake, interim, and completion survey scores

The design team applied three core principles: (1) concept-oriented presentation highlighting key patterns, (2) simplicity and accuracy supporting varying data literacy levels, and (3) contextual annotations and consistent color schemes clarifying meaning and flagging concerning changes. These priorities aligned with DN workflows, where DNs orient patients to weekly reports, explain symptom trends, and contextualize behavioral patterns.

Key refinements across development cycles included several usability and clarity improvements. First, color-coded indicators for data quality (red=low completeness; green/blue=sufficient) were added after clinicians reported difficulty distinguishing low-quality data from meaningful signals. Second, axis labels were simplified and paired with brief contextual summaries in response to feedback that the original labels were overly technical. Third, meaningful changes were visually highlighted to aid treatment decisions, addressing supervisors' emphasis on quickly identifying clinically significant shifts. Many patients found correlation matrices difficult to interpret without guidance, leading to the addition of contextual annotations and a shift to introducing these visualizations during DN sessions rather than as independent, patient-facing materials. Clinicians ultimately reached consensus on a final set of 6 visualization types, confirming they could be feasibly reviewed within the time limits of clinical and DN sessions. These refinements supported full integration of DNs into the Digital Clinic. Data collection, processing pipelines, and technical implementation details are described in Multimedia Appendix 1 [23,24] and Multimedia Appendix 2, and we share all code to create these visualizations to ensure that the work is generalizable to the community [23].

In addition to clinician-focused participatory design, the visualization reports and DN workflow were iteratively refined based on patient feedback obtained during the 8-week program. At the final session, DNs conduct a qualitative interview reviewing the final data report with the patient, ask about the usability and relevance of the visualizations, and document

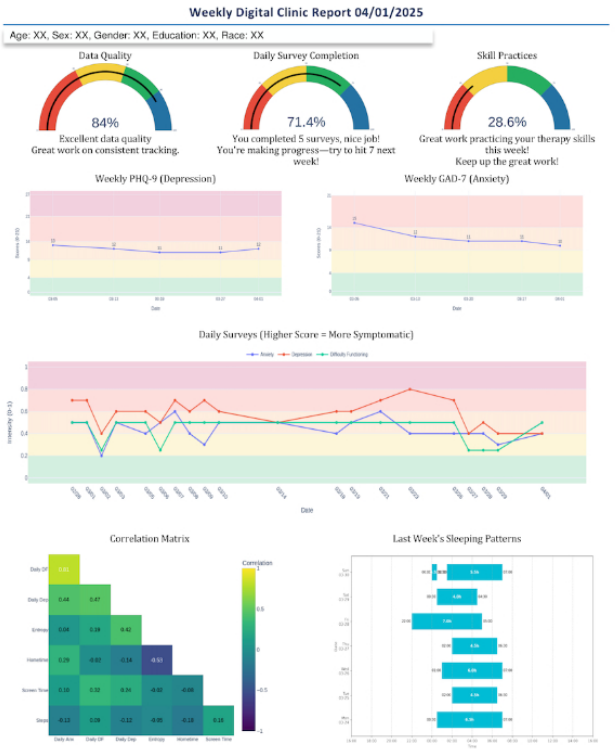
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suggestions for improvement that inform subsequent iterations of both the report and session structure. Patients valued seeing engagement patterns early but found the original layout overwhelming. Accordingly, the report was restructured to lead with gauge charts before more complex visualizations. Patients also requested clearer labeling of normal variability versus clinically meaningful change, leading to shaded threshold bands and plain-language annotations. Additional refinements included contextual annotations for irregular schedules (eg, shift work or academic deadlines) in sleep visualizations and a more accessible color palette with textual labels after some patients reported difficulty distinguishing colors. Together, these patient-driven adjustments illustrate how user feedback within routine care directly shaped both the content and presentation of the visualization reports.

Overview of Key Visualization Components in the Data Report

The weekly data report integrates multiple visualization types, each serving distinct clinical functions, and is provided at every clinical or research visit. While the specific details may vary across studies or sessions depending on the data collected and the needs identified by patients, clinicians, or researchers, the basic structure remains consistent, as shown in Figure 2.

Figure 2. Complete data report sample showing the core 2 pages, which can be delivered digitally or printed.



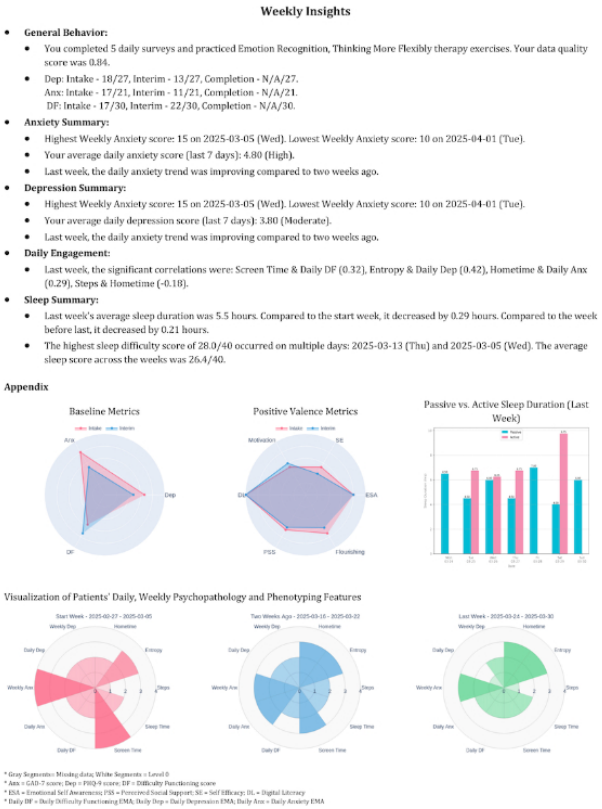


Table 1 provides more details on each visual type.

Each visualization type was designed to support both clinical decision-making and patient insight-building. The integration of multiple formats within a single weekly report enables a comprehensive understanding of symptom patterns, behavioral correlations, and treatment progress while accommodating diverse learning styles and levels of data literacy. DNs use these visualizations flexibly, emphasizing different components based on individual patient needs, clinical concerns, and phase of treatment.

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Table . Overview of visualization components in weekly data reports.

Visualization type	Visual format and key features	Data displayed	Clinical function
Gauge charts	Color-coded gauge charts using traffic-light system (red/yellow/green-blue)	Data quality, survey completion rates, and skills practice adherence	Quickly assess engagement patterns and identify weeks requiring additional support
Symptom trajectory graphs	Line charts with clinical thresholds marked; separate weekly and daily views	PHQ-9[a] (depression) and GAD-7[b] (anxiety) scores over time	Track symptom trends, identify treatment response patterns, and distinguish persistent symptoms from transient mood fluctuations
Correlation matrices	Heat maps with color-coded correlation strength (warm colors=positive correlations, cool colors=negative correlations; intensity=strength)	Spearman correlations between passive behavioral metrics (GPS-derived entropy, step count, hometime, screen time, and sleep duration) and active self-report measures (daily anxiety, depression, and difficulty functioning)	Identify behavioral targets for intervention by revealing which routines most strongly associate with symptom patterns
Sleep visualization	Column charts with contextual annotations for sleep patterns	Daily sleep duration with visual markers	Make sleep patterns immediately visible and support discussions about sleep hygiene's role in symptom management
Polar/radar charts	Multidimensional radar format with overlaid time points (intake-red, interim-blue, and completion-green)	Symptom domains (depression, anxiety, and difficulty functioning) and positive metrics (emotional self-awareness, perceived social support, self-efficacy, motivation, and digital literacy)	Enable rapid visual comparison across domains and time points to recognize multidimensional change patterns beyond single symptom reduction
Passive-active data integration graphs	Dual-axis line graphs overlaying behavioral metrics and symptom reports on shared timeline	Passive behavioral data (step count, screen time, and entropy) overlaid with active symptom reports (daily anxiety and depression) showing temporal alignment	Reveal relationships between behaviors and symptoms to support prediction making about behavioral-symptom connections

[a]PHQ-9: Patient Health Questionnaire-9.

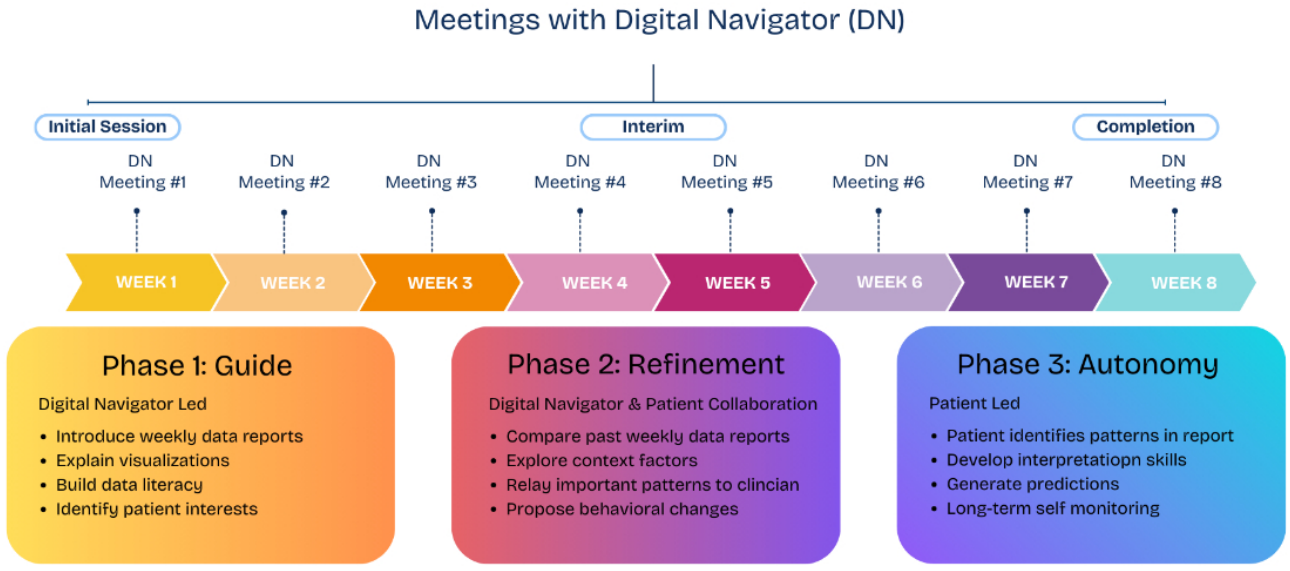
[b]GAD-7: Generalized Anxiety Disorder-7.

Integration of Visualizations Into Digital Navigator Workflow

Overview

DN sessions serve as the primary means for patient-facing interpretation of visual data reports. The DN workflow follows a 3-phase model based on the DOORS (Digital Outreach for Obtaining Resources and Skills) framework self-determination theory: guide, refinement, and autonomy [25]. Figure 3 illustrates how these phases map onto the 8-week treatment timeline, showing the progression from DN-led sessions toward patient-led data interpretation.

Figure 3. Digital navigator phases across an 8-week timeline.



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Phase 1: Guide

During the first data-focused DN session, the DN introduces the patient to the weekly report, explaining how each visualization is generated, simplifying visual elements, helping interpret early patterns relative to daily routines, and identifying initial correlations. This establishes foundational data literacy for the subsequent sessions and builds initial confidence in engaging with personal health data. The DN also prioritizes the patient's participation and self-interest by thoroughly going over the whole report to gauge which graph or visualization the patient found most enlightening.

Phase 2: Refinement

In weekly follow-up meetings, DNs and patients compare updated reports to prior weeks, examining changes in symptoms, behaviors, or data quality alongside potential contextual explanations (eg, work schedule shifts and sleep disruption). During this phase, DNs support the development of competency and skills in data interpretation. DNs relay notable patterns to clinicians, supporting treatment plan updates. Visualizations function as prompts for collaborative problem-solving between the care team and patient, helping patients develop confidence in their ability to identify meaningful patterns and connect behavioral data to lived experience.

Phase 3: Autonomy

As patients develop their data literacy skills, DNs progressively shift toward supporting patient autonomy in data interpretation and self-management. Patients increasingly take the lead in identifying patterns, generating predictions about behavioral-symptom relationships, and proposing behavioral changes. This transition supports the development of long-term self-monitoring skills that may extend beyond the program.

At the final meeting, DNs and patients review overall trends across the 8-week program and gather structured feedback on the data visualization's clarity, relevance, and how well visual patterns reflected their lived experiences.

Results

Overview

To illustrate how visualization design and DN workflow function in practice, we present a clinical case from a patient referred to the Digital Clinic with primary concerns related to anxiety. The patient is a current advanced degree student in their late 20s who was referred to the clinic regarding anxiety. This example demonstrates how weekly visual reports, passive-active data integration, and DN-guided interpretation supported insight and engagement across an 8-week treatment program.

The Role of Visualizations for Collaborative Interpretation

Across the program, the DN played a central role in translating the data visualizations into actionable clinical insights. Through structured weekly meetings, the DN helped the patient build data literacy, validate visual patterns against lived experience, and develop a nuanced understanding of relationships between behavioral routines and mental health symptoms. The visualizations served as anchors for collaborative interpretation: the DN used symptom trajectories to track progress, correlation matrices to identify behavioral targets, and polar charts to illustrate multidimensional change over time.

The weekly data reports reviewed by the DN and the patient contained multiple visualization types working in concert. Each visualization format served as a distinct anchor point for different aspects of clinical understanding, and their integration created a comprehensive system for tracking, understanding, and responding to the patient's mental health journey. Below, we describe how 3 core visualization types function as anchors across the guide, refinement, and autonomy phases of treatment.

Tracking Progress and Contextualizing Change

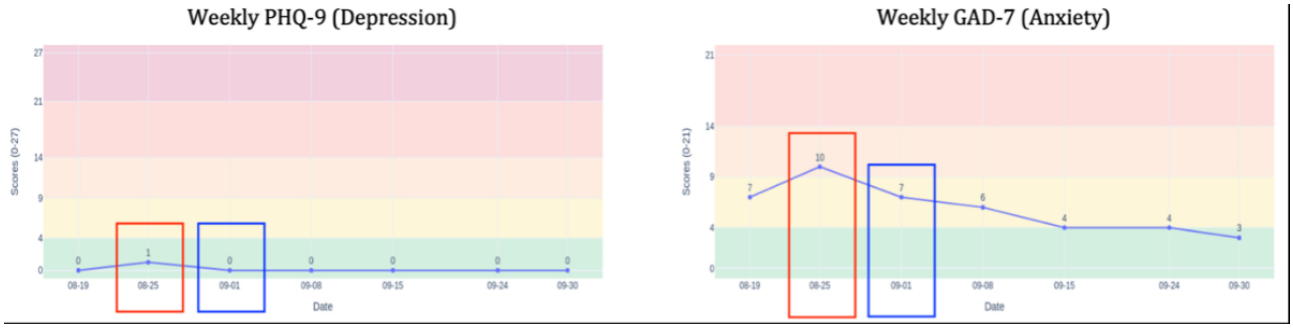
Line graphs displaying weekly PHQ-9 (depression) and GAD-7 (anxiety) scores over time served as the primary anchors for monitoring treatment response and distinguishing between persistent patterns and transient fluctuations. These temporal visualizations provided both the patient and DN with a shared reference point for discussing symptom evolution.

Early Validation of Visual Symptom Trajectories

During the initial session, the DN explained how the line charts were generated from weekly survey responses and pointed out clinical threshold lines that contextualized severity levels. Early trajectories showed low, stable weekly PHQ-9 scores but greater GAD-7 variability—a pattern the patient reported aligned with his lived experience of fluctuating anxiety, reinforcing early confidence in visualization accuracy. In Week 2, when both scores spiked (red boxes in Figure 4), the upward trajectory was visible in the graphs. The DN helped him connect this change to close friends moving out of state. The subsequent decline (blue boxes in Figure 4) as he returned to structured coping strategies (completing 5 journal entries) was equally visible in the graphs' return to baseline, reinforcing that his data accurately reflected his experiences.

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Figure 4. Weekly symptom trajectory graphs. GAD-7: Generalized Anxiety Disorder-7; PHQ-9: Patient Health Questionnaire-9.

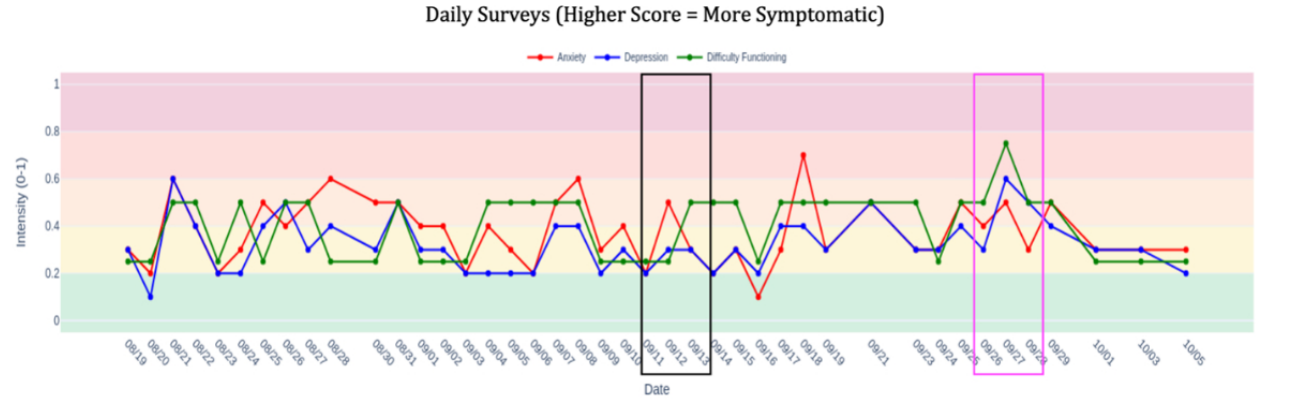


Critically, comparing daily versus weekly symptom graphs revealed an important clinical distinction. Daily depression ratings showed high variability while weekly PHQ-9 scores remained stable. The DN used this visual contrast, variable daily graphs versus stable weekly graphs, to help the patient understand that daily ratings reflected mood-level fluctuations rather than clinical depressive symptoms. This visualization-anchored reframing prevented misinterpretation of normal emotional variability as symptom worsening.

Distinguishing Situational From Persistent Patterns

During illness and academic pressures, weekly GAD-7 scores showed a slight but steady decrease in the line graph, while daily anxiety and difficulty functioning temporarily spiked around Week 3 (black box in Figure 5). The contrast between stable weekly trend lines and volatile daily graphs enabled the DN to help the patient distinguish expected situational fluctuations from persistent symptom patterns. This visual evidence, that underlying improvement continued despite temporary setbacks, maintained therapeutic momentum and prevented discouragement during a challenging period.

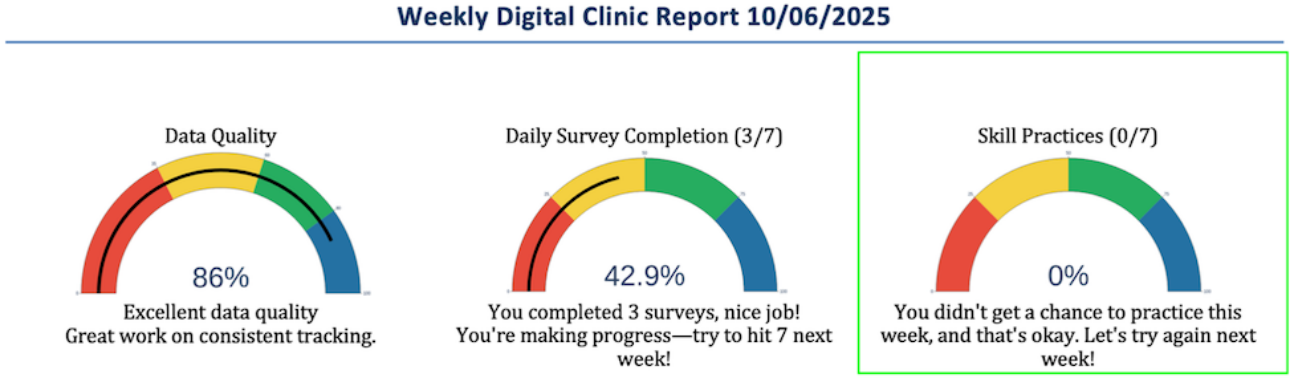
Figure 5. Daily symptom trajectory graph.



Independent Pattern Recognition

By Week 6, the patient independently identified a brief symptom spike (pink box in Figure 5) in the line graphs without the DN prompting, demonstrating autonomous data interpretation skills. More significantly, symptom trajectory graphs showed continued decline in weekly anxiety even as skills practice engagement dropped to 0% (green box in Figure 6). This visual dissociation between declining symptom severity and declining formal engagement provided evidence that the patient had successfully internalized coping strategies, with the graphs anchoring validation of his growing autonomy in symptom management.

Figure 6. Week 6 gauge graphs.



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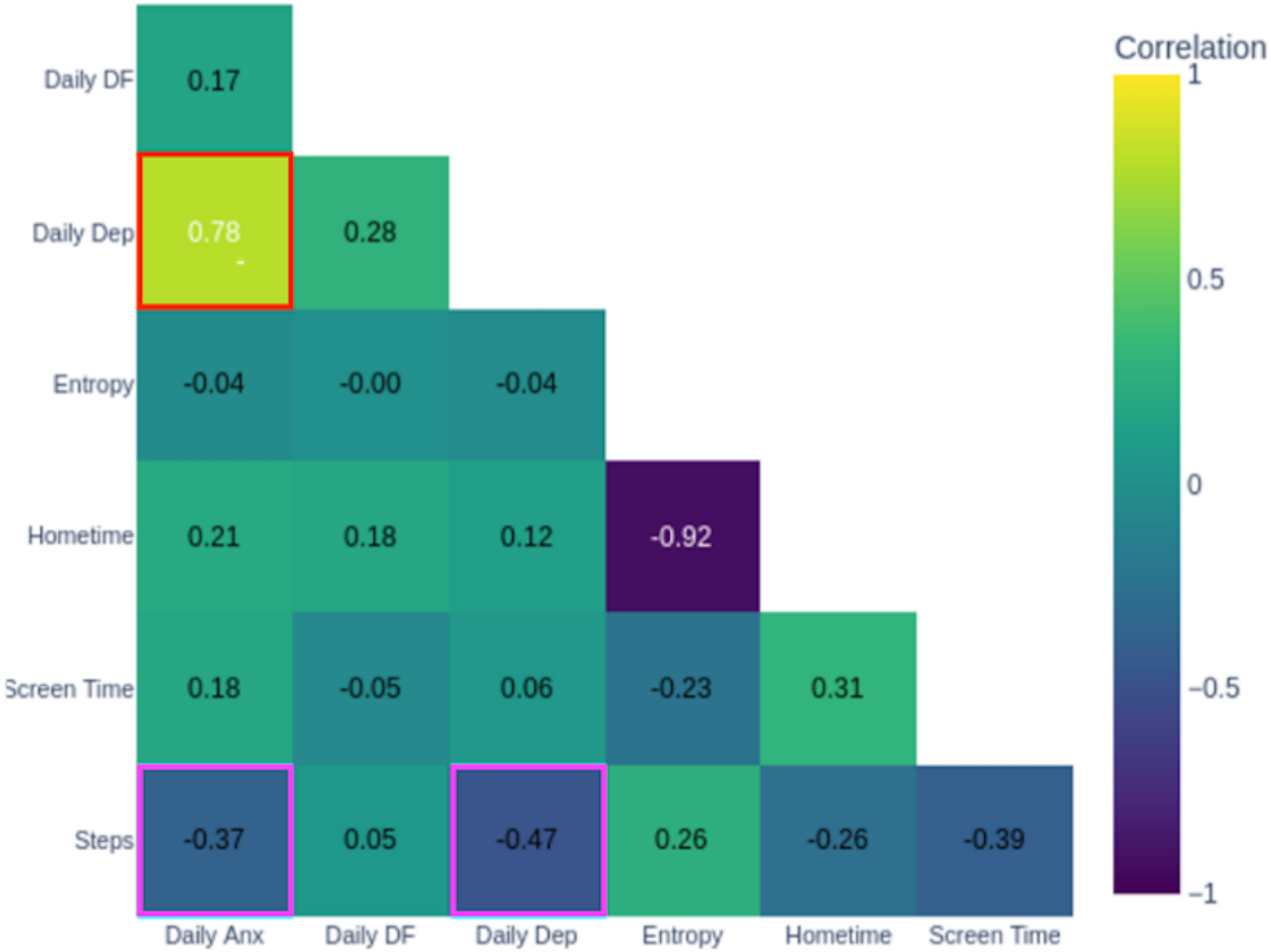
Identifying Behavioral Targets and Verifying Predictions

Heat map visualizations displaying Spearman correlation coefficients between passive behavioral metrics (GPS-derived entropy, step count, hometime, and screen time) and active self-report measures (daily anxiety, depression, and difficulty functioning) served as anchors for exploring and validating behavioral-symptom relationships. The color-coding system: warm colors indicating positive correlations, cool colors showing negative correlations, with intensity reflecting strength, made complex statistical relationships easily interpretable.

Learning to Read Behavioral-Symptom Relationships

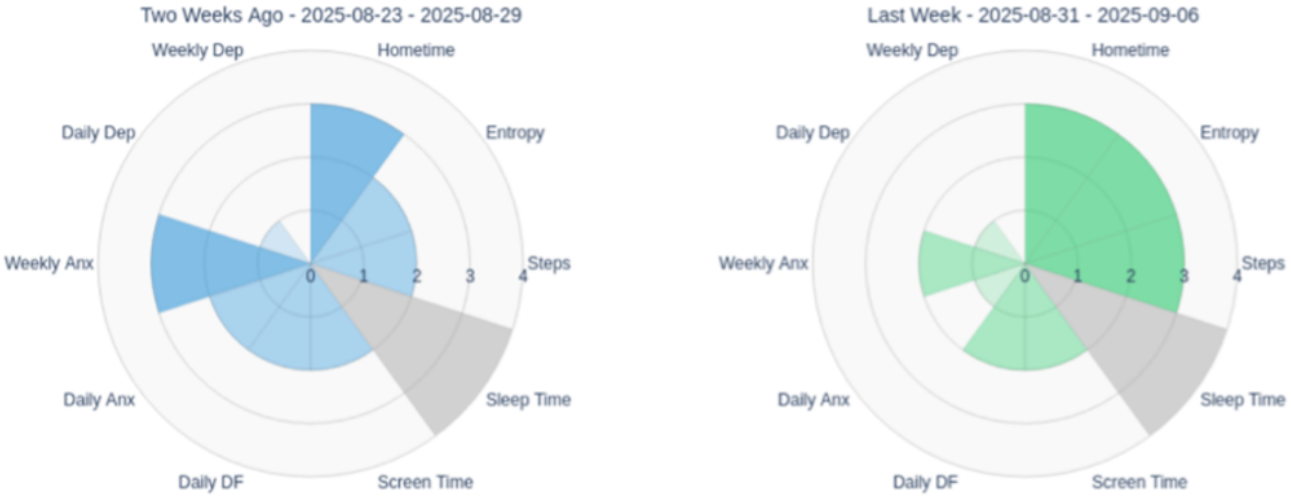
The DN introduced the patient to the correlation matrix by explaining how to interpret the heat map colors and what each axis represented. The matrix revealed that daily anxiety and daily depression showed positive correlations (red box in Figure 7), aligning with the patient's lived experience that anxiety episodes worsened his mood. More actionably, the matrix showed negative correlations (pink boxes in Figure 7) between step count and daily anxiety and depression, indicating that lower mobility may correspond with heightened anxiety. The DN emphasized that weekly and daily anxiety decreased when entropy and step count increased—a pattern visible in Figure 8. The patient validated this against his experience, noting that he felt worse on days he stayed indoors or skipped exercise. This validation, anchored in the visual representation, transformed an abstract statistical relationship into a personally meaningful and actionable insight: behavioral activation through movement and routine variety could potentially reduce his anxiety.

Figure 7. Week 2 correlation matrix. DF: daily functioning.



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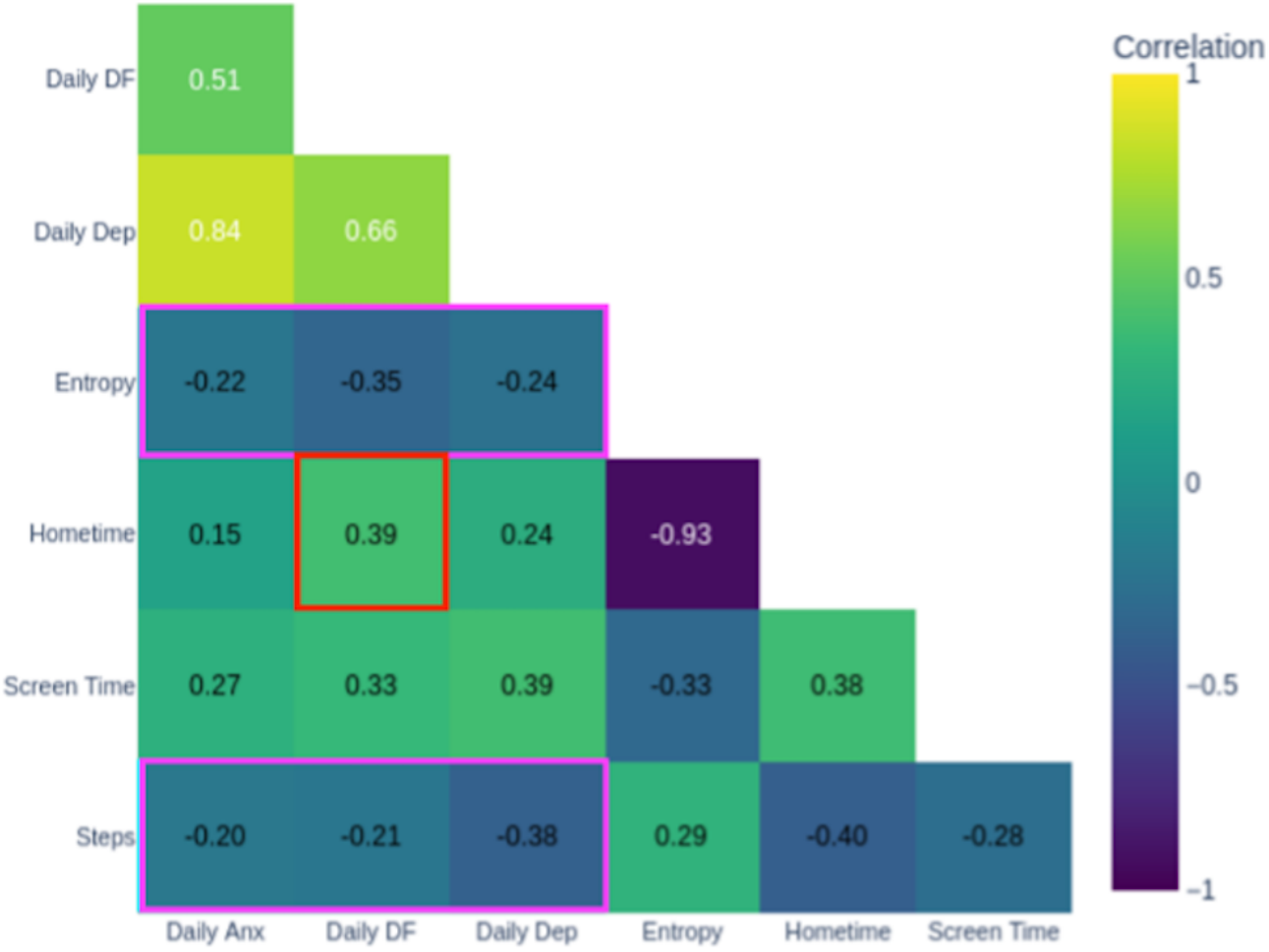
Figure 8. Week 2 passive-active data integration graphs. DF: daily functioning.



Contextualizing Disruptions Through Behavioral Data

During illness in Week 4, the correlation matrix became an anchor for understanding why symptoms temporarily worsened. The matrix showed that hometime was positively correlated with difficulty functioning (red box in Figure 9), reflecting days spent recovering at home, while entropy and steps remained negatively correlated with daily anxiety, depression, and difficulty functioning (pink boxes in Figure 9), consistent with disrupted routines. The DN used these visual patterns to help the patient understand that his symptoms increased during illness were contextually appropriate and linked to necessary recovery behaviors rather than indicating treatment failure. The patient also noted anticipating future increases in difficulty functioning with increased screen time as classes intensified—demonstrating he was using the correlation matrix to make predictions about future patterns. The matrix thus anchors not only behavioral target identification but also appropriate contextualization of symptom changes within life circumstances.

Figure 9. Week 4 correlation matrix. DF: daily functioning.



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Data Integration and Autonomous Patient Predictions

By Week 6, the patient autonomously used the correlation matrix to generate and test assumptions made from the previous weeks. He noted that screen time's positive correlation with both daily difficulty functioning and depression (red box in Figure 10) aligned with his academic workload and prior discussions about cognitive strain. Observing that both screen time and symptom scores had decreased that week (Figure 11), he independently anticipated that reduced screen time contributed most to his decreased scores. This analysis, integrating information from the correlation matrix, symptom trajectory graphs, and behavioral tracking data, demonstrated the ability to use visualizations as cognitive tools for understanding his mental health.

Figure 10. Week 6 correlation matrix. DF: daily functioning.

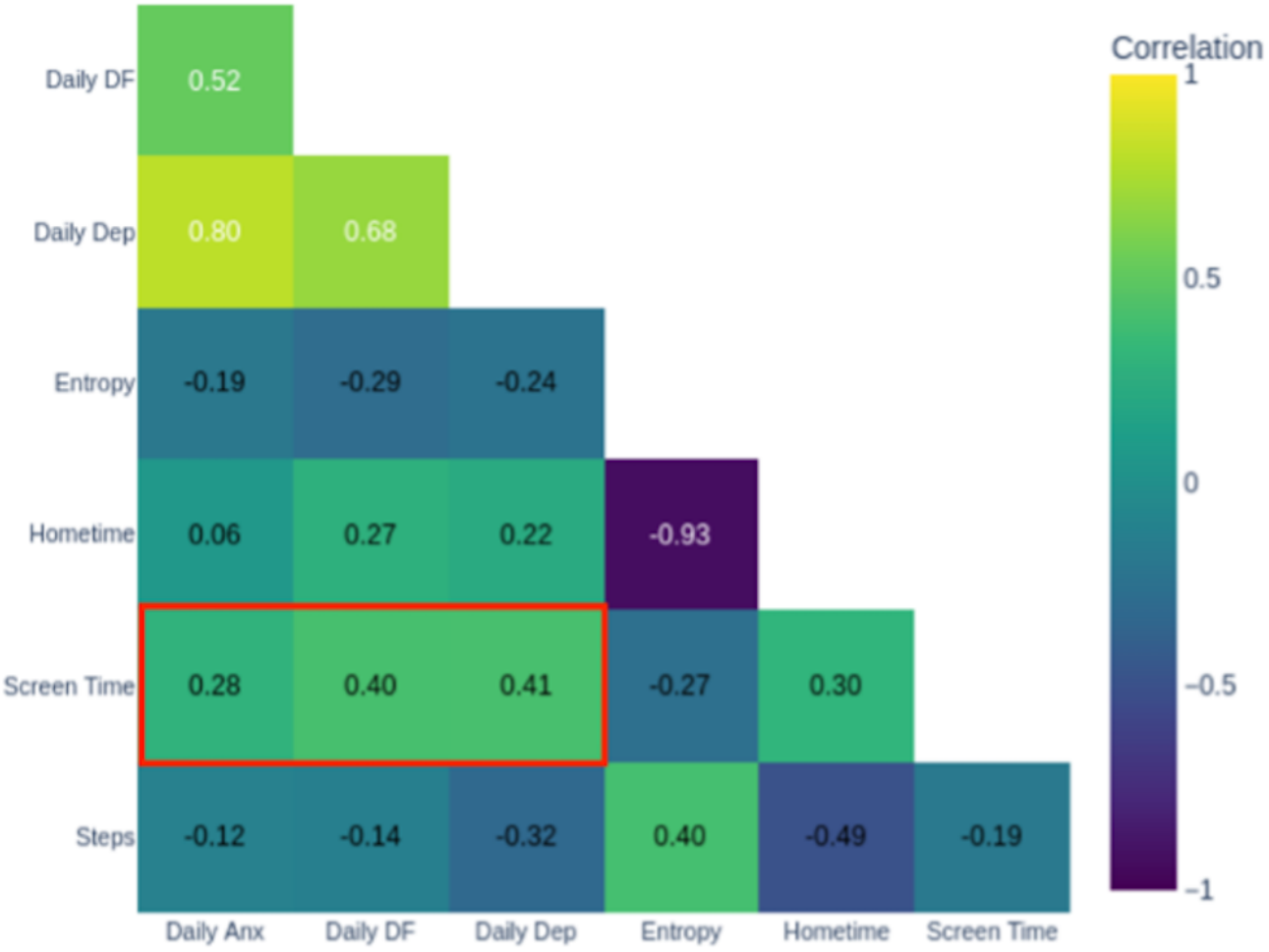
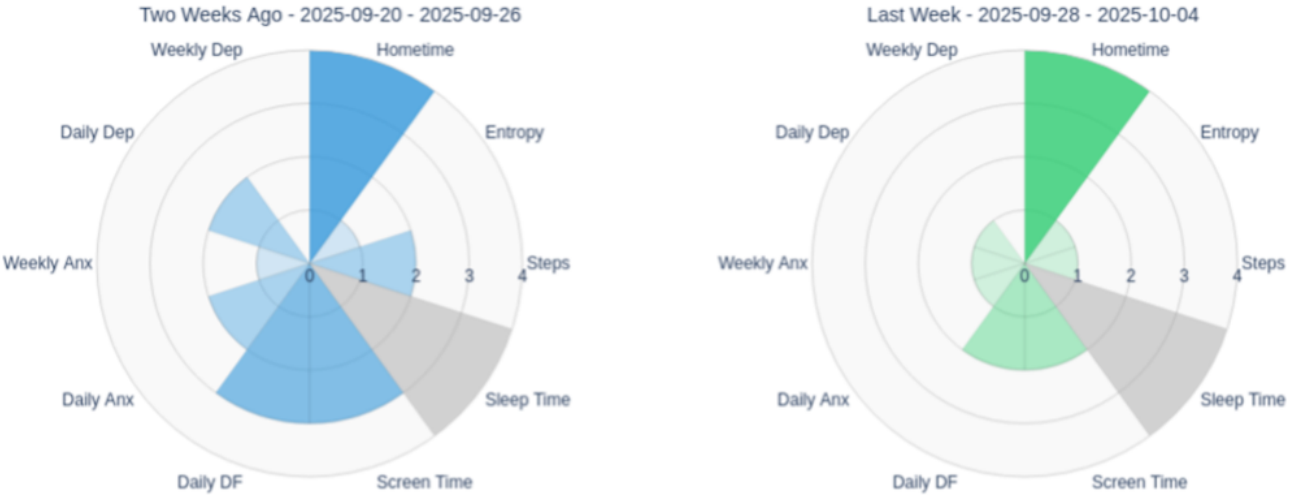


Figure 11. Week 6 passive-active data integration graph. DF: daily functioning.



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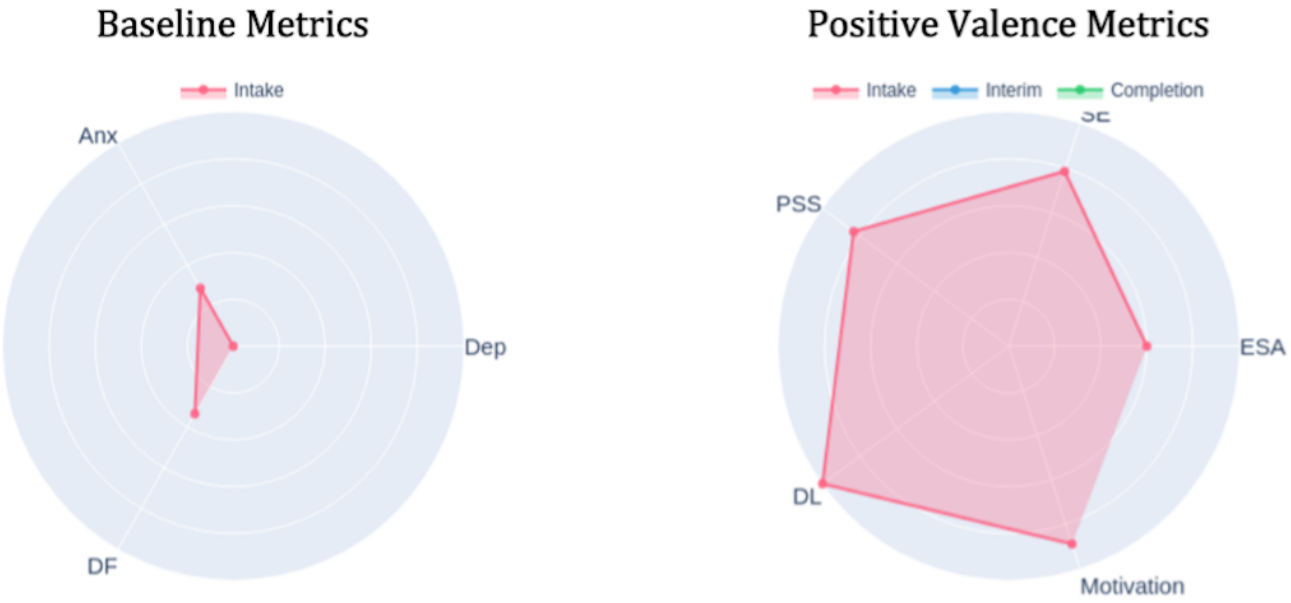
Recognizing Multidimensional Change and Validating Progress

Radar charts displaying scores across multiple domains, such as depression, anxiety, difficulty functioning, and positive psychological metrics (emotional self-awareness, perceived social support, self-efficacy, motivation, digital literacy), at 3 time points (intake-red, interim-blue, and completion-green) served as pillars for recognizing comprehensive treatment effects beyond single symptom reduction. The radar format's visual structure made multidimensional comparisons easily comprehensible: outward expansion indicated improvement in positive domains, while inward reduction showed reduction in symptom severity and functional impairment.

Establishing Baseline and Visual Data Literacy

At intake, the DN introduced the polar chart format by explaining how to read the radar pattern. The pink triangle showed higher anxiety and difficulty functioning relative to depression through the distinctive shape, with anxiety and difficulty functioning axes extended further outward, visually emphasizing anxiety as the primary concern (Figure 12). The chart also showed consistently elevated positive-valence measures, visible as outward extension on those axes, suggesting existing strengths. This visual representation validated the patient's subjective experience and helped establish shared understanding between the patient, DN, and clinician about treatment priorities. The DN explained that future reports would overlay interim and completion patterns to show change over time.

Figure 12. Intake polar chart. DF: daily functioning; DL: digital literacy; ESA: emotional self-awareness; PSS: Perceived Stress Scale.

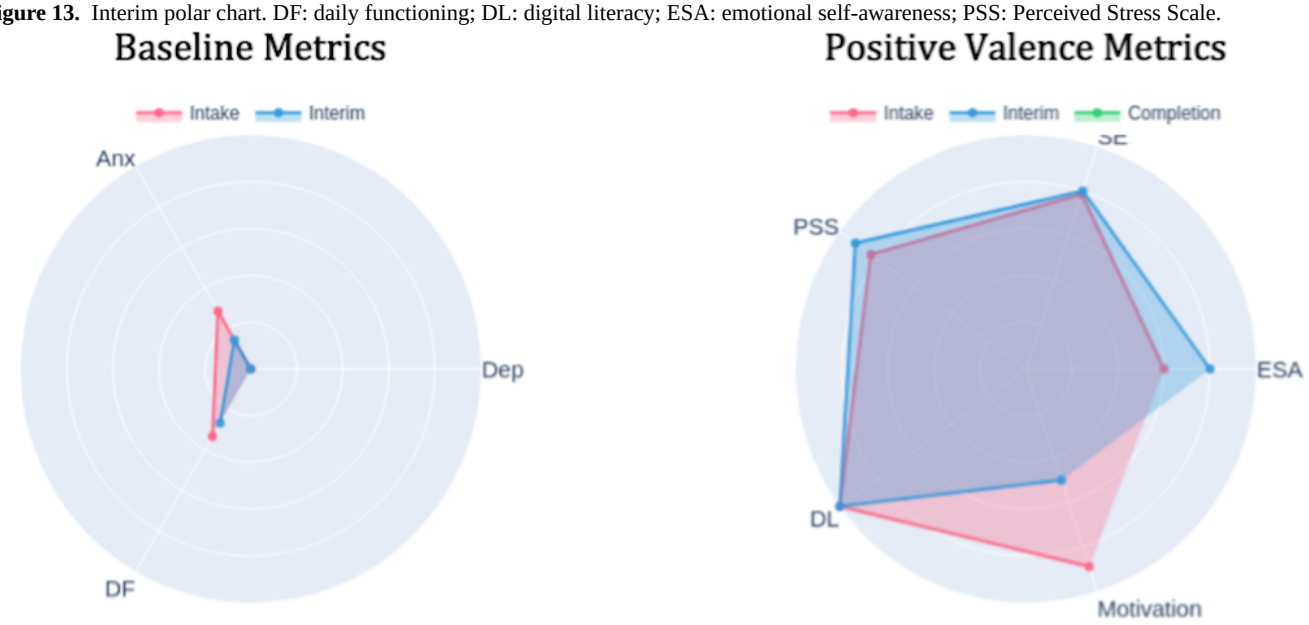


Visualizing Progress Despite Challenges

The interim polar chart (blue) overlaid on the intake measures (pink) made improvements immediately apparent despite ongoing illness and academic pressures (Figure 13). The blue line pulled inward on the anxiety and difficulty functioning axes while extending outward on emotional self-awareness and perceived social support axes. The DN used this visual comparison to help the patient connect these multidimensional gains to his growing use of coping strategies, including meditation practices he had begun incorporating. The radar format made these changes more noticeable than reviewing individual scale scores, as the patient could see his overall psychological profile shifting toward improved mental health. This visual validation was particularly significant during a challenging week; the polar chart helped anchor his sense of meaningful progress despite ongoing challenges and reinforced that continued engagement itself was an achievement.

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Figure 13. Interim polar chart. DF: daily functioning; DL: digital literacy; ESA: emotional self-awareness; PSS: Perceived Stress Scale.



Validating Comprehensive Growth

At completion, the green radar pattern showed sustained improvements across domains: difficulty functioning had contracted further inward compared with both intake and interim, indicating functional gains; anxiety and depression remained stable at reduced levels; and positive metrics, particularly motivation and self-efficacy, had expanded outward beyond interim levels (Figure 14). The visualization displays overlapping time points—intake (pink), interim (blue), and completion (green)—with darker shaded regions indicating where multiple assessments overlap. The DN used this visualization to anchor the final session's review of overall progress. The patient could see that his emerging sense of control and confidence in his subjective experience was reflected objectively in the change patterns. The polar chart format made the comprehensiveness of his improvement immediately visible: not just symptom reduction but psychological growth across multiple domains. This visual validation supported his confidence in maintaining gains posttreatment and reinforced that the self-monitoring skills he had developed were grounded in objective evidence of growth. The contrast between low formal skills practice completion (0% in wk 6) and continued psychological improvement validated that he had successfully internalized coping strategies.

Figure 14. Completion polar chart. DF: daily functioning; DL: digital literacy; ESA: emotional self-awareness; PSS: Perceived Stress Scale.



The progression across these 3 visualization types illustrates how the DN supports development from guided interpretation to autonomous engagement. Each phase built upon the previous. In the guide phase, the DN taught how to read each visualization format and helped validate patterns against lived experience. In the refinement phase, visualizations anchored understanding of how symptoms related to life circumstances and behavioral patterns, supporting adaptive treatment planning during challenges. In the autonomy phase, the patient independently used multiple visualization types altogether, integrating

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information from trajectories, correlation matrices, and polar charts to generate predictions and validate his subjective sense of improvement through objective data patterns.

This case demonstrates how thoughtfully designed, multi-format data visualizations, when delivered through structured DN facilitation, can transform passive data collection into active clinical tools. The visualizations enhanced patient engagement, promoted behavioral insight, supported symptom improvement, and ultimately facilitated autonomous self-management—outcomes that extended beyond what traditional clinical monitoring or standalone digital tools typically achieve in digital mental health care.

Discussion

Principal Results

This paper presents a model for integrating data visualizations into digital mental health care through a DN-supported workflow. Our case demonstrates that when complex digital phenotyping data is translated into interpretable visual formats and delivered through structured support, it can transform passive data collection into active insight-building that enhances patient engagement, contextualizes symptom fluctuations, and supports real-time treatment adaptation.

This case highlights a key advantage of integrating data visualizations into routine digital mental health workflows: the patient remained engaged with visual reports even when his use of app-based exercises declined to 0% in his final week. Interestingly, this pattern suggests that visualizations may serve as an anchor for maintaining therapeutic momentum during periods of lower formal engagement with other digital intervention components. Such a finding has important implications for retention and sustained participation in digital interventions, where fluctuations in engagement represent a common concern. Despite reduced active skill practice, the patient's continued interest in reviewing his weekly reports indicates that well-designed visualizations can sustain connection to treatment. A tiered approach offering progressive levels of detail may enhance accessibility for patients with varying preferences and literacy needs, while allowing more engaged individuals to explore deeper inferences from their data.

Second, the alignment between clinical trends and visualized data supports the feasibility of using these tools to track progress and guide treatment planning in real time. Clinician care coordination was enhanced through the DN's ability to relay data-informed insights, ensuring that behavioral patterns identified in weekly reports expanded therapeutic discussions during clinician sessions. The DN role is critical to this coordination: by serving as an interpreter and facilitator of the visualized data, the DN enabled efficient information transfer to the clinician without imposing a substantial burden. This finding suggests that with an organized workflow design, data visualizations can meaningfully augment traditional therapy by making passive monitoring data clinically actionable.

Additionally, across the treatment period, the review of the data visualizations helped transform raw data into actionable clinical insight by connecting concrete life events, such as illness, academic demands, and social changes, to emerging symptom patterns. This contextualization process proved essential for meaningful interpretation. For example, the patient's ability to link increased anxiety scores to specific academic stressors, or to recognize the impact of social schedule changes on his mood patterns, demonstrated how visualizations can become therapeutically valuable when paired with reflective discussion. The DN facilitated this interpretive process by prompting consideration of environmental and behavioral context, helping the patient move from passive data consumption to active insight-building. This outcome underscores the importance of designing visualizations that support nuanced interpretations accounting for everyday stressors, rather than suggesting rigid behavioral prescriptions disconnected from lived experience.

This case also suggests important directions for future refinement of the DN's role. The patient's ability to generate insightful predictions about behavioral-symptom relationships raises questions about optimal timing and intensity of DN support. Future work should examine whether DN involvement can be gradually reduced as patients develop data literacy and interpretive competence, or whether ongoing facilitation remains necessary to maintain engagement and insight quality. Additionally, further research is needed to determine which patient characteristics predict successful transition to more independent data interpretation versus continued need for facilitated review.

Finally, as digital phenotyping becomes increasingly integrated into mental health treatment, scalable models for making this data actionable will be essential. The data visualizations represent a replicable model that balances automation (standardized data processing and visualization generation) with personalization (individualized interpretation and contextualization). This may be particularly valuable for health systems seeking to implement digital phenotyping without overwhelming clinicians or expecting patients to navigate their data independently. The findings support the scalability potential of visualization-enhanced digital care models when key design principles are met. The DN role enables patients to develop both immediate symptom management insights and longer-term self-monitoring skills, representing an investment in patient capacity-building that may yield benefits beyond the acute treatment period. Further research should examine the cost-effectiveness of this model across diverse clinical settings and patient populations, as well as strategies for training and supervising DNs to ensure consistent quality of data facilitation.

Comparison With Prior Work

Our findings align with and extend prior research on data visualization in digital mental health. Previous work has demonstrated that clinicians are receptive to digital phenotyping data when interpretation support is available [11], and our structured DN workflow provides a practical model for delivering such support. The visualization types we developed address the need for actionable information summarized from raw behavioral data [13], while the participatory design process ensured alignment with clinical workflow feasibility.

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Our approach differs from previous data visualization tools [8] by embedding visualizations within a structured human support model rather than providing standalone tools for independent patient use. ESMvis and similar clinical dashboards [9] are primarily designed for researchers or clinicians' use without guided patient interpretation workflows. Our model introduces the DN as a bridge between data collection and meaningful understanding, reflecting evidence that patients willingly share data when they can derive insights with trusted support [14]. This design decision reflects evidence that patients express willingness to share personal data when they can derive meaningful insights with trusted support [14]. The DN model addresses many of the implementation barriers identified in prior digital phenotyping research by providing dedicated personnel for technical troubleshooting, data interpretation, and care coordination.

An important issue is how our approach relates to therapeutic alliance. Although we did not formally assess alliance with validated instruments, qualitative interviews at treatment end provided relevant insights: patients reported that reviewing data with the DN was "helpful," that they "understood their data more," and that the experience became "more meaningful." These findings suggest that collaborative data interpretation may itself serve as a relational intervention involving trust, validation, and shared understanding. Future research should use validated alliance measures (eg, the Working Alliance Inventory) to formally examine this relationship.

Implementation Considerations and Scalability

The DN role was developed to help ease clinician burden in the Digital Clinic, with several considerations relevant to broader implementation [22]. In terms of scalability, the DN model is designed to be adaptable across diverse clinical contexts. Because the role does not require clinical licensure, DNs can come from various professional backgrounds, depending on available resources and target populations. The structured training and supervision framework described in the Methods section provides a replicable model for onboarding DNs in new settings. However, feasibility depends on institutional capacity to support dedicated DN positions, and research on cost-effectiveness is needed to assess sustainability across different health systems.

Regarding data governance and privacy, the mindLAMP platform is open-source and designed with privacy protections in mind [26]. All passive data are aggregated and deidentified. Data collected through the Digital Clinic is managed under institutional data-use agreements and HIPAA-compliant protocols. During onboarding, patients are informed about what data is collected, how it is processed, and who can access the resulting reports. Currently, patients cannot directly download raw data from mindLAMP. However, they can request static copies of their visualization reports. When a patient expresses interest in retaining their reports for future reflection, their DN generates and emails a PDF containing their weekly summary reports, which provides access to their data even after the 8-week program has ended. Patients may also request these reports retrospectively, and DNs respond by sharing the relevant materials via secure email. The mindLAMP platform does not share individual patient data with third parties, and any future policy changes would require updated consent procedures.

For engagement monitoring and clinical safety, DNs track engagement metrics such as survey completion, app usage, and session attendance. When engagement or data quality declines, the DN addresses potential barriers in the next session and adjusts the support plan as needed. If disengagement persists, the supervising clinician is alerted, and a coordinated care plan is established. Data reports highlight low data quality or completion, and clinicians receive alerts when symptom scores exceed clinical thresholds. At present, there is no formal protocol specifying DN involvement when a patient is hospitalized or for follow-up contact with families in the event of a patient's death during the program. These scenarios are currently managed through standard clinical workflows outside the scope of the DN role, and the model does not systematically incorporate bereavement outreach or posthospitalization navigator support. Developing structured procedures for DN participation in these critical events represents an important area for future work, particularly given the potential role of DNs in providing support and continuity of care for patients and families during crises.

Limitations

This study has several important limitations that should be considered when interpreting findings and planning future research. First, interpretation depends on patients' subjective sense of whether visualizations align with their lived experience—a suitable approach given that mental health assessment already relies heavily on self-report measures like the PHQ-9 and GAD-7. However, patients may selectively validate patterns that confirm pre-existing beliefs while dismissing contradictory data. Future work should explore methods for balancing subjective validation with objective clinical markers. Second, these visualizations require smartphone ownership and willingness to share passive sensing data. While smartphone ownership is increasingly common, disparities remain across socioeconomic, age, and geographic groups. Data quality also varies between smartphone models, potentially introducing systematic bias [27,28]. The DN model addresses many of these concerns by helping patients troubleshoot technical issues and contextualize data quality indicators, though patients who are unwilling or unable to share data will be excluded from these approaches. Third, the case example shared to illustrate the potential of this approach may not generalize to other use cases, although in running this model of care for hundreds of patients, we have found the approach productive [29]. Finally, this study did not include formal measures of therapeutic alliance or patient satisfaction with the DN role, limiting our ability to make claims about the effects of this approach on the therapeutic relationship. Future studies should incorporate validated alliance measures to examine this dimension.

Conclusions

Smartphones can generate unprecedented volumes of clinically relevant behavioral data, yet this data richness has limited clinical utility due to interpretation challenges. Our model demonstrates one pathway forward: joining thoughtfully

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designed visualizations with human support to bridge the gap between technical capability and clinical practice. Future research should examine whether the guide-refinement-autonomy progression generalizes across diverse populations, explore optimal models for training and supporting DNs, and investigate how visualization design can support nuanced interpretation that accounts for individual life circumstances. As the field moves toward increasingly data-driven care, models that center on human connection and collaborative interpretation will remain essential for ensuring that technology enhances rather than replaces the therapeutic relationship.

Acknowledgments

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Data Availability

The code used to generate visualizations is available in the Cortex software package [23].

Authors' Contributions

KL contributed to formal analysis, investigation, methodology, visualization, and writing of the original draft, as well as review and editing of the manuscript. RB contributed to formal analysis, investigation, methodology, and writing of the original draft, as well as review and editing of the manuscript. SW and LS contributed to software development and writing of the original draft. KTL contributed to the review and editing of the manuscript. JT contributed to conceptualization, funding acquisition, supervision, and review and editing of the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

JT serves as the editor in chief of *JMIR Mental Health* at the time of this publication. All other authors declare no conflicts of interest.

Multimedia Appendix 1
Technical development and data processing.
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Multimedia Appendix 2
Python package table.
[DOCX File, 14 KB - jopm_v18i1e90255_app2.docx]

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Abbreviations

BIDMC: Beth Israel Deaconess Medical Center
DN: Digital Navigator
DOORS: Digital Outreach for Obtaining Resources and Skills
EMA: ecological momentary assessment
ESM: experience sampling method
GAD-7: Generalized Anxiety Disorder-7
PHQ-9: Patient Health Questionnaire-9

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Original Paper

Patient Preferences for Technology-Assisted Patient-Reported Outcomes Measurement of Mental Health Symptoms Among Veterans: Cross-Sectional Survey

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Abstract

Background: The Veterans Health Administration is promoting patient-reported outcome measure (PROM) collection for measurement-based mental health care. Understanding veteran preferences about how and when to complete PROMs is critical to support their implementation.

Objective: We examined veteran preferences for timing and use of different technology platforms to complete mental health–related PROMs.

Methods: We invited a national sample of 1373 veterans to complete a survey; 858 (62.5%) responded. Surveys asked about veteran preferences for how and when to complete mental health–related PROMs. We characterized responses using descriptive statistics and estimated multiple logistic regression models to examine associations between veteran demographic and health characteristics and preferences for completing PROMs.

Results: Most veterans preferred completing PROMs between appointments (607/801, 75.8%) using features of a patient portal (410/801, 51.2%), during appointments (589/801, 73.5%) verbally (413/801, 51.6%), and while at the medical center (480/801, 59.9%) on paper (189/801, 23.6%) or a tablet computer (180/801, 22.5%). Hispanic (vs non-Hispanic) veterans had 3.32 (95% CI 1.04-10.58) times higher odds of preferring to complete PROMs at the medical center, and veterans with lower (vs higher) socioeconomic status had lower odds (odds ratio 0.61, 95% CI 0.40-0.93) of preferring to complete PROMs in between appointments but 1.97 (95% CI 1.23-3.16) times higher odds of preferring to complete PROMs during appointments.

Conclusions: As the Veterans Health Administration and other health care systems seek to expand the integration of PROM data into health care services, adaptive and flexible approaches to PROM administration that align with patient preferences,

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including those that leverage technology platforms in the remote collection of these data, may bolster implementation. Our results indicate that such implementation efforts should consider patient ethnicity and socioeconomic status. Our findings further suggest that these efforts could benefit from incorporating PROM administration into online patient portals, developing mobile health apps that support PROM completion through patients' personal devices in between clinical encounters, and engaging care team members in PROM administration during appointments.

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KEYWORDS

measurement-based care; patient preferences; patient-reported outcomes; technology-based assessment; veterans

Introduction

Despite encouraging evidence of their clinical utility, the integration of patient-reported outcome measure (PROM) data into health care practice—also referred to as measurement-based care (MBC)—remains limited [1-5]. A recent Cochrane review of 116 randomized studies concluded that using PROM data in health care has a moderate effect on improving important aspects of clinical care, including accuracy of diagnoses, disease management, and patient-healthcare team member communication [4]. Nevertheless, only 60% of a recent sample of 600 hospital and clinic administrators reported wanting to implement routine PROM collection within their organization to improve patient experiences, and only 38% of the total sample indicated that they had done so [6].

There is recognition that PROM collection in the context of clinical care may be bolstered by leveraging technology platforms [7] either in between clinical encounters or before an encounter, while patients are waiting to see their care team members. In fact, several professional organizations have suggested that one strategy for bolstering implementation of MBC practices is to improve engagement by aligning PROM administration with patient needs and preferences [8,9]. However, additional information is needed regarding patient preferences for timing and use of different technology platforms to complete PROMs, particularly those related to potentially sensitive topics such as mental health–related symptoms.

To date, research regarding such patient preferences is mixed, largely relying on qualitative data or focused narrowly on specific contexts of care [10-12]. For example, one recent systematic review of 14 qualitative studies reported mixed findings among patients regarding preferred modality (paper-and-pencil vs electronic), timing (at home vs at the clinic), and frequency of completing PROMs as part of their health care [13]. This review further noted a range of reasons for patient preferences, including that patients who preferred to complete PROMs at home felt that they would be more likely to respond honestly, whereas patients who preferred to complete PROMs at the clinic liked that it gave them something to do while they waited for their appointment [13]. Other literature suggests that preferences may be influenced by demographic characteristics [14]; however, little research has been conducted regarding preferences for completing PROMs among diverse populations. Taken together, the existing literature base indicates that additional work focused on patient preferences for using technology platforms to complete PROMs is warranted.

The Veterans Health Administration (VHA), the largest integrated health care system in the United States, is currently working to further the integration of patient-generated health data (PGHD)—including PROMs—into practice; this is evidenced in part by national calls to incorporate MBC practices across mental health services and by the development of policies to guide veteran PGHD collection and use [15-17]. Tailoring the timing and mode of PROM administration, including through the use of relevant technology platforms, may increase the likelihood that veterans will share such data with their care team members.

Several technology platforms, including but not limited to VHA's online patient portal (ie, My HealtheVet), the VHA automated text messaging system (ie, Annie), and platforms targeted toward the implementation of MBC in mental health services (ie, Behavioral Health Lab, Mental Health Assistant, and Mental Health Checkup [18-21]), have been available within the VHA health care system to support the administration of PROMs and their integration into care. Taken together, these various technology platforms allow for the collection of PROMs in numerous ways, including having patients complete PROMs before a clinical encounter from outside of the clinic, before a clinical encounter while in a clinic waiting room, or verbally with a member of their care team. Depending on how PROM data are collected, patients may enter responses directly into one of these platforms, or their care team members may either enter the data or add text to a clinical note in the electronic health record. The objective of this analysis was to characterize veteran preferences for timing and use of different technology platforms to complete mental health–related PROMs and assess factors associated with preferences regarding when (eg, in between, during, or just before clinical encounters) to complete mental health–related PROMs.

Methods

Design

These data were collected as part of a longitudinal survey effort initiated in 2017 and referred to as the Veterans Engagement With Technology Collaborative (VET-C) cohort. The overall goal of the VET-C cohort was to collect veteran feedback on VHA patient-facing technologies intended to improve access to and delivery of care and support veteran self-management [22]. The VET-C cohort was initiated by the VHA's Office of Connected Care in partnership with investigators from the VHA's Quality Enhancement Research Initiative program. Survey data were combined with additional demographic and health information from VHA administrative data. Of note,

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surveys were reviewed by a veteran before their fielding for readability and relevance.

Sample

A set of 14 geographically dispersed VHA facilities were identified as VET-C recruitment sites. We identified veterans who were active users of VHA patient-facing technologies (ie, secure messaging) to be included in the cohort. Secure messaging use was defined as sending a minimum of 5 messages through the VHA's online patient portal in the year before cohort recruitment. Further details related to sampling for the VET-C cohort can be found in previous publications [22,23].

Procedures

Survey data were collected from members of the VET-C cohort at 3 time points: 2017 to 2018, 2019 to 2020, and 2021 to 2022. Data collection procedures for the first 2 rounds of surveys are described in previous publications [22,23]. Veterans who responded to the first 2 surveys were invited to complete the third survey, which was administered via mail. Nonresponders to the initial mailing were mailed a follow-up survey approximately 4 weeks later to enhance response rates. Veterans were also provided the option to complete the survey via phone with a member of our evaluation team; 2 veterans chose to do so. Survey data were entered into the VHA's secure electronic data capture platform, REDCap (Research Electronic Data Capture) [24].

Measures

The survey collected data on veteran demographic characteristics, health and health care use, technology ownership and use, and preferences for completing PROMs. Demographic characteristics included veteran age, sex, race, ethnicity, source of health care (ie, within or outside the VHA), level of difficulty paying for basics such as food and heating and cooling, and current housing situation. We asked veterans to rate their physical and mental health on a 5-point Likert scale ranging from excellent to poor. Veteran health conditions were obtained from diagnosis codes in the VHA Corporate Data Warehouse. We also used Corporate Data Warehouse data to fill in any missing survey data on key demographic variables.

To assess veteran preferences for completing mental health–related PROMs, we provided basic framing language to explain the purpose of PROMs: "Now we would like to know your preferences for providing information about your health to your VHA healthcare team. Sometimes, your VHA healthcare team members ask you to complete questionnaires about your symptoms or health status (these are called assessments). We are interested in how and when you prefer to complete such assessments." Following this framing, we asked veterans to report both when and how they preferred to complete PROMs (ie, "When and how do you prefer to complete assessments about your behavioral health (eg, depression, anxiety, alcohol use, stress)?"). Regarding preferences related to *when*, response options were "in between my appointment when I am not at the VHA," "when I am at the VHA," and "during my appointments with my VHA provider(s)." Regarding preferences related to *how*, response options included the use of different technology platforms: (1) secure messaging, a mobile health app, or mailed paper-and-pencil assessments for in between appointments; (2) on a kiosk, on paper-and-pencil, or on a tablet computer when at the VHA (in the waiting room before an appointment); and (3) on a tablet computer, on a kiosk, on paper-and-pencil, or verbally with their providers during appointments. Veterans were allowed to select more than one response per question, and we included all responses in our data analyses.

Analyses

We characterized veteran survey responses using descriptive statistics. We then used multiple logistic regression models to examine factors associated with veteran preferences regarding when to complete mental health–related PROMs, controlling for key demographic characteristics and health conditions. All statistical analyses were performed using Stata/MP (version 17; StataCorp).

Ethical Considerations

This work was reviewed by the institutional review boards at the VHA hospital in Hines, Illinois, and the VHA Bedford Healthcare System in Bedford, Massachusetts, and designated as program evaluation for quality improvement purposes, exempting it from further oversight (VHA Handbook 1058.05). Returning a survey was considered consent to participate in the evaluation. All data were deidentified for analysis. No compensation was provided to participants.

Results

Response Rate

We mailed surveys to 1373 veterans who completed rounds 1 and 2 surveys from the VET-C cohort and asked them to complete a third-round survey. Of the 1373 third-round survey invitations, 10 (0.7%) were returned due to bad addresses, and an additional 5 (0.4%) were returned because the veteran was deceased. From the sample of 1358 veterans who were thus eligible to complete a round 3 survey, we received responses from 858 (63.2%). We included veterans with complete data on model covariates in our analyses (801/858, 93.4%).

Sample Characteristics

Most survey respondents were aged >65 years (603/858, 70.3%), male (751/858, 87.5%), White (763/858, 88.9%), and married or in a civil union (582/827, 70.4%) and received their health care mostly from the VHA (617/857, 72.0%; Table 1). Nearly half (413/852, 48.5%) reported having obtained a master's degree or higher professional degree. Most reported being in excellent, very good, or good physical (596/854, 69.8%) and mental (695/856, 81.2%) health. The vast majority (807/837, 96.4%) lived in their own house or apartment. Approximately a quarter (189/776, 24.4%) of the sample reported low socioeconomic status (SES; ie, difficulties paying for basics such as food and heating and cooling). Nearly half (404/858, 47.1%) had a diagnosis consistent with an anxiety disorder, 38.1% (327/858) had a diagnosis consistent with a depressive disorder, and 29.3% (251/858) had a posttraumatic stress disorder diagnosis.

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Table 1. Veteran characteristics.

Characteristic	Participants, n/N (%)
Age (years)	
>65	603/858 (70.3)
≤65	255/858 (29.7)
Sex	
Male	751/858 (87.5)
Female	107/858 (12.5)
Race	
Black, African American, or other	95/858 (11.1)
White	763/858 (88.9)
Hispanic or Latino Ethnicity	
No	831/858 (96.9)
Yes	27/858 (3.1)
Relationship status	
Married or in a civil union	582/827 (70.4)
Neither married nor in a civil union	245/827 (29.6)
Educational level	
High school graduate or lower	106/852 (12.4)
At least some college or vocational education (1-4 y)	333/852 (39.1)
Master's, professional, or doctoral degree	413/852 (48.5)
Place where they received medical care	
Mostly at the VHA[a]	617/857 (72.0)
Other	240/857 (28.0)
Physical health	
Excellent, very good, or good	596/854 (69.8)
Fair or poor	258/854 (30.2)
Mental health	
Excellent, very good, or good	695/856 (81.2)
Fair or poor	161/856 (18.8)
Housing	
Own or rent an apartment or house	807/837 (96.4)
Other	30/837 (3.6)
Financial difficulties	
No	587/776 (75.6)
Yes	189/776 (24.4)
Mental health condition	
Anxiety disorders	404/858 (47.1)
Depression	327/858 (38.1)
Posttraumatic stress disorder	251/858 (29.3)

[a]VHA: Veterans Health Administration.

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Veteran Preferences for PROM Completion

Most veterans in our sample preferred completing mental health–related PROMs in between appointments when not at the VHA (607/801, 75.8%) or during appointments with their VHA providers (589/801, 73.5%; Table 2). Respondents endorsed to a lesser degree the option to complete PROMs when at the VHA before an appointment (480/801, 59.9%). Regarding preferences for how to complete PROMs, most veterans reported similar preferences for completing mental health–related PROMs: (1) using a secure messaging feature through a patient portal when completing these PROMs in between appointments when not at the VHA (410/801, 51.2%), (2) on paper-and-pencil (189/801, 23.6%) or on a tablet computer (180/801, 22.5%) when completing PROMs at the VHA before an appointment, and (3) verbally (413/801, 51.6%) when completing PROMs during appointments with their VHA providers.

Table 2. Veteran preferences for completing patient-reported outcome measures about mental health symptoms (N=801).

Preference	Participants, n (%)
In between my appointments when I am not at the VHA[a]	607 (75.8)
Using secure messaging through a patient portal	410 (51.2)
Using a mobile health app on a smartphone, tablet, or other computer	155 (19.4)
Completing paper-and-pencil assessments mailed to me	132 (16.5)
During my appointments with my VHA providers	589 (73.5)
Verbally	413 (51.6)
On a tablet computer	119 (14.9)
On paper-and-pencil	104 (13.0)
On a kiosk	48 (6.0)
When I am at the VHA	480 (59.9)
On paper-and-pencil in the waiting room before my appointment	189 (23.6)
On a tablet computer in the waiting room before my appointment	180 (22.5)
On a kiosk in the waiting room before my appointment	152 (19.0)

[a]VHA: Veterans Health Administration.

Factors Associated With Veteran Preferences for When to Complete PROMs

When controlling for demographic and health-related variables, veterans of Hispanic (vs non-Hispanic) ethnicity had greater odds of preferring to complete mental health–related PROMs (odds ratio [OR] 3.32, 95% CI 1.04-10.58) when at the VHA before an appointment (Table 3). Veterans reporting having (vs not having) financial difficulties had lower odds of preferring to complete mental health–related PROMs in between appointments when not at the VHA (OR 0.61, 95% CI 0.40-0.93) but greater odds of preferring to complete such PROMs during a visit with their VHA providers (OR 1.97, 95% CI 1.23-3.16).

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Table 3. Factors associated with preferences for when to complete patient-reported outcome measures about mental health symptoms.

Factor	In between appointments when not at the VHA[a], OR[b] (95% CI)	At the VHA, OR (95% CI)	During appointments, OR (95% CI)
Age (years)			
>65 (reference: ≤65)	1.35 (0.88-2.06)	1.09 (0.75-1.58)	1.21 (0.80-1.80)
Sex			
Female (reference: male)	1.35 (0.74-2.48)	1.28 (0.76-2.15)	1.05 (0.60-1.85)
Race			
Black or other (reference: White)	0.69 (0.37-1.29)	0.87 (0.50-1.51)	0.69 (0.38-1.25)
Hispanic or Latino Ethnicity			
Hispanic (reference: non-Hispanic)	1.36 (0.45-4.13)	*3.32*[c] (1.04-10.58)	3.27 (0.88-12.21)
Marital status			
Married (reference: not married or in a civil union)	0.77 (0.50-1.20)	0.93 (0.64-1.34)	0.91 (0.60-1.39)
Educational level			
At least some college or vocational education (reference: high school or lower)	0.83 (0.47-1.49)	0.87 (0.53-1.44)	0.61 (0.33-1.13)
Place where care is received			
Mostly at the VHA (reference: other)	0.96 (0.65-1.43)	0.86 (0.61-1.21)	0.97 (0.65-1.42)
Physical health			
Excellent, very good, or good (reference: fair or poor)	0.79 (0.51-1.21)	0.96 (0.67-1.38)	0.96 (0.63-1.45)
Mental health			
Excellent, very good, or good (reference: fair or poor)	0.62 (0.36-1.07)	1.10 (0.70-1.72)	1.46 (0.88-2.41)
Housing status			
Owning or renting (reference: other)	0.95 (0.32-2.80)	1.22 (0.50-2.96)	1.74 (0.67-4.53)
Financial difficulties			
Yes (reference: no)	*0.61*[c] (0.40-0.93)	1.34 (0.91-1.97)	*1.97*[d] (1.23-3.16)
Depression			
Yes (reference: no)	1.46 (0.92-2.30)	1.23 (0.83-1.83)	1.14 (0.73-1.78)
Anxiety			
Yes (reference: no)	1.37 (0.84-2.24)	0.81 (0.53-1.23)	0.97 (0.61-1.55)
PTSD[e]			
Yes (reference: no)	0.67 (0.41-1.11)	1.25 (0.82-1.91)	1.32 (0.81-2.14)

[a]VHA: Veterans Health Administration.

[b]OR: odds ratio.

[c]*P*<.05.

[d]*P*<.01.

[e]PTSD: posttraumatic stress disorder.

Discussion

Principal Findings

Overall, veterans indicated a preference for completing mental health–related PROMs either in between or during appointments with their VHA providers as opposed to before appointments in clinic waiting rooms and preferred to do so using secure messaging via a patient portal or verbally with their providers, respectively. However, our results suggested differences in preferences based on demographic characteristics, including ethnicity and SES. These findings suggest that technology platforms, including secure messaging features of online patient portals, may bolster implementation of remote MBC practices, although the rollout of such remote MBC practices may benefit from targeted improvement efforts among certain segments of

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the patient population, including those patients experiencing financial stressors. Our findings further suggest that care team members should elicit preferences for how and when to complete PROMs from each veteran and administer PROMs in accordance with those preferences to optimize the likelihood that veterans will provide PROM data as part of their health care. These results present a foundation through which the VHA, as well as other health care systems, can support patient-centered implementation of MBC practices and use of PGHD in clinical care.

Patient-facing technologies such as patient portals may facilitate completion of PROMs for MBC; however, more research is needed to understand when patients are willing to use technologies to complete PROMs and when they are not. Our findings suggest a high degree of comfort with completing PROMs through secure messaging via a patient portal among our cohort, which may be due in part to the fact that all our survey respondents had used secure messaging at some point. However, there is high engagement overall among veterans with the VHA's online patient portal, My HealtheVet [25,26]. As secure messaging was first implemented in the VHA nationwide in 2010, its use has continued to grow [25]. In May 2025 alone, the number of secure messages sent by veterans exceeded 1.7 million [27]. The literature also suggests that secure messaging has been used in the VHA to support MBC for behavioral health [26]. As such, facilitating PROM completion via secure messaging may bolster engagement in MBC practices among some veterans.

In addition, the literature has reported that older veterans are less likely than younger veterans to prefer using smartphone or tablet technologies [28,29]. Thus, the average age of our overall sample may be one reason for the low rate of reported preferences for using smartphone or tablet technologies to complete PROMs [30]. Alternatively, the low preferences for use of smartphone or tablet technologies, even in a sample of individuals who are known technology users, may suggest that veterans are more trusting of the security and privacy associated with other methods for completing PROMs, such as secure messaging through a patient portal. However, several studies in the context of cancer care have found that integration of smartphone apps with tethered patient portals increases patient engagement in completing PROMs [31]. As the use of health-related mobile apps increases, the ability to synchronize mobile app data with patient portals may facilitate veteran use of apps to collect and share data with the VHA [32,33].

Our findings further highlight the need to be sensitive toward differences across the demographic characteristics (eg, ethnicity and SES) of patients to ensure opportunity to complete PROMs. In line with previous research, we observed differences in preferences among certain segments of the veteran population that could contribute to the ongoing digital divide in health care access and outcomes [14,34-36]. While we are still unsure of the extent, there seems to be a strong preference among Hispanic veterans to complete assessments while present at the VHA. This is aligned with prior research suggesting that portal users of Hispanic ethnicity were less likely than users of White race to use secure messaging [37]. Similarly, in a 2007 nationwide survey on health IT use, respondents of Hispanic ethnicity were less likely to access technologies between appointments with providers [38]. This could be due in part to reduced access to technology at home, lower health or computer literacy, or other health management and health communication preferences [39,40]. Patients' prior experiences with PROM completion or use of technology for health may also at least in part drive their preferences regarding when and how to complete PROMs. Although our data do not speak to these points, future work exploring such relationships is warranted.

In addition, veterans in our sample who reported experiencing financial difficulties were less likely to prefer completing PROMs in between appointments. This may be due in part to lack of access to technology with which to complete PROMs remotely, lower technological literacy, or lower health literacy [41,42]. Studies have shown that patients with lower SES are more likely to have privacy concerns or report not trusting remote measurement options [34]. This is supported in part by the preferences reported by the veterans in our sample for completing assessments verbally with their providers.

Taken together, our findings can serve as a foundation for health care systems to design and implement patient-centered procedures to collect PROMs, including using technology platforms to assist with remote PROM collection. As our results suggest, methods of administering PROMs cannot assume a one-size-fits-all approach. The most effective ways to collect PROMs may depend on patient technology preferences and the availability of different technology platforms in different health care system settings [43]. It may also depend on the cadence with which PROMs are collected in different clinical contexts. For example, PROMs collected as part of mental health care services, such as evidence-based psychotherapies widely offered within the VHA, where patients are seen frequently (often weekly), may be collected much more often than in other medical settings such as primary care, where patients are typically seen 1 or 2 times per year. The frequency with which PROMs are collected may influence patient preferences for how to complete those PROMs—one can imagine that patients who are asked to complete the same PROMs every week in tandem with evidence-based psychotherapy visits may prefer to complete those PROMs virtually, whereas patients who are asked to complete PROMs annually in tandem with primary care visits may prefer to complete those PROMs in the clinic waiting room or verbally with a member of their care team. Additionally, older veterans may not use smartphones or tablets but may be more amenable to secure messaging as an alternative for PROM completion.

Moreover, although we cannot assume that changing the way in which a validated PROM is administered will retain its psychometric properties (eg, if a measure is validated to be administered on paper-and-pencil, having a health care team member verbally ask the questions may impact the psychometric properties of the measure), several reviews of the literature have concluded that different methods (eg, electronic vs paper-and-pencil) and even modest adaptations to collection procedures (eg, interactive voice response systems) do not reduce the validity of the results [44-46]. Thus, the ability to meet veteran preferences does not seem to reduce data quality and, in fact, may potentially improve PROM data by facilitating

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more genuine responses. Future research may examine more fully the extent to which the psychometric properties of PROMs are impacted based on the mode of administration used.

Limitations

Several limitations need to be considered when interpreting our results. First, our sample comprised veterans who were known users of patient-facing technologies, which may impact generalizability. Second, the homogeneity of our sample demographics (ie, mostly White, male, and aged >65 years) may limit the generalizability of our findings. Third, our relatively small sample size may have limited the statistical power of our analyses. Fourth, when completing surveys, there is the risk of recall and response biases. In addition, our data do not address patient perceptions of the usability of the various technology platforms that may be used to administer PROMs, a factor that could influence preferences and that should be assessed in future work. Finally, due to the nature of the cross-sectional design of the data collection, we cannot make any inferences about the causality between veteran characteristics and preferences for completing PROMs. Despite these limitations, these findings add important insights to our understanding of patient preferences for completing PROMs in different contexts and using different technology platforms.

Conclusions

As the VHA seeks to expand initiatives related to the use of MBC practices and PGHD as part of health care services, adaptive and flexible approaches to PROM administration that align with veteran preferences [47] and leverage technology platforms to collect PROMs remotely [7] may be beneficial. Our findings provide foundational insights into veteran preferences for completing PROMs and can be used to design patient-centered PROM data collection procedures. Furthermore, our findings suggest that initiatives focused on promoting the administration of PROMs as part of clinical care could incorporate administering PROMs using the VHA's online patient portal, developing mobile health apps that support veteran completion of PROMs using their personal devices in between VHA clinical encounters and building veteran trust in the privacy and security of those apps, and engaging care team members in the administration of PROMs during appointments.

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Data Availability

The datasets generated or analyzed during this evaluation are not publicly available because they are not permitted to leave the Veterans Health Administration (VHA) firewall without a data use agreement but are available from the corresponding author on reasonable request and with appropriate documentation.

Conflicts of Interest

None declared.

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Abbreviations

MBC: measurement-based care
OR: odds ratio
PGHD: patient-generated health data
PROM: patient-reported outcome measure
REDCap: Research Electronic Data Capture
SES: socioeconomic status
VET-C: Veterans Engagement With Technology Collaborative
VHA: Veterans Health Administration

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Original Paper

Occupational Therapy Services for Community-Dwelling Patients With Stroke in Thailand: Explanatory Sequential Mixed Methods Study

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Abstract

Background: Stroke is a major cause of long-term disability, and upper extremity (UE) impairment frequently limits independence in activities of daily living (ADLs) and community participation. In Thailand, although acute stroke care has improved, continuity of rehabilitation in community settings remains uneven. Currently, there is limited empirical evidence identifying occupational therapy (OT) services and the barriers affecting service delivery in practice.

Objective: This study aimed to examine current OT practices among community-dwelling patients with stroke in Thailand, identify barriers affecting service delivery, and explore therapists' perspectives on the future development of community-based rehabilitation.

Methods: An explanatory sequential mixed methods design was used. Phase I (survey phase) involved an online survey of 59 occupational therapists to describe service patterns and perceived barriers, while phase II (interview phase) comprised semistructured interviews with 7 experienced occupational therapists to obtain deeper insight into practice contexts and challenges. Quantitative data were analyzed descriptively, and qualitative data were analyzed using thematic analysis.

Results: OT services were primarily individualized and focused on functional activities, particularly basic ADLs (49/59, 83.05%), cognitive (44/59, 74.58%), and sensorimotor training (40/59, 67.80%). Service frequency was generally limited, and nonstandardized assessments were commonly used alongside policy-required measures, such as the Barthel Index. Major barriers were identified at organization/leadership, client, and therapist levels, including resource shortages (50/59, 84.75%), inaccessible to service (45/59, 76.27%), lack of public awareness about OT (45/59, 76.27%), and lack of time (42/59, 71.19%). Occupational therapists described adapting practice through client-centered and culturally responsive approaches, with active caregiver involvement. A proposed home-based stroke rehabilitation box set emerged as a potential strategy to support continuity of rehabilitation.

Conclusions: Community-based OT in Thailand operates within structural constraints, while maintaining occupation-centered practice. Strengthening services may require system-level support and practical strategies to enhance continuity of care.

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KEYWORDS

stroke; occupational therapy; rehabilitation; community; barriers; social participation; quality of life; qualitative study; mixed methods

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Introduction

Stroke remains a leading cause of long-term disability both in Thailand and worldwide [1,2]. Although improvements in acute management have enhanced survival rates, many patients with stroke continue to experience persistent functional limitations that affect daily life [3,4]. In particular, upper extremity (UE) dysfunction is common and often long-lasting, restricting independence in self-care, work-related tasks, and community participation [5]. Limitations in activities of daily living (ADLs) are closely associated with reduced quality of life and diminished social engagement [6]. For many individuals, meaningful recovery depends not only on early medical treatment but also on sustained rehabilitation within the home and community environment.

In Thailand, considerable progress has been made in strengthening acute stroke pathways; however, continuity of rehabilitation remains uneven [2,7]. The length of hospital stay is typically short, averaging between 3 and 7 days [7-10], and only a proportion of patients with stroke receive structured inpatient rehabilitation prior to discharge [7,11]. As a consequence, many patients are discharged with ongoing impairments and variable access to follow-up rehabilitation services [12]. The introduction of the Intermediate Care (IMC) policy by the Thailand Ministry of Public Health sought to address this gap by promoting transitional and community-based rehabilitation through multidisciplinary collaboration [13]. Although evaluations of IMC programs report improvements in functional outcomes [11,14,15], implementation at the service level continues to face practical challenges. These include resource limitations, administrative demands, transportation barriers, and uneven service distribution across regions [16]. Such challenges are not unique to Thailand but are characteristic of rehabilitation systems operating within constrained resource environments.

Occupational therapists play a crucial role in supporting patients with stroke in regaining functional independence and participation. Through occupation-based assessment and intervention, occupational therapists address not only motor recovery but also the integration of meaningful activities into daily routines and life roles [17,18]. In a community setting, practice extends beyond impairment-focused approaches and requires an in-depth understanding of broader environmental, cultural, and social contexts [19-22]. In Thailand, where family caregiving plays a prominent role and community resources vary widely, culturally responsive and context-sensitive practice becomes especially important [23,24]. However, despite the recognized importance of community-based occupational therapy (OT), there remains a limitation of empirical research evidence describing how these services are delivered in practice. Much of the existing literature focuses on program outcomes or policy implementation, while less attention has been given to therapists' day-to-day experiences, service structures, and the barriers they encounter when working with community-dwelling patients with stroke. A clearer understanding of current OT practice patterns and contextual challenges is necessary to inform sustainable service development. Exploring therapists' perspectives may provide insight into how rehabilitation is adapted within existing policy frameworks and resource realities. It may also reveal locally grounded innovations that can strengthen continuity of care beyond clinical settings. Therefore, the aim of this study was to examine current OT practices for stroke rehabilitation among community-dwelling patients with stroke in Thailand, identify key barriers affecting service delivery, and explore occupational therapists' perspectives on future development of community-based rehabilitation services. By integrating findings from a nationwide survey with in-depth qualitative interviews, this study sought to contribute contextually grounded evidence to inform the improvement of community stroke rehabilitation in Thailand.

Methods

Study Design

This study used an explanatory sequential mixed methods design consisting of two phases [25]. Phase I (survey phase) was a cross-sectional online survey designed to collect quantitative data on existing OT practices and barriers in community-based OT services for Thai patients with stroke living in the community. Phase II (interview phase) used a generic qualitative design to build upon the initial findings. Through semistructured interviews, this phase gathered qualitative insights regarding service experiences, barriers to practices, and occupational therapists' perspective on developing effective OT services in community stroke rehabilitation. The explanatory sequential mixed methods design enhanced the comprehensiveness of the findings and allowed qualitative data from the descriptive qualitative design to clarify and expand upon the quantitative results [26].

Participants

Phase I: Survey Phase

Participants were recruited using purposive sampling from the official registry of the Occupational Therapist Association of Thailand (OTAT), which contained 1171 registered occupational therapists at the time of the study. To ensure relevance to the study objectives, participants were required to (1) be registered occupational therapists in Thailand, (2) have at least 1 year of experience working with community-dwelling patients with stroke, and (3) confirm their willingness to participate. In total, 75 occupational therapists who met these criteria were formally invited to participate in the online survey via OT social media networks.

Phase II: Interview Phase

A selective sampling strategy was used to identify key informants based on their primary practice setting and expertise in providing community-based stroke rehabilitation. This approach aimed to reflect a range of service contexts and professional perspectives. Inclusion criteria for the interview phase were (1) at least 3 years of experience delivering services to community-dwelling patients with stroke, (2) active provision of community stroke rehabilitation at least twice per week, and (3) willingness to provide informed consent for audio-recorded interviews. Due to the anonymous nature of the survey phase, participants for the qualitative phase were recruited

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independently of the survey respondents. Initial key informants were purposively selected based on their recognized expertise and primary practice setting in providing community-based stroke rehabilitation. Subsequently, the snowball sampling technique was used, wherein initial participants identified other practitioners with significant experience in providing OT services for community-dwelling patients with stroke in Thailand to ensure a comprehensive range of professional insights. Recruitment and interviews continued until data saturation was reached. Saturation was assessed through a concurrent analysis process, where interviews were transcribed and coded in tandem with ongoing recruitment. The researchers monitored for thematic redundancy, specifically looking for the point where no additional insights or new themes emerged from subsequent interviews [27]. Given that the participants were expert key informants with extensive experience in community-based stroke rehabilitation, a high degree of conceptual density was reached. Recruitment was concluded when the last two consecutive interviews confirmed that the existing thematic framework was stable and sufficiently addressed all research questions.

Research Instruments

Given the contextual characteristics of community OT practice in Thailand and the lack of a validated instrument specific to this topic, the authors developed the research instruments. Instrument development was informed by a review of the relevant literature on community rehabilitation, stroke recovery, and OT practice.

In the survey phase, a questionnaire consisting of two sections was used. The first section of the questionnaire consisted of 13 items designed to collect demographic and practice-related information. These items included personal demographics (sex, education level, and employment status) and clinical practice characteristics (eg, primary practice setting, years of experience in community-based stroke rehabilitation, average number of stroke patients per week, frequency and duration of services, intervention formats, and the recovery stages of stroke patients served, categorized by Brunnstrom stages). The second section focused on perceived barriers to rehabilitation services for community-dwelling patients with stroke. This section also included open-ended questions to gather participants' views on the characteristics of an effective community-based rehabilitation program. A combination of dichotomous, multiple-response, and open-ended questions was used to gather both quantitative trends and qualitative insights.

For the interview phase, a semistructured interview guide was developed to explore therapists' experiences in service delivery, practical challenges encountered in community settings, and perspectives on future development of OT services. The interview questions are presented in Textbox 1.

Textbox 1. Questions in the semistructured interview guide.

1. Please introduce yourself (educational background, work history, and experience in providing services to Thai patients with stroke living in the community).
2. What is the form or nature of providing services to patients with stroke with limited arm and hand movement living in your community?
3. What do you think of the form of occupational therapy (OT) for patients with stroke living in the community with limited arm and hand movement in Thailand from the past to the present?
4. What do you think should be the form of OT rehabilitation for this group of patients?
5. What do you think are the barriers to OT rehabilitation for this group of patients?
6. How do you think these barriers should be eliminated?
7. What do you think will help promote OT rehabilitation for this group of patients to be more effective?

Instrument Validation

The developed instruments were evaluated for content validity and clarity by three experienced occupational therapists, each with more than 5 years of experience in stroke rehabilitation. They independently reviewed all surveys and interview guide questions. The Index of Item-Objective Congruence (IOC) was used to assess the alignment of each item with the study objectives. Items with IOC scores between 0.50 and 1.00 were retained, while items scoring below 0.50 were revised or removed [28]. In addition, a pilot test was conducted with five occupational therapists. Their feedback was used to refine the wording, clarity, and practicality of the instruments.

Ethical Considerations

Ethical approval was obtained from the Ethical Review Committee for Human Research, Faculty of Associated Medical Sciences (approval #161/2562). All procedures complied with national ethical guidelines for research involving human participants [29].

In the survey phase, eligible participants received detailed information about the study and the informed consent process. The online survey in this study was reported in accordance with the CHERRIES (Checklist for Reporting Results of Internet E-Surveys) checklist [30].

In the interview phase, participants' consent was obtained to audio-record interviews and take field notes to capture contextual details. Written informed consent was obtained prior to the interviews.

Data Collection

In the survey phase, eligible participants were provided with the study objectives and procedures, together with a link to the online survey distributed via OT social media networks. Reminder messages were sent to eligible participants 1 week and 3 days before survey closure to increase response rates and

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reduce nonresponse bias [31]. In the interview phase, in-depth interviews were conducted either face to face or via online videoconferencing, depending on participant preferences and logistical considerations. Each interview lasted approximately 30-45 minutes.

The data collection was divided into two distinct periods:

- Phase I (survey phase): conducted from February 2020 to December 2021. This phase captured the initial impact of the COVID-19 pandemic on OT services.
- Phase II (interview phase): conducted from January 2022 to April 2025. This phase focused on long-term adaptations and current challenges in the postpandemic landscape.

Data Analysis

Quantitative Analysis

In the survey phase, survey responses were exported from Google Forms and analyzed using Microsoft Excel. Descriptive statistics, including frequencies and percentages, were used to summarize demographic characteristics, practice patterns, and perceived barriers. Responses to open-ended questions were analyzed using content analysis [32], in which responses were grouped inductively into thematic categories based on recurring patterns and shared meanings.

Qualitative Analysis

In the interview phase, interview recordings were transcribed verbatim. Thematic analysis was conducted following the six-phase framework by Braun and Clarke [33]. This trustworthy process included (1) familiarization with the data, (2) generation of initial codes, (3) searching for themes, (4) reviewing themes, (5) defining and naming themes, and (6) writing the report. Two researchers (authors SA and WC) independently conducted the initial coding using both inductive and deductive approaches. Discrepancies were resolved through discussion and consensus. Themes were further refined through collaborative review to ensure they accurately represented the data. Thematic analysis was completed between May 2022 and April 2025, ensuring that the integration of findings reflected the most recent professional context.

Trustworthiness and Rigor

This study used credibility, transferability, dependability, and confirmability as strategies to ensure trustworthiness and rigor. The credibility triangulation strategy used both quantitative and qualitative data obtained from participants among various contexts to ensure accuracy of the findings. The transferability strategy of thick descriptions was used by providing detailed background information, including participants' experiences, main practice settings, and the procedures for data collection and analysis. The confirmability strategy of peer debriefing was used by researchers to interpret results and reduce data bias [34,35].

Results

Quantitative Findings

The online survey was successfully completed by 59 occupational therapists, yielding a response rate of 78.67%. Table 1 shows the demographic and professional characteristics of the participants. The majority were female (35/59, 59.32%) and held a bachelor's degree (50/59, 84.75%) in OT, while the remaining participants had postgraduate qualifications. Almost all participants (58/59, 98.30%) reported full-time employment. A substantial proportion worked in district hospitals (25/59, 42.37%), suggesting that occupational therapists in these settings are actively involved in providing community-based stroke rehabilitation services.

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Table 1. Demographic and professional practice profiles of quantitative study participants (N=59).

Characteristics	Participants, n (%)
Sex	
Female	35 (59.32)
Male	24 (40.68)
Highest academic qualification	
Bachelor's degree	50 (84.75)
Master's degree	9 (15.25)
Main practice setting	
Subdistrict hospital	1 (1.70)
District hospital	25 (42.37)
Provincial hospital	12 (20.34)
Specialized hospital/institute	17 (28.81)
University hospital	1 (1.70)
Private hospital	3 (5.08)
Employment status	
Full-time	58 (98.30)
Part-time	1 (1.70)
Experience working with community-dwelling Thai patients with stroke (years)	
1-2	7 (11.86)
3-5	11 (18.64)
6-10	14 (23.73)
>10	27 (45.77)
Primary Brunnstrom stage of UE[a] recovery in patients with stroke served (ranked by frequency)	
1	8 (13.56)
2	12 (20.34)
3	20 (33.90)
4	14 (23.73)
5	5 (8.47)
6	0
Average number of patients with stroke per week	
1-5	19 (32.20)
6-10	13 (22.03)
>10	27 (45.77)
Average number of services per case per week	
1 time	29 (49.15)
2-3 times	15 (25.42)
4-6 times	5 (8.47)
Every day	10 (16.96)
Average service duration per case (minutes)	
<30	2 (3.39)
30-60	49 (83.05)
>60	8 (13.56)
Intervention forms	

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Characteristics	Participants, n (%)
Individual	40 (67.80)
Group	1 (1.70)
Both individual and group	18 (30.50)

[a]UE: upper extremity.

In terms of professional experience, nearly half of the participants (27/59, 46%) reported more than 10 years of experience working with community-dwelling patients with stroke. Most patients served by these therapists were classified as Brunnstrom Stage 3 (20/59, 34%), followed by stages 4 (14/59, 24%) and 2 (12/59, 20%), reflecting a population with moderate motor impairment. Individual therapy (40/59, 68%) was the most common mode of intervention. Many participants (27/59, 46%) reported managing more than 10 stroke cases per week. The most common service frequency per case was once per week (29/59, 49%), and the average duration of each session ranged from 30 to 60 minutes (49/59, 83%). These findings suggest a relatively high workload with limited service frequency per individual client. Nearly half of the participants had over 10 years of practice experience and managed a high weekly caseload of patients with stroke, indicating a significant depth of clinical experience of participants.

Almost all participants (36/59, 61%) allocated the majority of their time (51%-75%) to intervention rather than assessment, referral, or documentation, as shown in Table 2. Physicians (49/59, 83%) were the most frequent source of referrals, followed by nurses (20/59, 34%) and self-referrals (19/59, 32%), indicating that referral pathways remain largely a hospital-based (Table 3).

Table 2. Distribution of time allocation across OT[a] service components (N=59).

Service component	Time allocation				
	Never, n (%)	<25%, n (%)	26%-50%, n (%)	51%-75%, n (%)	>75%, n (%)
Assessment	0	44 (74.57)	14 (23.73)	1 (1.70)	0
Intervention	0	0	7 (11.86)	36 (61.02)	16 (27.12)
Referral	9 (15.25)	49 (83.05)	0	1 (1.70)	0
Documentation	0	58 (98.30)	1 (1.70)	0	0

[a]OT: occupational therapy.

Table 3. Frequency of referrals from various sources to OT[a] services (N=59).

Referral source	Not applicable, n (%)	Never, n (%)	Sometimes, n (%)	Often, n (%)
Physicians	0	3 (5.09)	7 (11.86)	49 (83.05)
Nurses	7 (11.86)	14 (23.73)	18 (30.50)	20 (33.91)
Occupational therapists	3 (5.08)	10 (16.95)	44 (74.58)	2 (3.39)
Self-referral	3 (5.08)	5 (8.47)	32 (54.24)	19 (32.21)
Family referral	9 (15.26)	23 (38.98)	18 (30.50)	9 (15.26)
Community health center/community agency staff	3 (5.08)	10 (16.95)	37 (62.71)	9 (15.26)
Health insurance system	13 (22.03)	31 (52.55)	11 (18.64)	4 (6.78)
Screening from the community by occupational therapists	7 (11.86)	17 (28.82)	24 (40.68)	11 (18.64)

[a]OT: occupational therapy.

Table 4 illustrates assessment tools used in community OT services according to standardized, nonstandardized, or both standardized and nonstandardized assessments. All participants (59/59, 100%) reported assessing basic activities of daily living (BADLs) and cognitive function. Sensorimotor (58/59, 98.30%), and physical (57/59, 96.61%) components were also commonly evaluated. Nonstandardized assessments were widely used across most occupational performance domains. Standardized assessments were used more frequently in the evaluation of BADLs (42/59, 71.19%) compared to other domains, suggesting greater accessibility or familiarity with formal measurement tools in this area.

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Table 4. Characteristics of assessment instrument use across occupational performance domains (N=59).

Occupational performance domain	Standardized assessment, n (%)	Nonstandardized assessment, n (%)	Both standardized and nonstandardized assessment, n (%)	Never assessed, n (%)
BADL[a]	42 (71.19)	12 (20.34)	5 (8.47)	0
IADL[b]	25 (42.37)	23 (38.98)	8 (13.57)	3 (5.08)
Rest and sleep	2 (3.39)	38 (64.41)	0	19 (32.20)
Education	4 (6.78)	45 (76.27)	0	10 (16.95)
Work/productive activities	5 (8.47)	50 (84.75)	0	4 (6.78)
Play	4 (6.78)	39 (66.10)	0	16 (27.12)
Leisure	4 (6.78)	49 (83.05)	0	6 (10.17)
Social participation	5 (8.47)	45 (76.27)	0	9 (15.26)
Sensorimotor components	25 (42.37)	25 (42.37)	8 (13.56)	1 (1.70)
Cognitive components	29 (49.15)	21 (35.59)	9 (15.26)	0
Psychosocial and psychological components	11 (18.64)	41 (69.50)	2 (3.39)	5 (8.47)
Temporal aspects	4 (6.78)	48 (81.35)	1 (1.70)	6 (10.17)
Physical components	6 (10.17)	49 (83.05)	2 (3.39)	2 (3.39)
Social components	5 (8.47)	49 (83.05)	1 (1.70)	4 (6.78)
Cultural components	3 (5.08)	51 (86.44)	1 (1.70)	4 (6.78)

[a]BADL: basic activity of daily living.

[b]IADL: instrumental activity of daily living.

As shown in Table 5, the most frequently implemented interventions were BADL training (49/59, 83.05%), cognitive training (44/59, 74.58%), and sensorimotor training (40/59, 67.80%). These patterns correspond closely with the reported assessment priorities and reflect a significant focus on restoring BADL function and physical and cognitive functional recovery.

Table 5. Frequency of OT[a] intervention types across occupational performance domains (N=59).

Occupational performance domain	Never, n (%)	Sometimes, n (%)	Often, n (%)
BADL[a]	0	10 (16.95)	49 (83.05)
IADL[b]	4 (6.78)	34 (57.63)	21 (35.59)
Rest and sleep	32 (54.24)	23 (38.98)	4 (6.78)
Education	26 (44.07)	27 (45.76)	6 (10.17)
Work/productive activities	8 (13.56)	41 (69.49)	10 (16.95)
Play	28 (47.46)	26 (44.07)	5 (8.47)
Leisure	12 (20.34)	34 (57.63)	13 (22.03)
Social participation	15 (25.42)	29 (49.16)	15 (25.42)
Sensorimotor components	3 (5.08)	16 (27.12)	40 (67.80)
Cognitive components	1 (1.70)	14 (23.72)	44 (74.58)
Psychosocial and psychological components	12 (20.34)	32 (54.24)	15 (25.42)
Temporal aspects	20 (33.90)	30 (50.85)	9 (15.25)
Physical components	5 (8.48)	27 (45.76)	27 (45.76)
Social components	14 (23.73)	28 (47.46)	17 (28.81)
Cultural components	18 (30.51)	31 (52.54)	10 (16.95)

[a]BADL: basic activity of daily living.

[b]IADL: instrumental activity of daily living.

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Perceived barriers identified from survey responses were grouped into three categories: client related, occupational therapist related, and organizational/leadership related (Multimedia Appendix 1). The most frequently reported client-related barriers were inaccessibility to rehabilitation services (45/59, 76.27%) and limited public awareness of OT (45/59, 76.27%). Among therapist-related barriers, time constraints (42/59, 71.19%) were most frequently reported, indicating perceived workload pressures. Interestingly, the shortage of occupational therapists (6/59, 10.17%) was reported less frequently than other barriers. Organizational and leadership-related barriers were most commonly associated with resource shortages (50/59, 84.75%), including limited equipment, funding, and transportation.

Qualitative Findings

Seven occupational therapists with diverse backgrounds in community rehabilitation participated in the semistructured interviews. Their experience in working with community-dwelling patients with stroke ranged from 10 to 18 years (Table 6). All participants were involved in community rehabilitation services, including the IMC program. Thematic analysis generated several key themes, which are presented next with illustrative quotations.

Table 6. Demographic and professional experience profiles of qualitative study participants (N=7).

Participant ID	Sex	Main practice setting	Experience working with community-dwelling Thai patients with stroke (years)
T1	Female	District hospital	10
T2	Female	District hospital	12
T3	Female	District hospital	18
T4	Female	District hospital	16
T5	Female	Subdistrict hospital	15
T6	Female	Provincial hospital	17
T7	Female	Provincial hospital	16

Theme 1: Occupational Therapy Service and Clinical Reasoning

The setting in which OT services were delivered influenced both the frequency and the structure of the services. In community rehabilitation settings, therapists scheduled sessions once per month over a 6-month period, consistent with the IMC protocol. For clients who were able to access outpatient services, sessions were more frequent, usually two to three times per week. For long-term patients with stroke facing geographic, financial, or motivational barriers, service frequency was often reduced, sometimes occurring only every 4-6 months. In some cases, clients were lost to follow-up due to these combined constraints.

Most services were delivered individually, with sessions lasting approximately 60 minutes. Each session generally included assessment, intervention, referral, and documentation components. Documentation was described as essential, particularly for meeting IMC key performance indicators and supporting funding requirements. These highlight the influence of administrative structures on clinical practice.

Participants described their professional reasoning as grounded in a client-centered approach, emphasizing individualized OT goals within specific environmental contexts. Although nonstandardized assessments were commonly used due to time constraints and contextual variability, the Barthel Index (BI) was routinely administered to fulfill IMC reporting requirements. This illustrates how therapists balance clinical judgment with policy-mandated procedures. As one participant clearly stated:

> *Most stroke cases are both chronic and acute. The first assessment is with the Barthel Index before looking at ADL. It must be done for IMC data entry and financial reimbursement. Treatment remains functionally oriented-focusing on ADL-but incorporates techniques like PNF, Rood, NDT, and weight-bearing, with activities used to promote function. If the patient has a caregiver, we train them for continuity at home.* [Therapist 1]

Theme 2: Cultural Orientation

Participants emphasized the importance of culturally responsive practice in community rehabilitation. A recurring pattern was the integration of family-centered approaches that align with Thai collectivist values. Caregiving was often framed as a shared responsibility rather than a burden. Therapists described actively supporting and empowering family members to participate in the rehabilitation process. One therapist explained:

> *Emphasize the importance in the beginning: Encourage, let the relatives prepare themselves that the patient is not a burden. If we train them, they will get better, and we will not be tired...enhance the confidence of the caregiver to go to see the patient at home and empower them, because the main thing is that they need to be taken care of.* [Therapist 4]

This approach reflects the integration of cultural awareness into therapeutic relationships and service delivery.

Theme 3: Task-Oriented, Individualized Interventions

Interventions were described as combining preparatory and occupation-based approaches. Therapists highlighted the importance of task-oriented training to improve functional ADL performance. Programs were tailored to the individual's occupational roles and daily routines, reflecting client-centered practice. One therapist provided the following example:

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> *Each case will have a different program...For example, the chicken rice seller is not yet strong in holding a knife, so we try to make the knife handle bigger. We start with weight training, then wrap putty around a steel rod to mimic his work tool. He practices cutting the putty into pieces before returning to cutting chicken, starting by preparing food for personal use first.* [Therapist 4]

Theme 4: Challenging in Developing Home-Based Rehabilitation Tools

Participants identified the need for practical home-based rehabilitation tools to support continuity of care. One therapist proposed the development of a stroke rehabilitation box set consisting of portable, low-cost equipment designed to facilitate UE functional training and enhance accessibility of rehabilitation in home and community settings.

Beyond the equipment itself, participants emphasized the importance of training caregivers and community health volunteers to use these tools effectively. This was viewed as a strategy to extend rehabilitation beyond clinical visits and reduce therapist workload.

> *I want to develop a set of equipment designed for a stroke box set that can be used practically and be portable—no one has done it yet. It should include safe glasses, balls of different sizes, ADL items, functional training tools, or even special equipment for hand strength and dexterity…having one box to demonstrate or rotate could really help.* [Therapist 3]

Theme 5: Factors Influencing Program Feasibility

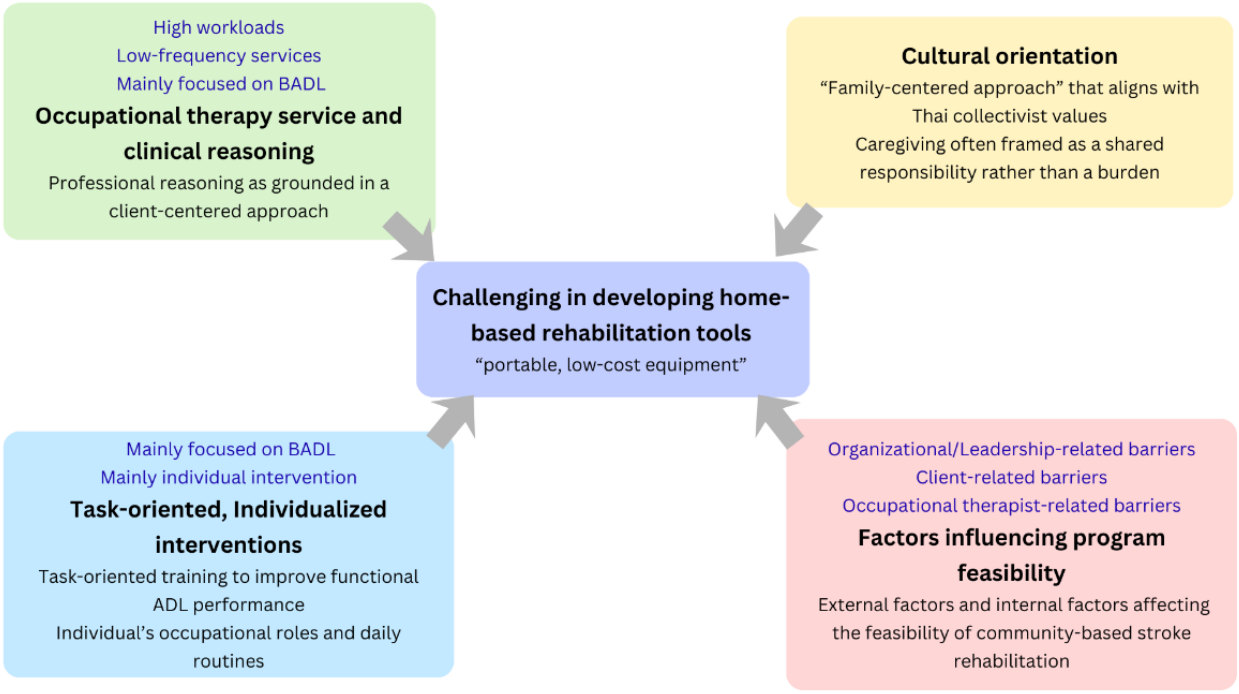
Participants identified both external and internal factors affecting the feasibility of community-based stroke rehabilitation. External factors included policy constraints, fund shortages, and limited availability of rehabilitation equipment. Internal factors included client motivation, caregiver burden, and therapist workload

The roles of caregivers and community health volunteers were also discussed. Some caregivers received formal training and compensation through long-term care systems, while others participated voluntarily. Participants noted that structured training and ongoing professional guidance could enhance the effectiveness of both caregivers and volunteers in supporting rehabilitation, particularly in rural communities. One participant reflected:

> *Volunteers or caregivers can be the same person, but caregivers must have at least 70 hours of certified training. They are paid per visit. Volunteers work out of goodwill and are not paid, but many people in the community take on several roles.* [Therapist 5]

The integrated findings from quantitative and qualitative data are summarized in Figure 1.

Figure 1. Integrated findings from quantitative and qualitative data. ADL: activity of daily living; BADL: basic activity of daily living.



Discussion

Principal Findings

This study examined current OT practices among community-dwelling patients with stroke in Thailand and explored the contextual factors shaping service delivery. The findings suggest that community-based OT services are largely individualized, functionally oriented, and delivered within practical constraints that influence frequency, assessment approaches, and intervention planning.

The quantitative findings indicate that most therapists manage relatively high caseloads, while providing services at a limited frequency per client. Sessions are predominantly focused on BADL, cognitive interventions, and sensorimotor interventions,

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which correspond to the clinical presentation of patients with stroke commonly classified within moderate motor impairment stages. The interviews revealed that these are delivered through task-oriented training adapted to the client's home environment. This synergy demonstrates that Thai community occupational therapists maintain occupation-based practice by embedding therapeutic goals within the practical functional needs of patients with stroke. These patterns reflect pragmatic prioritization of functional independence within available time and resource limitations. Similar trends toward function-focused, time-limited community rehabilitation have been reported in other low-, middle-, and high-income countries, where service intensity is often shaped by workforce capacity and infrastructure constraints rather than ideal clinical dosing [36-38]. The relatively frequent use of nonstandardized assessments, alongside routine administration of the BI for IMC reporting purposes, suggests that therapists balance clinical judgment with policy requirements. Rather than indicating inconsistency in practice, this pattern may represent contextual adaptation to administrative and system-level expectations.

Barriers to service delivery were reported at multiple levels. Organizational and leadership-related barriers, particularly resource shortages and transportation limitations, were most frequently identified in quantitative data. These findings highlight the structural factors that shape community rehabilitation, beyond individual therapist effort. Client-related barriers, including limited public awareness of OT and restricted access to services, further affect continuity of care. These findings are supported by our qualitative data, which elucidate the practical reality that occupational therapists experience a discharge rehabilitation gap postdischarge were geographic, financial, or motivational barriers directly hinder continuity of care. Interestingly, although workforce shortages were reported less frequently, time constraints were commonly identified, suggesting that workload pressures and administrative responsibilities may reduce opportunities for sustained therapeutic engagement. Our findings are consistent with previous studies, which have identified infrastructure, workforce, and policy challenges in Thai community OT rehabilitation services [12,39]. The qualitative narratives explain this discrepancy, revealing that therapists' time is not necessarily consumed by a lack of colleagues but by heavy administrative burdens linked to IMC reporting and the logistical challenges of traveling between community sites. This suggests that the perceived barrier is not a lack of clinicians per setting but a lack of clinical time within the current administrative framework. A related study conducted among Thai community-dwelling patients with stroke and their family caregivers revealed that a lack of knowledge and information related to rehabilitation contributes to a major barrier to the restoration of the functional abilities of patients with stroke [40]. For these participants, education from health care professionals and social support from local and central governments in accessing rehabilitation were perceived as crucial for well-being [40]. Together, these findings indicate that strengthening community rehabilitation requires attention not only to clinical training but also to system organization and resource allocation. Previous studies have suggested that strengthening community rehabilitation systems requires integrated service models, improved referral pathways, and policy-level investment in workforce and infrastructure [40-43]. These system-level strategies may complement the practice-level adaptations identified in this study, particularly in addressing structural barriers, such as resource limitations and service accessibility. The qualitative findings provide further insight into how therapists respond to these constraints. Participants described clinical reasoning that remains grounded in client-centered and occupation-based principles, even within policy-driven environments. The influence of IMC key performance indicators was evident in documentation and assessment procedures [11]; however, therapists continued to tailor interventions according to clients' occupational roles and daily routines. Examples of task-oriented training adapted to specific work contexts illustrate how occupation-based practice is maintained in community settings [39].

Cultural context also emerged as an important factor shaping rehabilitation processes. Therapists described actively engaging family members as partners in care and framing caregiving within culturally meaningful values. In settings where service frequency is limited, caregiver involvement becomes central to continuity of rehabilitation. This finding is consistent with the literature emphasizing caregiver-mediated rehabilitation in community stroke recovery [24,40]. In the Thai context, strong family networks may serve as a practical resource that supports functional recovery when formal services are constrained. International studies have likewise emphasized the value of caregiver-mediated interventions in sustaining home-based stroke rehabilitation, particularly where professional contact time is limited [44,45].

The COVID-19 pandemic acted as a catalyst for home-based rehabilitation in Thailand [46]. As hospital resources were diverted to the pandemic response, OT services were forced to adapt quickly to community-dwelling environments. This temporal context may have influenced the patterns observed and should be considered when interpreting the findings. This context likely intensified the barriers identified in Multimedia Appendix 1, such as resource shortages and the need for caregiver-mediated interventions, as practitioners had to rely more heavily on family support when face-to-face clinical visits were restricted.

This cultural reliance, combined with identified resource shortages, directly informed the participants' proposal of a stroke rehabilitation box set to support home-based intervention. Although conceptual at this stage, the idea reflects therapists' efforts to extend rehabilitation beyond clinic visits through portable, low-cost tools combined with caregiver training. Although home-based technologies offer the advantages of flexibility in location and time for rehabilitation therapy, they also allow patients to receive feedback from therapists remotely as the use of rehabilitation technologies in the home environment requires technical training [47,48]. Rather than representing a technological innovation, this proposal suggests a practical strategy for improving continuity of care within existing resource limits. Future research should examine the feasibility, acceptability, and clinical outcomes of such home-based support models.

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Limitations and Future Research

Although this study presents its strengths, certain limitations should be acknowledged. First, although the survey included participants from a range of practice settings, it may not fully represent the geographical diversity or variability of rehabilitation service structures across all regions of Thailand. Service organization and resource availability may differ in areas not captured within the sample. Second, the qualitative component included only occupational therapists. The perspectives of patients with stroke, their primary caregivers, and other rehabilitation professionals were not explored in this study. Including these stakeholders' voices in future research would provide a more comprehensive understanding of community rehabilitation processes and challenges. Third, although the study identified practice-based ideas, such as the proposed home-based rehabilitation kit, these concepts remain exploratory and require further investigation regarding their feasibility, effectiveness, and scalability within community settings. Fourth, a notable limitation of this study is the extended 5-year data collection period, which spanned the pre- and post–COVID-19 eras. The global pandemic significantly disrupted health care systems in Thailand, potentially causing shifts in OT practice and practitioners' perspectives over time. Although the sequential design allowed us to explore these transitions, the long duration may introduce historical bias, as participants' responses might be influenced by systemic changes not present in 2020. This temporal context should be considered when interpreting the findings. However, a strength of this prolonged engagement is the ability to capture the resilience and evolution of OT services during one of the most challenging periods for the Thai health care system.

Conclusion

Overall, the findings illustrate that community-based OT in Thailand operates within identifiable structural constraints, while maintaining core occupation-centered principles. Therapists demonstrate flexibility in adapting assessment and intervention strategies to local realities. Efforts to strengthen community rehabilitation should therefore address both system-level factors, such as resource allocation, transportation, and administrative workload, and practice-level supports, such as caregiver training and context-specific intervention tools.

Taken together, these findings offer a contextually grounded understanding of community-based OT practice in stroke rehabilitation, which may help inform ongoing efforts to strengthen services in similar settings.

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Data Availability

The data used in the manuscript are available from the corresponding author upon reasonable request.

Authors' Contributions

Conceptualization: SA, JPD, PC, ST, and PT
Data collection: SA, WC, and PC
Formal analysis: SA, WC, and JPD
Funding acquisition: SA, JPD, PC, ST, and PT
Supervision: JPD
Writing—original draft: SA, WC, and JPD
Writing—review and editing: SA, JPD, PC, ST, PT and WC

Conflicts of Interest

None declared.

Multimedia Appendix 1
Perceived barriers to community OT services. OT: occupational therapy.
[PNG File , 245 KB - jopm_v18i1e94765_app1.png]

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Abbreviations

ADL: activity of daily living
BADL: basic activity of daily living
BI: Barthel Index
IADL: instrumental activity of daily living
IMC: Intermediate Care
IOC: Index of Item-Objective Congruence
OT: occupational therapy
UE: upper extremity

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Using Partner-Driven Maximum Variance Sampling to Form a Lived Experience Panel: Step-by-Step Tutorial

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Abstract

Research projects conducted in collaboration with patients and caregivers are more rigorous, relevant, and impactful within the communities of focus. One mechanism for facilitating patient and caregiver engagement in research is through a lived experience panel (LEP)—an intentionally assembled group of people with personal experience relevant to the research topic. LEPs can engage in any or all aspects of the research project, from study ideation to participant recruitment to dissemination and translation of findings. Fully realizing the potential of an LEP to inform the research process requires intentionality in LEP composition, as members should align with the range of lived experiences in the community of focus. Mechanisms to recruit patient or caregiver advisors for research may require researchers to reach beyond pre-existing relationships if they intend to achieve maximum variability. However, explicit processes for forming a maximally variable LEP are scarce. In this guide, we outline an LEP formation process that includes laying the foundation for recruitment with academic and community partners; collaboratively developing promotional materials and an interest survey; using community-embedded promotional channels to share information about the LEP opportunity; and selecting interviewees and LEP invitees using a process called maximum variance sampling. Outcomes of our LEP formation process include the relative productivity of each promotional channel, the specific timeline from LEP ideation to formation, the sociodemographic variability of our applicants, and real LEP members' feedback on the formation process. We conclude by highlighting what we perceive as keys to success, including collaboration with trusted community partners and a thoughtfully designed interest survey that enabled us to narrow a large applicant pool to a diverse set of invitees. We also describe challenges and lessons learned, including opportunities to better articulate LEP responsibilities during interviews and ways to navigate the tensions inherent in selecting members based on maximum variance. Researchers are encouraged to invest time and resources into building relationships with community partners, knowing that these relationships lay the groundwork for reaching diverse patients and caregivers to advise research.

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KEYWORDS

tutorial; patient engagement; maximum variance sampling; lived experience panel; advisory board; family caregivers

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Introduction

Patients and caregivers are increasingly recognized as vital to the development of evidence-based practices in clinical care [1]. The benefits of engaging patients and caregivers in any or all phases of a research project are numerous. Research projects conducted in collaboration with patients and caregivers show more sensitive, inclusive, innovative, and rigorous research designs [2-4]; improved enrollment and lower rates of attrition [5,6]; and greater satisfaction among study participants [3]. When research engages patients and caregivers in its design, its priorities become more relevant to the needs of the population as a whole [3]; findings are more meaningful and accessible [3,5]; and any resulting interventions enjoy greater uptake and faster evaluation by regulators and other decision-makers, thereby accelerating their potential for positive impact [3]. Meanwhile, patients and caregivers engaged in research from the development of supportive relationships derive personal meaning from the work and gain professional skills and opportunities [4,7,8].

One mechanism for facilitating engagement with patients and caregivers is through a lived experience panel (LEP). An LEP is an intentionally assembled group of people with relevant personal experience related to the research topic in question [9,10]. LEPs can be engaged in any or all aspects of the research project, such as identifying research priorities [11], reviewing study instruments [10], disseminating recruitment materials [12], interpreting results [10], and providing other input on how studies are conducted and how findings are disseminated [9,11]. LEP activities include, but are not limited to, participating in regular meetings, spending time preparing for meetings, and providing feedback on meeting proceedings, with opportunities for further engagement or learning in between [9,11].

Fully realizing the potential of an LEP to meaningfully inform the research process requires intentionality in LEP composition [13]. LEP composition should align with the range of lived experiences in the population of focus to ensure that the research is maximally relevant [14]. The population of focus could be relatively narrow, such as rural older adults living with chronic heart failure, or a broader population, such as adults living with chronic health conditions. Within a given patient or caregiver population, there are myriad intersecting identities, contextual factors, and experiences that lead to critical differences in the patient or caregiver experience. Even within the more narrowly defined population of rural older adults living with chronic heart failure, variables such as years since diagnosis, gender, race and ethnicity, distance from health care facilities, and caregiver support create distinct experiences that are important to represent in an LEP [15,16]. LEP composition is not only informed by the variation within the population of focus but also by the need to include patients and caregivers who have historically been underrepresented in research and thus excluded from evidence-based care [13,17]. This includes health disparity populations, as well as those with limited technology access, those who are not located near a major academic medical center, and those whose health condition or role in the health system has not been a focus of major federal research funding [18,19].

There are several challenges associated with intentionally composing an LEP with the appropriate variability. Mechanisms to recruit patient or caregiver advisors for research are often based on convenience or pre-existing relationships [9,20]. Assembling an LEP may require researchers to reach beyond the people they already know if they wish to achieve maximum variability [10]. Recruiting "into the unknown" may be overwhelming because of the perceived time commitment, financial expense, and staff effort [5,6]. Furthermore, prioritizing variability raises questions about how to approach potential LEP members, in part on the basis of their unique identities, while steering clear of tokenism [21]. It must be made clear that the research team is not simply trying to meet a diversity requirement or "check a box," but rather trying to truly integrate a multitude of perspectives to generate more nuanced, responsive, and ethical research [21,22].

In this paper, we present a process for forming an LEP that is grounded in 3 motivating factors: the benefits of engaging patients and caregivers in research, the importance of engaging a maximally variable subset of a given patient population, and the relative absence of explicit processes for achieving these goals [23]. We provide a process for intentionally and respectfully forming an LEP and describe its feasibility.

Context for LEP Formation

We formed an LEP of US caregivers of adults with chronic health conditions to partner with researchers on a study about how the context of caregiving shapes research engagement. We defined a caregiver as someone—a family member, friend, or other community member—who provides unpaid support for another adult (or adults) with a long-term health condition. The aims of the broader study are to identify and characterize the contextual barriers and facilitators that shape caregiver research engagement and to develop an original, comprehensive measure of the contextual barriers and facilitators to meaningful research engagement.

The team comprised dual principal investigators and research staff, an academic advisory panel (AAP), and community coinvestigators in addition to the 7-member LEP. Table 1 provides a description of each role and the rationale for inclusion. The LEP was established following award notification and was designed to span the full 2-year study period, with panel members participating in quarterly 90-minute meetings. All meetings were virtual. The budget allocated US $500 per meeting for participant stipends to offset lost wages or to pay for care for the care recipient. There was a separate budget for necessary accommodations, including access to technology and interpretation services.

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Table . Function of each project team role and rationale for inclusion.

Role	Rationale	Function	Engagement frequency
Academic advisory panel	• Breadth of expertise in designing, conducting, and disseminating community-engaged research • Methodological input • Access to populations of interest	Advisory role on key decisions	Quarterly
Lived experience panel	• Experiential knowledge derived from caregiving responsibilities • Increase relevance of project and fit within real-world caregiver context	Advisory role on key decisions	Quarterly
Community coinvestigator	• Expertise in primary project content areas, including caregiving and community advocacy • Continuous integration of contextual knowledge into decision-making	Collaborator on all decisions	Weekly

Ethical Considerations

Engaging an LEP was not considered to be human subjects research by the Vanderbilt University Medical Center and University of Virginia Institutional Review Boards because the interested individuals are not potential research participants [24,25]. Rather, they are potential partners in the project.

Process for Forming the LEP

Step 1: Laying the Foundation With Academic and Community Partners

Community Coinvestigators

Prior to initiating this research project, the principal investigators established relationships with community partners through years of engaged research. From these relationships, the principal investigators engaged 5 partners as coinvestigators on the team for the project while writing the proposal. Community coinvestigators included caregivers and community members with lived experience in community advocacy and in engaging health disparity populations.

Academic Advisory Panel

When writing the proposal, the principal investigators identified 5 researchers with experience and academic expertise that complemented those of the academic members of the research team and invited them to join the AAP.

Community Organizations

During the grant-writing phase of the project, our team reached out to community organizations to explain the goals of the project and to request their assistance with disseminating materials. Contact with community organizations was established through warm handoffs by community coinvestigators and members of the AAP.

Step 2: Development of LEP Promotional Materials

The community coinvestigators and AAP members were instrumental in creating promotional materials that would resonate with caregivers while seeking to use understandable and respectful language. We shared a brief description of the LEP that could be copied and pasted into an email to make it easier for others to promote the opportunity. Our team also developed a printable flyer to advertise the opportunity to join the LEP (Multimedia Appendix 1). The flyer was developed in English and Spanish to account for the large population of Spanish-speaking caregivers; it included photos of caregivers of different genders and racial and ethnic identities, specified that all responsibilities were virtual, and indicated that the opportunity was paid, though the amount of compensation was not included [26]. We omitted compensation details to minimize interest from individuals who were primarily financially motivated, including individuals pretending to be caregivers.

Step 3: Development of the Interest Survey

Our team developed an interest survey to act as an initial screening tool for those wanting to join the LEP (Multimedia Appendix 2). In creating the survey, we sought to balance the competing priorities of gathering information relevant to the caregiver context without creating an undue workload. The first step in creating the interest survey was to identify the primary and secondary variables across which representation was important. These variables were selected through a review of the caregiving literature and full team consensus-building discussions, and included dimensions of sociodemographics, caregiving experience, and prior research engagement experience [26-30]. In addition to these variables, we inquired about applicants' reasons for their interest in joining the LEP, whether they had engaged in research before, and how the caregiver learned about this opportunity. The full interest survey

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can be found in Multimedia Appendix 2 and was also available in Spanish.

Step 4: Distribution of Materials to Share the Opportunity

All team members, including principal investigators, the AAP, and community coinvestigators, were actively engaged in distributing promotional materials. Community organizations and research networks or registries also shared the opportunity. All were asked not to share the survey on social media to prevent fraudulent responses [31]. After the survey had been live for 2 weeks, we reviewed the maximum variance sampling matrix (see "Step 5: Selecting Interviewees Using Maximum Variance Sampling" section) to understand who had expressed interest and identified key gaps in representation. We used this information to determine which additional partners to engage.

Step 5: Selecting Interviewees Using Maximum Variance Sampling

Our objective was to create an LEP with a broad range of identities and experiences relevant to caregiving for adults with chronic health conditions, positioning the LEP to reflect key dimensions of variability found among US caregivers. To this end, we used a maximum variance sampling approach to identify which applicants to interview [32]. To do this, a matrix was created listing each interested individual by the maximum variance sampling criteria. In this matrix, each column represents an eligible applicant, and each row represents a sampling criterion (eg, relationship to care recipient, US region, and gender). Table 2 provides an example of a maximum variance sampling matrix.

Table . Example of a maximum variance sampling matrix.

Characteristic	Applicant 1	Applicant 2	Applicant 3
Relationship to care recipient			
Child	✓		
Partner or spouse		✓	
Neighbor			✓
US region			
Northeast	✓		
Midwest		✓	
Southwest			✓
Gender			
Female	✓		
Male		✓	
Nonbinary			✓

We prioritized variability in characteristics that are demonstrated to shape the caregiving experience, while acknowledging that we could not capture every relevant factor [27]. In terms of demographics, we sought variability across race or ethnicity, gender, and geographic location. In terms of caregiver experience, we prioritized variability across caregiver relationships, cohabitation status, and chronic conditions. In terms of research engagement experience, we sought a mix of caregivers with and without research engagement experience. For those with experience, we sought variability in the type and duration of engagement. To the extent possible, we also attended to additional factors in constructing our maximum variance sample, including identities associated with health disparities and other caregiver and engagement experiences.

Because the LEP size was intentionally small, it was not possible to represent every combination of identities and experiences. Rather, applicants with multiple characteristics of interest were prioritized. For example, a research team might identify a potential interviewee who is a female caregiver of a parent living in the Northeast. The team would then look for a caregiver who differed in terms of their gender, relationship to the care recipient, and/or geographic location. This was the process used by 1 principal investigator to review the matrix and make interviewee recommendations based on prioritized criteria to the rest of the team. Team members then reviewed the matrix to suggest additional interview candidates.

Step 6: Interviewing Potential LEP Members

Each potential LEP member was invited to participate in a 30-minute interview with the dual principal investigators and the project manager. A coinvestigator fluent in Spanish attended the interviews to provide interpretation. Interviewers began by providing background information on the goal of the broader research project and the required and optional responsibilities of the LEP. Interviewees were informed that they might be asked to assist with study activities such as the creation of promotional materials, the development of an interview guide, the analysis of interview data, survey development, and the dissemination of findings. An example question asked of interviewees was as follows: "Can you start out by telling us why you are interested in joining the lived experience panel?" Interviewees were invited to ask any questions or express any concerns. The full interview guide can be found in Multimedia Appendix 3.

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Step 7: Selecting LEP Members

Following each interview, 3 interviewers discussed the applicants' responses and reviewed their sociodemographic variability as described in the maximum variance sampling matrix. After 8 interviews were completed, the interview team met to discuss an initial set of invitations to join the LEP. Five applicants were selected and emailed invitations to join. The interview team then conducted 3 additional interviews with the goal of inviting 2 additional applicants.

Email invitations indicated our desire for the LEP member to join and included a statement that we would follow up with study onboarding activities, such as setting up payment processes, should they choose to accept our invitation. We also noted that the first LEP meeting would occur approximately 2 weeks from the date of the invitation, so that the LEP could advise on recruitment for the research study, and we noted that future meetings would be scheduled well in advance with consideration of their availability. Prior to the first meeting, LEP members were asked if they would like a Spanish translator present, and all members declined.

Approach to Evaluation

We evaluated the feasibility of the process using quantitative and qualitative approaches.

Quantitative Approach

We assessed (1) the time spent forming the LEP, from developing promotional materials to the final formation of the LEP; (2) the success (in terms of the number of applications) of each channel used to reach potential LEP members; and (3) the sociodemographic and caregiving characteristics of those who applied, were interviewed, and were invited to join the LEP.

Qualitative Approach

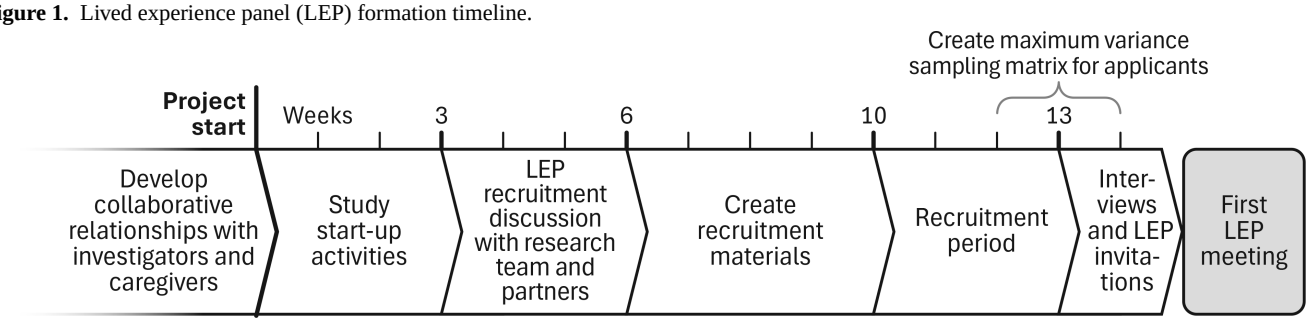
We obtained LEP members' feedback on the LEP formation process through an open-ended question: "From your perspective as a potential LEP member, what felt easy or challenging about recruitment?" Responses were collected from LEP members via email and through discussions at an LEP meeting. We summarize the responses of LEP members to these questions.

Results

Time Spent Forming the LEP

The entire promotional process, from drafting and finalizing materials to closing the interest survey, spanned from May 2025 to June 2025. The interest survey was published and distributed beginning on June 3, 2025, and remained open for 4 weeks, during which time we received a total of 44 applications to join the LEP. Most applicants who received an interview invitation (10/11) responded on the same day it was sent. All invitees scheduled their interviews for within 8 days of receiving the invitation. All but 1 invited LEP member accepted the invitation to join on the day it was sent. Figure 1 provides a detailed LEP creation timeline.

Figure 1. Lived experience panel (LEP) formation timeline.



Success of LEP Promotional Channels

The LEP opportunity was distributed directly via 12 distinct community coinvestigators, academic advisors, and community partners. Of the 44 applicants, 14 (31.8%) heard about the opportunity through a promotional channel other than our direct partners, signaling that the opportunity was further disseminated through word-of-mouth. Table 3 provides the number of applicants gained through each promotional strategy.

Table . Lived experience panel applicants gained through each promotional strategy.

Source	Applied (n=44), n (%)	Interviewed (n=11), n (%)	Invited (n=7), n (%)
Community coinvestigator (n=5)	23 (52.3)	3 (27.3)	3 (42.9)
Community organization (n=2)	5 (11.4)	4 (36.4)	2 (28.6)
Academic advisory panel member (n=5)	2 (4.5)	0 (0)	0 (0)
Unspecified email, friend or fellow caregiver, support group, wellness center, and social media account	14 (31.8)	4 (36.4)	2 (28.6)

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Sociodemographic and Caregiving Characteristics of LEP Applicants

We conducted 11 interviews and extended 7 invitations to join the LEP. All participants who were invited to join accepted the invitation. Table 4 provides the demographic and clinical characteristics of those who applied, were interviewed, and were invited to join. It took a median of 23.01 (IQR 37.05) minutes to complete the interest survey.

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Table . Demographic and clinical characteristics of the applicants, interviewees, and invited lived experience panel members.

Demographic or caregiving characteristic	Applied (n=44), n	Interviewed (n=11), n	Invited (n=7), n
Age (y)			
30 - 39	4	1	0
40 - 49	7	2	1
50 - 59	17	5	4
60+	16	3	2
Gender			
Female	35	8	4
Male	8	3	3
Nonbinary	1	0	0
Race and ethnicity[a]			
Asian or Asian American	1	1	1
Black or African American	12	3	2
Hispanic or Latino	2	2	2
White or Caucasian	28	6	3
Not listed: West Indian	1	0	0
I don't want to answer	2	0	0
LGBTQIA+[b]			
Yes	1	1	0
No	40	10	7
I don't want to answer	3	0	0
Education			
Finished high school	1	1	1
Some college	5	0	0
Finished 2-year associate's degree or certificate	8	5	2
Finished a bachelor's degree at a 4-year college	9	1	0
Finished master's degree(s)	15	4	4
Finished a PhD, MD, JD, or PharmD	6	0	0
State of residence			
California	2	2	1
Colorado	1	0	0
Indiana	2	1	1
Illinois	9	1	1
Michigan	3	2	2
Georgia	2	1	1
New Jersey	1	0	0
New York	2	0	0
North Carolina	1	1	0
Ohio	1	0	0
Pennsylvania	1	1	1

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Demographic or caregiving characteristic	Applied (n=44), n	Interviewed (n=11), n	Invited (n=7), n
South Carolina	1	0	0
South Dakota	15	2	0
Wisconsin	3	0	0
Geographic region			
Rural	9	2	1
Suburban	15	3	2
Urban	17	6	4
I move between types of places	2	0	0
Not listed: midsized city	1	0	0
Employment outside of unpaid caregiving[a]			
Looking for work	4	3	3
Working 30 hour/week	9	1	0
Working ≥30 hour/week	17	4	2
Student (full or part time)	2	2	1
Retired	9	1	1
Not working	3	0	0
Other (“adjunct professor”)	1	0	1
I don’t want to answer	2	0	0
Experience in research			
Yes	20	6	4
No	23	5	3
Relationship to care recipient[c]			
Nonrelative	9	2	2
Sibling	3	0	0
Partner or spouse	13	2	1
Parent or parent-in-law	22	6	4
Other relative	7	3	2
Years spent caregiving			
<1	1	1	0
≥1 and 10	29	8	5
≥10	14	2	2
Top 10 care recipient condition[a,c]			
Alzheimer disease and related dementias or cognitive decline	33	7	4
Diabetes mellitus (type 1 or 2)	12	4	4
Heart failure, cardiac issues, or atrial fibrillation	10	5	5
Kidney disease, renal disorder, or low function	10	2	2
Parkinson disease	5	1	1
Stroke (including paralysis, recovery, and aphasia)	6	2	2

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Demographic or caregiving characteristic	Applied (n=44), n	Interviewed (n=11), n	Invited (n=7), n
Arthritis, osteoarthritis, or rheumatoid arthritis	6	2	1
High blood pressure	7	1	1
Cancer (prostate, lung, ovarian, brain, and pancreas)	5	2	2
Chronic obstructive pulmonary disease	3	1	1
Time spent caregiving[c]			
A little time	4	1	1
A fair amount of time	8	2	1
A significant amount of time	14	4	2
A lot of time	10	2	2
I provide 24-hour support	18	4	3
Frequency of contact with care recipient[c]			
They live with me	24	5	3
I see them daily	5	2	2
I see them a few times a week	8	3	2
I provide support from a distance	4	1	1
Other	13	2	1

[a]Participants could select more than 1 response option.

[b]LGBTQIA+: lesbian, gay, bisexual, transgender/transsexual, queer, and other minority sexual orientations and gender identities.

[c]Participants who cared for 2 people selected 2 or more response options.

LEP Member Feedback on the Formation Process

Five LEP members provided feedback by email, and 2 of them expanded on their comments during a subsequent live LEP discussion.

Overall Process

In response to our request for feedback on the steps to joining the LEP, 1 LEP member reported that it "was done in such a way as to help applicants feel valued (choice of words, tone, organized process, individual interview, invitation to contact researchers with questions)" (LEP1). Another LEP member described the LEP formation as a "smooth process" that did not overwhelm him, "I'm busy, working full time, caregiver and stuff, so it had to be easy enough that I could find a time to do it" (LEP5). Two LEP members (LEP1 and LEP2) shared that they wished there had been more concrete information in the interview about the "number of hours or type of responsibilities/work" associated with joining the LEP (LEP2). One wrote, "I haven't always been clear on what is expected of me as an LEP member, especially given the generous compensation... I would simply feel more comfortable with a general guideline, such as expecting about 1 request per month" (LEP1).

Interest Survey

According to 1 LEP member, the interest survey questions "felt meaningful, not just like a checklist" and helped her to "reflect on why my voice and story could be helpful" (LEP4). In a group discussion, another LEP member noted that the questions in the interest survey seemed to have a clear rationale, noting that this is not always the case in research engagement (LEP1). After submitting the interest survey, 1 LEP member said it was challenging when the research team did not confirm its receipt (LEP2).

Interviews

Regarding the interview process, 1 LEP member found this to be the most challenging part, stating, "Not knowing if I was the right person for the job" (LEP3). One member indicated that "The interview was good as I got to ask a number of questions about the aim of the LEP, the [redacted] study, and the kind of research that was being undertaken" (LEP2). Another member used the interview to "decide if this is a safe space" (LEP4). According to this LEP member, those conducting the interview "leveled" the power dynamic and created a "peer-to-peer connection" by sharing their own perspectives and admitting that they did not have all the answers. These small steps signaled to the interviewee that "this was a space where real experiences mattered" (LEP4).

Deciding to Join

One LEP member reported that the decision to join was challenging given the time constraints associated with caregiving. This member noted, "I wanted to be sure my time, my story, and my emotional labor would be respected as well"

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(LEP4). Ultimately, she joined because she believed that "my presence could genuinely make an impact" (LEP4). For another LEP member, the decision to join was easy. He surmised that "most people who embrace their role as a caregiver are more than eager to participate and get involved" (LEP5). A third LEP member provided their rationale for joining the LEP, explaining that it "could somehow help future generations" and that he saw it "as a learning experience, contributing and also receiving input from others in similar situations" (LEP3).

Discussion

Summary

In this study, we describe a process for intentionally and respectfully forming an LEP and evaluate its feasibility. We worked with a broad range of partners to form an LEP of 7 caregivers, previously unknown to the principal investigators. Moreover, the resulting LEP included caregivers with a broad range of characteristics aligned with the diverse lived experiences of the US caregiver population [26]. Feedback from LEP members indicated that while some experienced the process of joining as relatively smooth, others identified areas for improvement. LEP members' decisions to join were shaped by their experiences at each step, from hearing about the opportunity to completing the interest survey to engaging in the interview. With refinements to better support applicants, the process for forming an LEP described here can be adopted to facilitate research engagement across multiple patient and caregiver populations.

Key Takeaways

We identified 2 key takeaways from our process of forming an LEP. First, we found success in promoting the LEP opportunity through our trusted community partners. Relationships with these partners allowed us to quickly form an LEP that is diverse in the characteristics that shape the caregiving experience. We recommend that research teams focused on building variable LEPs prioritize first building relationships with community members. As a second takeaway, we were rewarded for our strategy of intentionally selecting questions for the LEP interest survey in ways we did not predict. Not only did the selected questions allow us to rapidly narrow a pool from 44 applicants to 11 interviewees to 7 invitations to join, but the questions served a second purpose of building trust with applicants, with 1 LEP member describing the survey questions as well-justified and meaningful. We recommend that research teams invest time and thought into crafting an interest survey that provides actionable information for researchers and communicates respect to applicants.

Lessons Learned

In addition to our key takeaways, we learned 3 lessons that will shape how our team forms LEPs going forward. First, with input from our LEP members, we learned that our interview process could have more clearly conveyed the expectations and responsibilities of LEP membership. LEP members' desire for specificity raises an important question for future work: how to offer concrete information about engagement responsibilities while allowing LEP members to shape the nature of their involvement. One approach is to introduce an LEP charter during the interviews—a document describing the scope and commitment of LEP engagement. During interviews, we would describe a formal process for revising the charter so that it is continuously responsive to LEP members' needs and goals. For example, a group charter could address attendance expectations, alternatives to attendance if meeting as a group is not possible or preferred, processes for member withdrawal, and approaches to facilitating balanced participation between LEP members. The introduction of a charter and its collaborative codevelopment could serve the equally important purpose of building trust with potential LEP members.

Second, the maximum variance sampling approach introduces a central tension: decisions made to maximize variability may inadvertently imply to nonselected applicants that the researchers are not interested in their experiences. This tension felt especially acute when variability was the key reason for not inviting an interviewed applicant, as we felt connected to the interviewees and knew more about the depth and nuance of their experiences. In future applications of the maximum variance sampling approach, we will emphasize throughout the interest survey and interview process that all caregiving experiences are meaningful, even though the limited size of LEPs means not all caregivers can be invited to join. We will explicitly state that our selection decisions prioritize variability, not because it is the only relevant guiding principle, but because diverse LEPs strengthen the relevance and impact of the research they inform [33,34]. As another attempt to respect applicants' time and contributions, in future iterations of LEP formation, we will interview and accept applicants sequentially rather than in batches so that we do not interview many more people than we can invite to join.

Finally, although we were successful in disseminating the LEP opportunity to a diverse community of caregivers, certain gaps in our applicant pool persisted. For example, we heard from few caregivers who identified as Latino, who had less than a high school education, who identified as LGBTQIA+ (lesbian, gay, bisexual, transgender/transsexual, queer, and other minority sexual orientations and gender identities), or who lived in the southwestern region of the United States. These gaps highlight the need for our team to leverage different promotional strategies (eg, posting flyers in-person rather than relying on digital dissemination) and to further expand and diversify our community partnerships.

Conclusions

The findings of this paper bring to light a second, central tension: engaging patients and caregivers requires a significant, and not directly compensated, investment of time and resources. Our formation of an LEP hinged on existing relationships with community partners, in which trust was sufficient for them to agree to be coinvestigators or assist with the dissemination of LEP promotional materials. To those intimidated by this proposed groundwork, we offer 3 forms of encouragement. First, researchers new to patient and caregiver engagement can reach out to colleagues and mentors with long-standing relationships in communities of interest to help accelerate the building of trust. Second, investments in community

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relationships do not signify a net loss of time. Instead, these investments are reallocations of time toward earlier phases of the work, increasing our productivity downstream in meeting LEP formation milestones and the successful dissemination of materials. Finally, there are undoubtedly additional, innovative strategies for reaching diverse and previously unknown patients and caregivers, and teams that blend research and community perspectives are more likely to uncover them. These maximally variable LEPs, comprising people embedded in patient and caregiver communities, can substantially enhance the relevance and impact of any research they support.

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Disclaimer

All statements in this manuscript are solely those of the authors and do not necessarily represent the views of the Patient-Centered Outcomes Research Institute, its Board of Governors, or its Methodology Committee.

Authors' Contributions

Conceptualization: AJ, NEW, RSV
Data curation: AJ, TT
Funding acquisition: NEW, RSV
Supervision: NEW, RSV
Writing—original draft: AJ
Writing—review and editing: TT, JA, GLB, DJD, UTG-M, MH, SH, HJ, NO, A Richmond, A Rosales, PW, RSV, NEW

Conflicts of Interest

None declared.

Multimedia Appendix 1
Promotional flyers to join the lived experience panel.
[DOCX File, 1116 KB - jopm_v18i1e95145_app1.docx]

Multimedia Appendix 2
Interest survey to join the lived experience panel.
[DOCX File, 39 KB - jopm_v18i1e95145_app2.docx]

Multimedia Appendix 3
Lived experience panel interview questions.
[DOCX File, 22 KB - jopm_v18i1e95145_app3.docx]

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Abbreviations

AAP: academic advisory panel
LEP: lived experience panel
LGBTQIA+: lesbian, gay, bisexual, transgender/transsexual, queer, and other minority sexual orientations and gender identities

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Patients and Caregivers Leveraging AI to Improve Their Health Care Journey: Case Study and Lessons Learned

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Abstract

Artificial intelligence (AI) is increasingly integrated into everyday life. Yet in health care, patients and families are challenged to understand how AI may be helpful. As a result, real-world patient stories remain scarce. Generative AI can serve as a learning partner to help patients interpret complex medical information, prepare for appointments, and navigate care decisions. A case study is presented from the perspective of a caregiver and a clinician colleague, describing how one family used generative AI (ChatGPT; OpenAI) to better understand test results, possible diagnoses and treatments, prepare for visits, and summarize and share information with an extended care team. This paper also shares tips and lessons learned with others navigating similar health care challenges. A first-hand account of family interactions with ChatGPT is described during a period between diagnostic imaging and surgical consultation. Real-world use of AI by a caregiver is showcased, including strategies used to understand and summarize health record data, querying AI using medical documents, and resulting actions taken by the family. Using the case study as a springboard, the authors provide a separate section to share lessons learned for patients and caregivers in their use of AI. The family reported benefits of AI, including the ability to comprehend health information by translating medical records into patient-friendly language; to emotionally process and prepare for visits; to research diagnoses and treatments; to streamline communication with care teams by using concise patient summaries; and to feel more empowered to take timely, informed action. Generative AI can serve as a valuable companion tool for patients and caregivers navigating complex medical information. By translating results, providing education about diagnoses and treatment options, and helping prepare for visits, AI may reduce care delivery delays and raise family confidence in decision-making. However, limitations exist, and patients and caregivers need to validate AI output to ensure accuracy and privacy.

(J Particip Med 2026;18:e69790) doi:10.2196/69790

KEYWORDS

artificial intelligence; caregiver AI; care journey; medical information translation; patient-physician relationship; healthcare navigation; large language models; medical documentation; patient education; participatory medicine; healthcare communication; health literacy; LLM; large language model; patient engagement; patient activation; patient learning; patient experience; shared decision making; self efficacy; patient efficacy; generative AI; patient AI; patient friendly; patient empowerment

Case Study of Patient and Caregiver Use of Artificial Intelligence

Introduction

"Over the course of a few weeks, he went from completing a 3-day golf tournament to being unable to walk and needing to crawl up the stairs to go to bed."

This dramatic decline was due to RL's lower back pain, which was observed by MBS, the patient's spouse, and the primary author of this paper. The co-author (DC) is a colleague of MBS in patient advocacy and artificial intelligence (AI) work and was not clinically involved in this case. MBS's experience as a caregiver and patient advocate offers unique insight into how AI can transform the patient experience. Her systematic approach to using AI tools not only improved her husband's care experience but also demonstrated the practical implementation of participatory medicine principles. As she notes:

> *The ability to understand complex medical information immediately, rather than anxiously waiting, was a game changer, allowing us to act more quickly.* [MBS]

This paper presents a case study from the perspective of a family caregiver who explored how AI can support care by improving the interpretation of medical test results, clarifying potential diagnoses and treatment options, and facilitating more effective care navigation. The case study demonstrates practical ways patients and caregivers can apply AI tools to translate medical information into plain language, increase understanding of

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conditions and treatments, and summarize health data to prepare for specialist visits.

In addition to the case study, the paper expands on key insights and lessons learned—including additional patient use cases for AI, strategies to address its limitations, highlights of current AI tools, and opportunities for future patient-centered innovation (Section 2).

The Challenge

The patient, RL, developed intense back pain over a short time period that quickly prevented him from standing or walking. In such moments, patients and their families must rapidly navigate complex medical information, understand treatment options, and make critical decisions—all while dealing with the emotional impact of a rapid health decline.

Today's health care system gives patients unprecedented access to their medical information through online portals, test results, and clinical notes [1]. However, this access often introduces new challenges. While patients can view their magnetic resonance imaging (MRI) results within hours of a scan, the technical language and medical terminology can make these records more confusing than informative [2]. Limited appointment availability and delays between receiving results and seeing specialists further compound these difficulties [3]. According to a recent study, it now takes an average of 31 days to schedule a physician appointment in 15 of the largest US metropolitan areas—and in the city featured in this case study, the average wait is 65 days [4]. This time lag leaves patients struggling to understand crucial information about their health.

One Solution: Using AI as a Learning Partner

Artificial intelligence, particularly large language models (LLMs) like ChatGPT (OpenAI), has emerged as an unexpected ally for patients navigating these challenges. In MBS's words:

> *These AI tools offered me immediate, around-the-clock assistance in translating complex medical information into language I could understand, when I needed it. That really helped us prepare for appointments, gave us a chance to digest the information, and allowed us to make time-sensitive decisions about my husband's care.*

Patient AI Journey

MBS discovered that starting with AI to translate MRI results into patient-friendly language and then gradually conducting deeper research led to a greater understanding of the situation. By taking things step by step over several days—each new question adding to her understanding—she steadily built her knowledge and was able to take informed action at each step.

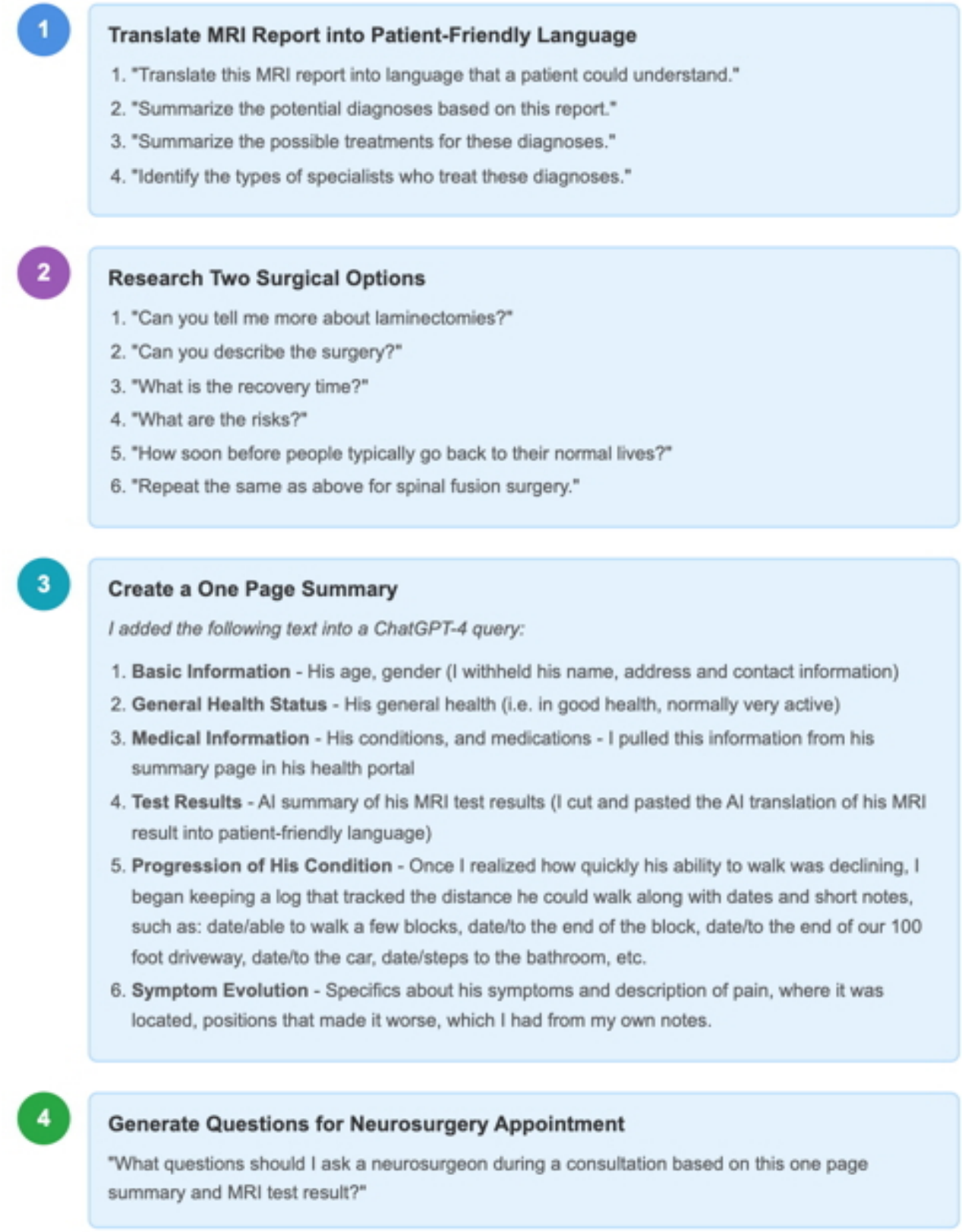
Figure 1 shows the sequence that MBS followed, along with the topics and questions used in the AI conversations. Keep in mind, inputs and questions posed to AI can be combined into a single sentence, or can be part of an iterative conversational flow with the AI chatbot. Patients can type in questions in the same way one would ask a doctor or a friend.

This case shows how generative AI can act as a learning partner for patients and families, helping them make sense of complex medical information through a step-by-step "just-in-time" approach to learning (Figure 1). Instead of having either too little information or being overwhelmed with information all at once, they were able to ask questions and build understanding gradually—learning only what was relevant at each stage of their journey. This reflects the idea of situated learning [5,6], where people learn most effectively when information is connected to real-life needs. It also demonstrates the concept of distributed cognition [7], in which tools like AI extend a person's ability to think and act.

By engaging with information only when it became meaningful to them, the family strengthened their sense of understanding and control—a pattern long recognized in patient empowerment research [8] and a concept referred to as patient activation, which is linked with improved health outcomes [9].

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Figure 1. Approach used with generative artificial intelligence by the family caregiver in the case presented. MRI: magnetic resonance imaging; AI: artificial intelligence.



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Step 1: Using ChatGPT to Understand MRI Results

When RL received his MRI results through the patient portal, the technical language made it difficult to understand the findings—let alone the implications. Rather than waiting anxiously for the upcoming specialist appointment, MBS turned to ChatGPT for assistance.

First, some background on the AI tool chosen: ChatGPT is one option in the "generative AI" category. It is free to use (with an account) and can be easily found by typing "ChatGPT" into a browser search bar on a mobile device or computer. Once in ChatGPT, users see an empty text field with the words "Ask me anything." A user can paste text into that field and/or ask questions. Generative AI takes your questions, reviews large sets of data, and then creates new text in response.

ChatGPT is considered a large language model (LLM), a type of generative AI, because it learns patterns from large datasets and generates new output, within the context of the questions you've asked. Other forms of AI are "non-generative" and work to analyze or classify information from existing data but do not create new outputs. Nongenerative AI can, for example, recognize patterns in a mammogram and predict "normal" versus "possible tumor." Generative AI, using an LLM like ChatGPT, is more like a writer, while nongenerative AI is more like a judge. MBS outlines how she used ChatGPT:

> *When we accessed my husband's MRI report from the patient portal, we found it difficult to understand because it was written for clinicians. I decided to see how ChatGPT could help us. I copied and pasted the MRI report text, with name and personal information removed, into ChatGPT and asked it the following questions:*

In literally seconds, ChatGPT came back with results from this query with information that was much easier to understand. This approach benefited MBS and RL in a number of ways:

First, clear understanding: the AI provided plain-language explanations of the medical terminology and findings, allowing for immediate understanding of the situation.

Second, emotional processing: having time to digest the information privately at home enabled both patient and caregiver to process the implications before the specialist visit. It is well established that receiving bad news, particularly news about a serious or life-altering medical condition, can significantly impair a patient's ability to recall information presented during that conversation [10].

Third, recall: In a study examining patient recall of information after a neurosurgery consult, 44 patients were able to remember correctly 24.8 % of medical information on the next day after consultation by a neurosurgeon on average. Findings showed a correlation between patient mood and level of recall: a higher level of anxiety or depression before surgery was associated with less memory of medical information by patients [11].

In MBS's words:

> *When we read the interpretation of my husband's MRI test from our AI questions, we learned that he likely had to have neurosurgery, so that sent us reeling. It took us each several days to process that. I actually cried on and off for two days thinking about how that would impact my husband because he's such an active guy. If we were in the doctor's office when we learned about the need for spinal surgery, we would have been too shell-shocked to process much of the medical information.*
>
> *Before we read the AI results, we didn't even know what kind of doctor we should see as a next step. From the AI results, we knew that he should see a neurosurgeon, and we were then able to talk to people who had personal experience with the back surgeries he probably needed, and were able to get surgeon recommendations. Those conversations were very comforting. Without AI, our timeline for doing those things would have taken weeks versus days because we were able to take action right away.*

Step 2: Using AI to Understand Treatment Options Enabled Faster, More Confident Action

After MBS received the results to her initial query (sometimes called an "AI conversation"), she performed a second query, doing a deeper dive using new questions to understand more about two of the possible surgical treatments: a laminectomy and a spinal fusion. Armed with new information, MBS was able to move forward with greater confidence. This helped them plan for possible surgery, prepare their home for recovery, and decide whether to postpone an upcoming trip.

> *In my case, I used the result of my first query to formulate my second set of questions to learn more about two of the possible surgeries and recoveries. The ability to keep doing research, jumping off of new information, allowed both of us to digest information in smaller pieces, and really drive the information gathering process according to the questions that were top of mind at the time. I used the following questions for each of the possible surgeries:*

Step 3: Using AI to Create a 1-Page Summary Supports Faster and More Efficient Care Navigation

In terms of next steps, the family knew they needed to communicate with their primary care physician, a neurosurgeon, a physical therapist, and the administrative staff to start. In order to communicate the complexities of the situation, MBS thought a 1-page summary would be helpful, especially to inform them about her significant concern about RL's rapid progression. MBS went to her husband's patient portal to view his health summary but found it insufficiently presented the information pertinent to his situation; she then used ChatGPT to create a single-page summary using the following approach:

> *I basically created a document in Microsoft Word as a place to gather information across multiple documents: my husband's health portal, his radiology portal, and my own notes. I cut and pasted information from a variety of sources into the Microsoft Word document.* [MBS]

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This information included demographics, health status, test results, symptoms, and observations over time. Details are shown in Figure 1.

After all of this information was collected in the Microsoft Word document, MBS was careful to remove the identifying information, such as name, address, and contact information in anticipation of cutting and pasting the information in ChatGPT. ChatGPT was then asked to create a 1-page summary of the above information, and be sure to include the complete progression of symptoms.

> *One of the strengths of ChatGPT is that it is great at organizing messy information—both visually and from an organizational standpoint. ChatGPT generated a nice, clean summary, with clear headings to organize the information. I took that 1-page summary and put it in a new Microsoft Word document, then added my husband's name, our address, and contact information back into the document and saved it as a PDF document so it would be easy for me to share in text, email, and faxes.* [MBS]

With the help of AI, multiple documents and reports were pulled together into a single, streamlined summary containing all key details. This made it easier to share the information and provided clinicians and administrative staff a quick "at-a-glance" view of RL's case without the need to search through portals, test results, and scattered files.

The family shared the summaries with a handful of people along their journey—the primary care physician to request a referral, 2 physical therapists, their insurance company, a hospital access nurse who facilitated neurosurgery scheduling, and the surgeon who requested to review the case to determine if a consult would be scheduled.

MBS explained:

> *I believe this saved us significant time in navigating the health care system. It was also really important to me that the neurosurgeon heard our direct account of how fast my husband's progression happened, rather than having that information filtered through a third party. I'm confident that having clear documentation of my husband's symptoms and rapid decline helped move his surgery forward more quickly.*

Step 4: Generating Questions With AI to Prepare for a Surgical Appointment

Once the family scheduled a consultation with a neurosurgeon, they returned to ChatGPT, asking: What questions should I ask a neurosurgeon during a consultation based on this 1-page summary and MRI test result?

MBS then reviewed the AI-generated questions and went about editing the list of questions; "I modified the list of questions, adding several about upcoming travel and capacity to walk, exercise, and golf." She prioritized the most and least important questions in case the visit time became limited. MBS felt that ChatGPT suggested questions that she would not have thought about on her own. The family felt more prepared and equipped with a thorough list.

> *We also felt much better prepared because we had a deep understanding of the implications of my husband's test results and possible surgeries, and weren't burdened with the anxiety of just hearing bad news for the first time about him needing neurosurgery. We were much more educated, having done our deep dive on the two possible surgeries, so we didn't have to waste time having the neurosurgeon educate us on those. It was a much more productive doctor's appointment than we would have had otherwise.* [MBS]

Lessons Learned in Patient and Caregiver Use of AI

This case revealed several practical insights about how generative AI can support patients and caregivers in real time. The following lessons highlight what worked, what to watch for, and how others might benefit from similar and/or additional uses.

Balancing AI's Potential With Its Risks

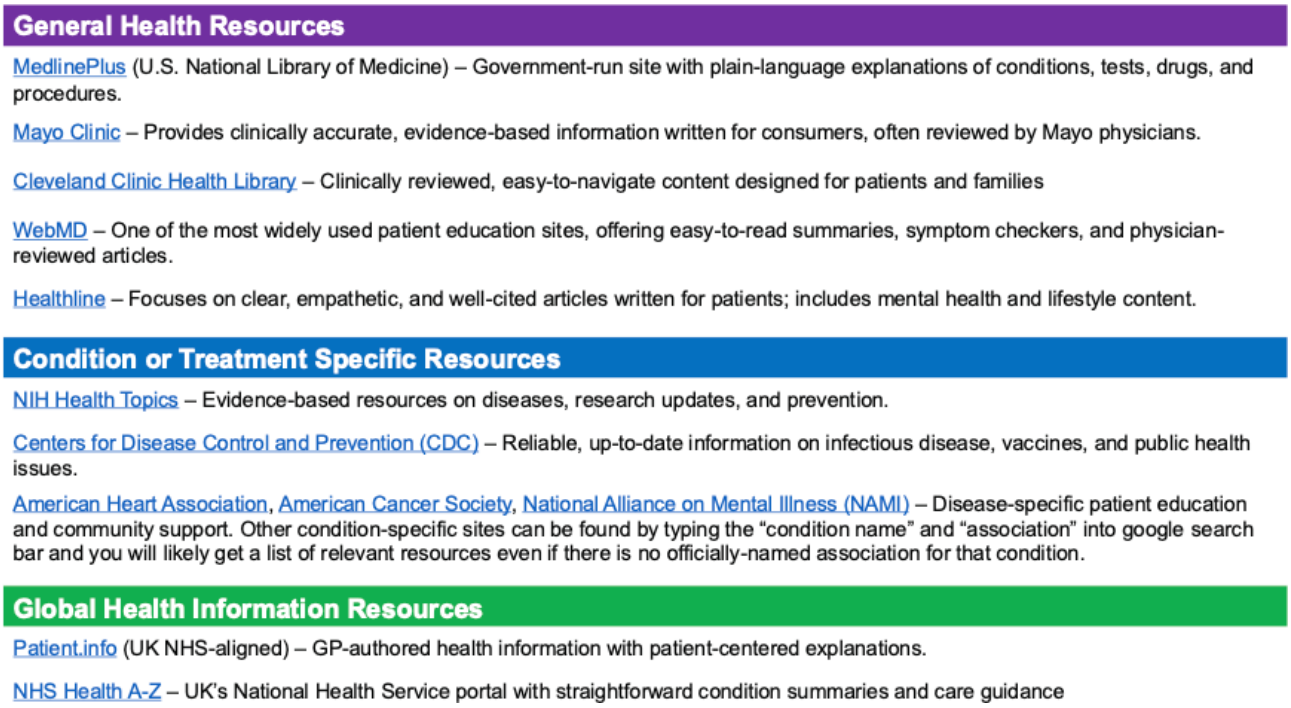
Once patients gain access to and understand their medical documentation, AI can become a powerful tool to research conditions and explore treatment options. A research or inquiry phase requires a careful balance between gathering comprehensive information and maintaining awareness of AI limitations. While AI can aggregate and explain medical information rapidly, all findings should be verified with other sources and with clinicians. MBS explains how she cross-checked AI results, all of which helped validate the output:

- Try more than one AI tool: it can help to compare answers. MBS asked both ChatGPT and Claude (Anthropic) the same question about MRI results to see if they gave similar responses.
- Look for sources: many AI tools provide links to sources at the end of their answers. Click on them to see where the information came from. If no sources are shown, you can ask the AI tool to provide them.
- Be cautious with vague sources: if a source looks unclear or takes you to a website that does not seem professional, double-check the information on a more reliable site (Figure 2).
- Check across websites: type the same keyword into the search bar on 2 or more trusted health websites (Figure 2). If what you find matches the AI's response, it's likely accurate.
- Ask someone knowledgeable: If possible, share the AI's answer with a friend, family member, or health care professional who has medical experience. They might be able to confirm whether it makes sense.
- Use "research" features: some tools, like ChatGPT or Claude, offer deeper research modes. These can generate results that are verified and offer citations, but the process takes longer. Each LLM has a different method for using

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Deep Research Mode, so it is best to ask the LLM for directions on how to access it.

Figure 2. Some of the top sources that can be used by patients to verify medical information. NIH: National Institutes of Health; NHS: National Health Service; GP: general practitioner.



Some Reputable Sources and Why Validation Matters

In MBS's case, AI tools were helpful at multiple points of their journey—to translate complex medical data, summarize information, and guide them to questions for the doctor. Yet AI can produce mistakes or hallucinations—plausible-sounding answers that are factually incorrect or incomplete. These can be tricky because they seem so realistic. Since health decisions depend upon accurate information, it is essential to double-check AI output against trusted sources and, whenever possible, confirm with a health professional. While there are scores of reputable health-related websites, the list above is a short list of reliable, patient-friendly websites that can be used to verify information and lower the risk of acting on misinformation.

Using LLMs to Understand Medical Documents

One of the most immediate applications of AI in patient care is the translation of complex medical documentation into understandable language. The disconnect between information access and understanding can lead to anxiety, delays in care, and missed opportunities for informed decision-making. Figure 3 shows some document types, elements to be explored within them, and sample questions one can use to reach those elements using tools like ChatGPT or other LLMs.

Transforming complex medical language into accessible information is powerfully illustrated in MBS's case, but AI translation extends beyond imaging reports. Laboratory results, often presented as a series of numbers and technical terms, can be transformed into meaningful insights. When reviewing a comprehensive metabolic panel, for example, AI can explain not only what each value means, but also the relevance and gravity of any abnormalities in the context of a patient's condition. With these explanations, patients can use AI to craft thoughtful questions to ask their health provider.

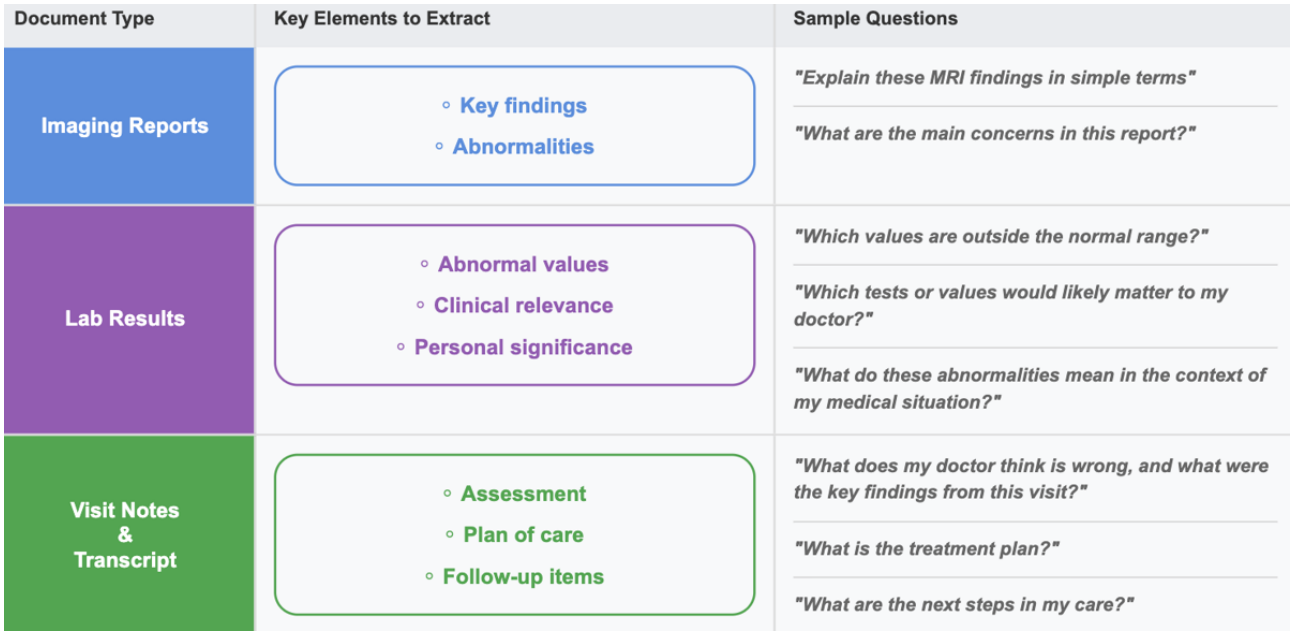
Some patients can become anxious when seeing test results on their own outside the doctor's office. In a survey conducted by the University of Colorado of over 8000 patients, 96% of respondents preferred immediate delivery of test results—even before discussing results with their clinician. The authors noted, however, that about 8% of the respondents were worried when receiving the information [12]. Therefore, it is important to recognize that using AI to gain understanding of test results—without context from a clinician—can increase worry in some people.

Clinical notes, traditionally written in medical shorthand and jargon, can become more accessible to patients through AI interpretation, assuming AI is specifically asked to transform clinical notes into patient-friendly language. This helps patients better understand treatment options and plan next steps. Additionally, it allows patients to identify and track critical action items that might otherwise be lost in technical language.

Though a note of caution—when submitting health information such as test results to an AI tool, users should always remove all identifying details such as name, phone number, patient ID, birthdate, social security number, address, etc. This protects privacy and helps ensure personal health information is not exposed or misused. It is also recommended to remove the names of your health professionals.

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Figure 3. Strategies for patients and caregivers to use artificial intelligence to understand medical documentation. MRI: magnetic resonance imaging.



Diagnosis and Treatment Research is Valuable but Requires Understanding AI Shortcomings

Once patients understand their medical documentation, AI can become a powerful tool for researching conditions and exploring treatment options. This research phase requires a careful balance between gathering comprehensive information and maintaining awareness of AI's limitations.

In MBS's case, understanding the implications of various surgical options before the specialist consultation allowed for a more productive discussion focused on specific concerns rather than basic explanations. AI can help break down:

- Potential treatment approaches and their rationales.
- Common risks and benefits of each option and the type of specialist that can provide treatment.
- Typical recovery timelines and requirements.
- Questions that would be important to discuss with specialists.

As previously discussed, while AI can aggregate and explain medical information rapidly, all findings should be validated with reputable sources and ideally with health professionals.

Figure 4 shows examples of research that patients can conduct using ChatGPT or other LLMs, with some sample questions showcasing several areas where patients might find AI helpful in researching their own medical conditions.

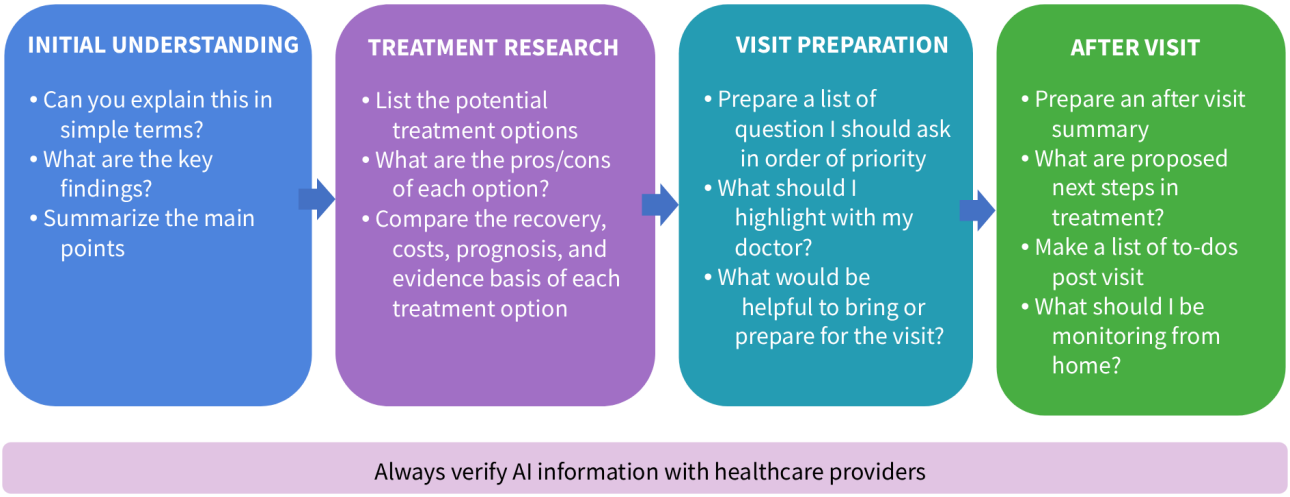
Keep in mind that sophisticated AI skills are not necessarily needed to get valuable information. Users can simply ask questions as if sitting in a doctor's office, and continue asking as you learn from the AI output. AI users can also specify how results are desired, for example—as a bulleted list, no more than 1 page, in Spanish or other languages, using only academic research reports, or in patient-friendly language, etc.

A major advancement in consumer health is the ability for patients to track vitals and symptoms using a variety of apps. AI tools can help organize symptoms into timelines and summaries, identify known medical conditions, and suggest possible diagnoses ranked by likelihood. AI can connect the dots—highlight patterns, surface insights, and suggest questions patients may want to ask their doctor. This allows patients to go beyond simple internet searches on a single symptom and better understand what individual symptoms, groups of symptoms, or changes in symptoms over time might mean. Again, any AI-generated results need to be validated against reliable medical sources and a clinician.

Treatment plans, particularly for complex conditions requiring multiple interventions, can be broken down into manageable steps. Complex treatment—such as daily wound care, intricate medication dosing schedules, or tracking specific symptoms—can be separated into clear, actionable daily checklists that improve adherence and outcomes. In MBS's case, a systematic approach was used and resulted in a compressed timeline between receiving medical information and taking informed action.

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Figure 4. Sample prompts and queries to research patient health data and medical information.



Bringing Patient and Caregiver Voice to Clinicians Across Care Teams

Navigating today's complex health care system is a significant challenge for families, particularly during health crises. AI tools can help patients manage this complexity by organizing information, preparing for appointments, and coordinating between providers.

The value of using AI for health system navigation was evident in MBS's case when coordinating care across multiple specialists. What traditionally may require multiple, lengthy phone calls with repeated explanations could be streamlined: a single concise summary can be shared with the primary care and specialist physicians and used to facilitate referrals and second opinion consultations.

Using AI-generated text to support patient verbal explanations can offer consistent communication across all clinicians while preserving the authentic voice of patients and caregivers. This approach is especially valuable when a patient needs to explain complex information—often involving multiple symptoms over time. AI text summaries of patient-reported information can help ensure that patients and caregivers do not lose their personal voice or lived experience and can communicate accurately and efficiently. By reducing reliance on patients' memory "in the moment" or need for verbal explanations to be repeated for each provider, AI helps prevent important details from being overlooked.

Visit Preparation Can Optimize Time With Doctors

Visit preparation represents another area where AI can significantly improve patient care. When patients arrive at visits with a basic understanding of their condition and well-researched questions, clinicians can focus on the more complex and personalized aspects of care. Patient and symptom summaries can condense a lot of information into "quick takeaway" documents that make the most of short appointment times. As MBS's case demonstrates, patients who arrive better informed and confident can have more meaningful conversations. Some examples of preparation include:

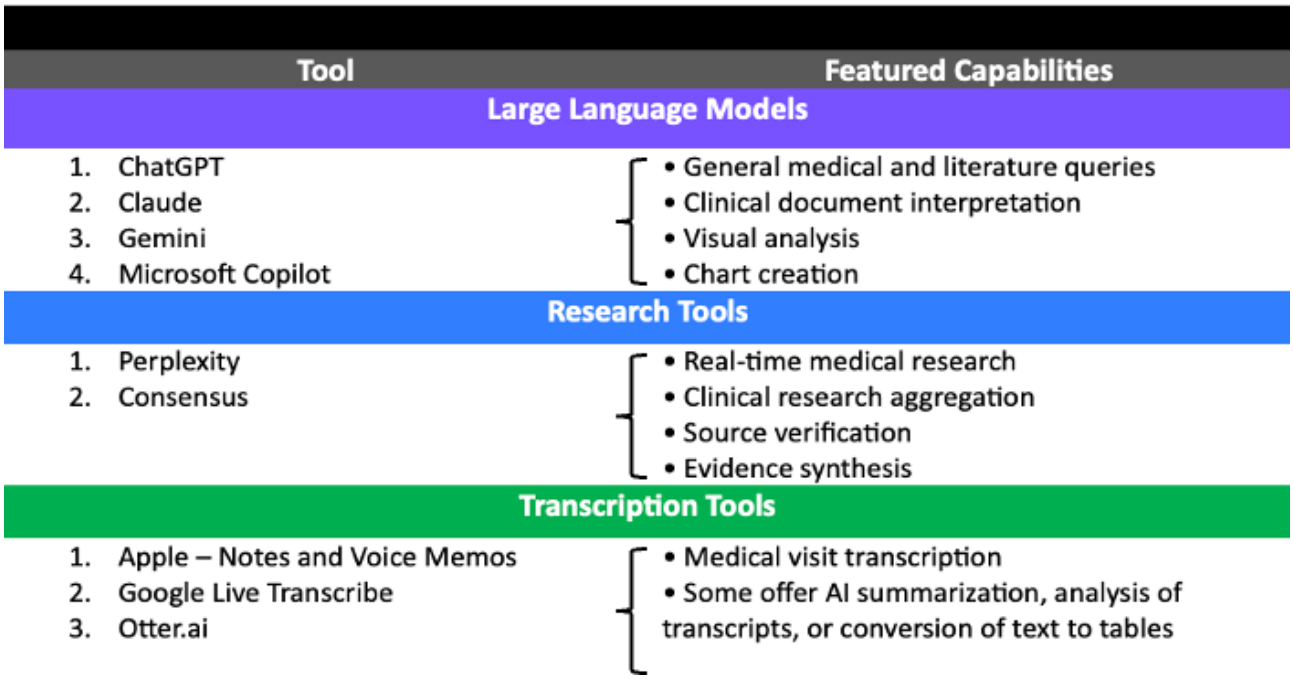
- Summarizing your current health situation, or updates since last visit.
- Organizing test results, summary of symptoms.
- Developing specific, informed questions.
- Preparing clear descriptions of new concerns.

Some AI Tools for Patient Empowerment in Health Care

The effective use of AI in health care requires understanding the diverse landscape of available tools and selecting the right one for each task. While many AI tools exist, they broadly fall into 3 main categories, each with different strengths. Examples of several tools are shown in Figure 5.

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Figure 5. Sample artificial intelligence tools for patient and caregiver empowerment that may help a health care journey.



Large Language Models

The foundation of patient AI use typically starts with general-purpose AI tools like ChatGPT, Claude, or Google's Gemini. These serve as versatile assistants capable of handling a wide range of medical information needs, functioning as digital "Swiss Army knives" for health care applications. LLMs can perform tasks ranging from basic medical terminology translation to visual analysis of skin conditions through image recognition features. LLMs can review and organize even complicated medical texts, including research papers and clinical guidelines, into a more patient-friendly language.

Part of what makes LLMs so powerful is that LLMs are "trained on" (have access to) massive amounts of information—the equivalent of reading millions of books or the entire internet many times over. This includes publicly available data such as websites, articles, news, blogs, educational resources, and public health information from sources like the Centers for Disease Control and Prevention, World Health Organization, and the National Institutes of Health, as well as open-access scientific journals. Some LLMs also include licensed content**,** including textbooks, databases, or large datasets. LLMs do not have access to private health records, real-time clinical databases, or most subscription-based information.

LLMs are also trained on general medical knowledge sources (not patient-specific), including medical textbooks, clinical guidelines, reference materials, and research abstracts or summaries from medical databases. Using this vast amount of information, LLMs can connect related pieces (eg, 4 different symptoms that might not seem related) and present them in clear, easy-to-understand ways. By contrast, humans have experiential knowledge, intuition, clinical judgment, and real-world pattern recognition, whereas LLMs have statistical patterns from text, but no direct experience. Both can be valuable, and even more so when combined.

It is important to emphasize that AI output does not constitute a medical diagnosis or should not drive clinical decision-making. Medical knowledge evolves rapidly, and there can be lags between new research and what is reflected in LLM training data. The ability to "link four different symptoms" is pattern recognition based on an LLM's training data, but not clinical reasoning and view of the full patient background that a health care provider would have.

Research Tools

When patients need to delve deeper into medical literature or find specific clinical information, specialized research tools become invaluable. Perplexity AI stands out for its ability to find and synthesize current medical information, guidelines, and reviews in real time. Its advanced search capabilities allow patients to specifically target medical journals for scientific evidence, or alternatively, explore patient communities on platforms like Reddit for valuable real-world experiences and insights.

Transcription Tools

Recording conversations can help many patients to remember all of the fine details from doctor's appointments. Transcription capabilities are available, whether through native apps like Apple's voice memo transcription or dedicated tools, which enable patients to record and transcribe medical consultations. Many health systems now use what is referred to as "ambient documentation" technology that records visits, and these transcripts are often available upon request. These transcriptions can then be input into LLMs to understand health care providers' rationale and planned next steps, giving AI comprehensive data to better serve patient needs.

It is important to obtain a clinician's consent before recording a medical visit, just as they would need patient consent. Often required by law, this helps maintain trust, respect, and transparency between patient and provider [13].

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Future Directions

After reviewing what has worked and what to be mindful of in terms of how patients use AI, the next step is to consider how AI can be improved and better support patients in the future. The evolution of AI in health continues at a rapid pace. Going forward, with emerging technologies and changing health care dynamics, there are exciting possibilities and important considerations for patient empowerment through AI. Current publicly available AI applications operate independently of health care organizations; AI integrating with health care systems represents perhaps the most promising frontier.

When MBS wanted to use AI to translate MRI results, she needed to manually copy text from the patient portal into ChatGPT. Imagine patient portals equipped with AI assistants that can immediately help interpret new test results or explain changes in treatment plans. These applications could achieve levels of privacy and security of existing health care platforms, while adding the immediate comprehension support that patients need. A more streamlined future might include:

- "Explain This" buttons next to medical terms in patient portals.
- AI assistants that maintain context across multiple health documents or care providers.
- Tools that help prepare visit summaries by combining AI analysis of both clinical notes and visit recordings.
- Allowing electronic health record data to be exported and deidentified for use with other AI tools.
- Systems that suggest relevant questions based on upcoming appointment types.

Visual Interpretation Tools

Visual interpretation tools also show particular promise. While current AI applications excel at text interpretation, emerging technologies demonstrate increasing capability in analyzing medical imaging. Future systems might help patients better understand their X-rays, MRIs, or computed tomography scans through:

- Interactive 3D visualizations of findings.
- Comparative analyses with previous imaging.
- Plain-language explanations of visual changes.
- Preparation guides for upcoming imaging procedures.

Personalization

Personalization represents another crucial area of development. Future AI systems will likely become more adept at tailoring their support based on:

- Individual language preferences.
- Personal medical history.
- Individual health literacy levels.
- Learning style preferences (eg, text, video, and photos).
- Specific medical conditions.

This personalization extends beyond mere language adjustments to encompass comprehensive adaptation of information delivery and support strategies.

Diagnostic Support

A significant portion of medical research never reaches clinicians or their patients, and translating new evidence into routine practice is often estimated to take about 17 years [14]. AI can analyze large medical datasets, detect subtle patterns, and link symptoms that might otherwise seem unrelated, making it a powerful tool for diagnostic support [15,16]. Although AI lacks access to every piece of medical data, it can draw on extensive, diverse sources to provide insights directly to patients. Like humans, AI can make mistakes, but it offers an important advantage: generating a list of potential explanations or conditions for patients and clinicians to review and validate together.

Supporting Underserved Communities

Supporting underserved communities with AI can assist them by providing health information around the clock and in multiple languages, even when clinics are closed. For example, a patient could ask the same questions MBS used but add, "Translate this into Spanish." As shown in MBS's case, AI can translate complex medical reports into plain-language summaries that increase patient understanding [17] and deliver information in ways that overcome language barriers and limited clinic hours.

Additionally, certain populations, such as older people, may be more comfortable interacting via speech, which is a feature in many LLMs, as some individuals may find the dexterity involved with typing on small keypads on smartphones challenging [18].

Overcoming Barriers

There are barriers that some patients may face in using large language models, including subscription costs, limited digital literacy, and a lack of knowledge about how to work with AI tools. Public libraries, senior centers, and community organizations—such as local councils on aging—can help bridge these gaps by offering free internet access, technology training, and support to help build skills.

It's important that these advancement suggestions above be balanced against important considerations. Privacy and security concerns will require ongoing attention as AI systems become more integrated with personal health information. The development of robust security protocols, clear ethical guidelines, and strategies to detect and mitigate data bias must proceed in parallel with technological advancement.

Perhaps most importantly, future developments must maintain focus on a fundamental goal: enhancing patient care and outcomes. Technology should serve patient needs with development priorities shaped by actual patient experiences and health care requirements.

As we look ahead, several key principles should guide the evolution of AI in patient care:

1. Improve patient outcomes and experiences.
2. Enhance understanding and engagement.
3. Maintain human connection in care.
4. Ensure equity, access, and privacy.
5. Support clinical judgment—and cause no harm.

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The future of AI in patient care holds tremendous promise, but realizing this potential requires thoughtful development and implementation. Progress should be measured less by technological innovation and more by meaningful improvements in patient outcomes and experiences. Further study is needed to better understand the impact of these emerging tools on both. As MBS's case demonstrated, the goal is not to revolutionize health care but to make it more accessible, understandable, and effective for patients navigating their health journeys.

Conclusion

This case study shows how integrating AI tools into patient care can greatly enhance the patient and caregiver experience. ChatGPT helped turn a stressful period into one of clearer understanding and active engagement. Such tools can increase patient understanding, improve communication with clinicians, support treatment research, ease emotional strain, and shorten the care timeline.

As health care evolves, AI has the potential to support patients across their health care journey, working alongside providers. Properly implemented, AI can empower patients to participate more effectively in their care, provided its output is validated by trusted sources. To succeed, these tools must be designed with patients and caregivers at the center, addressing their distinct challenges and needs.

Conflicts of Interest

None declared.

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Abbreviations

AI: artificial intelligence
LLM: large language model
MRI: magnetic resonance imaging

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Characterizing Veteran Engagement Groups for Research at the US Department of Veterans Affairs

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Abstract

At the US Department of Veterans Affairs (VA), Veteran engagement groups (VEGs)—an integral component of VA research—have two-way impacts, as reported by group facilitators: they ensure that VA researchers, clinicians, and operational leaders conduct Veteran-centric work, and they confer several benefits, including health and social benefits, to Veteran members.

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KEYWORDS

Veterans; research engagement; health systems research; participatory methods

Introduction

Patient engagement groups in research have been shown to improve the feasibility and quality of research while simultaneously providing patients with a voice in improving health and health care for themselves and others [1,2]. At the US Department of Veterans Affairs (VA), the Health Systems Research (HSR) portfolio in the Office of Research and Development (ORD) has a strong history of involving Veterans in all aspects of the research process through Veteran engagement groups (VEGs) [3].

Prior work on subsets of HSR VEGs highlights that although local implementation varies by research center location, groups share a common goal of providing Veterans with opportunities to shape the research that is for and about them [4-6]. To assess the state of the field and better understand the scope of VEG efforts, we characterized VEGs affiliated with all VA HSR centers as of 2025, focusing on their structure, composition, activities, and impacts.

Methods

Overview

A brief survey was developed in VA Research Electronic Data Capture (REDCap; version 14.12.0) and distributed via email by ORD staff (AVK, BJB) to VEG facilitators across all VA HSR Centers of Innovation (COINs; n=20) and Consortia of Research (COREs; n=7) in May 2025. We used closed-ended questions to assess VEG geographic location, group size, member makeup, and meeting frequency and format. Open-ended questions were used to assess topic foci, activities, and impacts. Respondents could also optionally share anonymous quotes from Veterans about the impacts of participating in VEGs. In the initial email, respondents were informed that responses would not influence ORD's support for their VEG.

We generated descriptive statistics for closed-ended survey questions (analyses in RStudio, version 2024.12.1; Posit Software, PBC) and qualitatively analyzed open-ended survey responses using a constant comparison process [7]. Two authors (AVK, KMC) met via video conference on two separate days to identify and formulate consensus about themes for the questions about both VEG activities and impacts.

Ethical Considerations

VA's Central Institutional Review Board determined that project activities were quality improvement work and not research involving human subjects.

Results

All VEG facilitators (100%) responded, providing information on 37 unique VEGs; some COINs/COREs had more than one affiliated VEG. All VEGs had ORD sponsorship and had significantly interacted with VA HSR research studies. About half of the VEGs (n=21) reported a specialty focus (eg, women Veterans, Veterans experiencing homelessness), while the

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remainder were more general in the research topics discussed. Groups ranged in size (3 - 17 members, median: 9.5, IQR 8-12); 11 groups included caregivers in addition to Veterans, and 4 included VA employees or others. See Table 1 for additional VEG characteristics.

Table . Veteran engagement group characteristics.

Characteristics	Groups (N=37), n (%)
Member geography	
National	15 (40)
Local	15 (40)
Local, with some remote members	7 (19)
Meeting format	
Virtual	30 (81)
Hybrid	7 (19)
Meeting frequency	
Biweekly	2 (5)
Monthly	12 (32)
Bimonthly	8 (22)
Quarterly	7 (19)
Semiannually	4 (11)
Other	4 (11)

Responses to open-ended questions revealed that VEGs participate in activities along the full research lifecycle (Figure 1), with the goal of fostering more Veteran-centric research. Several VEGs noted that they also have social activities for rapport building, and some engage in strategic planning for their own VEG.

Veterans reported experiencing positive impacts from participating in VEGs, as relayed by VEG facilitators. These included making a difference and having their voices heard, having increased trust in VA research and clinical care, experiencing health and social benefits (eg, community building) and personal development (eg, seeking employment opportunities at VA), participating as members of research project teams and in high-profile research activities, and gaining new content knowledge on health topics and research processes.

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Figure 1. Summary of the full spectrum of the research lifecycle, which Veteran engagement group (VEG) members provide input on. Veterans' health and care experiences are relevant for all aspects of the research lifecycle. Data are based on responses from 37 VEGs from the qualitative constant comparison analysis of VEG activities and impacts.



Discussion

Veteran engagement groups (VEGs) connected with VA ORD's HSR portfolio have bidirectional impacts: they ensure that VA researchers, clinicians, and operational leaders conduct work that stays Veteran centered, and these groups confer multiple benefits, including health and personal benefits, to Veteran members. VEGs vary in their specific structure and member composition, highlighting that they are a flexible mechanism for ensuring that research incorporates the unique perspectives and experiences of Veterans and their caregivers. Our assessment reinforces the benefits of VEGs, which have been described for subsets of these groups at the VA [6,8] and other patient research engagement groups [2], extending these findings to ORD's HSR VEGs as a whole.

Patient participation and feedback are critical for the functioning of learning health care systems [9]. VA HSR's engagement of Veterans through VEGs is a model that could be replicated by others for meaningfully engaging patients in large, complex organizations. In VA, this engagement model has led to measurable advances in care delivery by ensuring that Veteran priorities drive research priorities and thereby evidence-based system improvement [10].

One limitation of this work is that, due to our rapid assessment strategy, there may have been VEGs interacting with ORD HSR projects that were not identified (eg, rural groups consulting with HSR researchers that receive some ORD support). We also did not assess project-specific Veteran engagement efforts. Future work should focus on characterizing all VEGs associated with ORD, including those outside the HSR portfolio, to more comprehensively characterize the contributions Veterans make to all VA research areas. Second, our assessment did not systematically capture a few areas, including how engagement groups were set up, who VEGs provide feedback to (eg, only local VA researchers, any VA researcher nationwide, clinical operations partners), researcher demand for these groups, or how engagement is measured and tracked in projects. These gaps should be addressed in future work to better facilitate targeted support for VEG infrastructure and growth. Lastly, our work only captured the perspectives of VEG facilitators, rather

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than those of Veterans directly, which likely influenced the reporting of positive impacts. Future work should engage Veterans directly.

Overall, our work describes the current state of the field for HSR research engagement efforts, which can be extended to patient engagement groups more broadly. Given the meaningful outcomes for researchers and Veterans that come from participating in VEGs [6], there should be increased focus on prioritizing engagement efforts; one example already in place is ORD's requirement for submitted research proposals to include a Veteran and provider engagement plan. Continued investment and infrastructure support efforts by ORD will optimize the impacts of VEGs, which directly advance VA's mission to provide the best health care to Veterans.

Acknowledgments

First and foremost, we thank all the Veterans and their loved ones who have chosen to contribute meaningfully to Department of Veterans Affairs (VA) research by participating in Veteran engagement groups. We also thank the Veteran engagement group facilitators for their time completing the survey.

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Data Availability

The data reported in this manuscript are available from the corresponding author on reasonable request.

Authors' Contributions

Formal analysis: AVK, KMC
Methodology: AVK, BJB, KMC
Writing – original draft: AVK
Writing – review & editing: AVK, BJB, KMC

Conflicts of Interest

None declared.

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Abbreviations

COIN: Center of Innovation
CORE: Consortium of Research
HSR: Health Systems Research
ORD: Office of Research and Development
VA: Department of Veterans Affairs
VEG: Veteran engagement group

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Perspectives of Individuals With Obsessive-Compulsive Disorder on the Role of Artificial Intelligence in Therapy and Treatment: Thematic Qualitative Study

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Abstract

Background: AI has become increasingly used in mental health care for applications such as diagnosis, monitoring, and treatment support. These include tools like clinician support systems, large language models, and conversational agents used to augment psychotherapy and clinical decision-making. While prior research suggests potential benefits of and concerns with AI, little is known within the domain of obsessive-compulsive disorder (OCD). Given the expanding role of AI in psychiatry, understanding these perspectives is essential to ensuring AI implementation aligns with patient priorities and values.

Objective: This study aims to explore the perspectives of individuals with OCD on the use of AI in health care, including perceived benefits, risks, and its role in relation to human clinicians.

Methods: We conducted semistructured interviews with 24 adults self-reporting OCD, recruited through online communities and advocacy networks. Eligible individuals (≥18 y with self-reported OCD) completed screening, provided informed consent, and participated in remote Health Insurance Portability and Accountability Act (HIPAA)-compliant Zoom (Zoom Communications, Inc) interviews (May-December 2024). Transcripts were deidentified, open-coded, and used to develop a codebook. Focused codes were applied using a thematic analysis framework in Dedoose (v9.2.22; Sociocultural Research Consultants, LLC). Each transcript was independently coded by 2 reviewers, with discrepancies resolved through consensus. Themes were developed through iterative interpretive analysis of code clusters.

Results: Participants' perspectives encompassed concerns and benefits of AI in mental health care. Participants expressed concerns about the accuracy and efficacy of information provided by AI, as well as a limited ability for clinical judgment in psychiatric care. Additionally, participants emphasized the importance of human connection, particularly therapeutic alliance, empathy, and reassurance provided by clinicians, which they felt AI could not replicate. Concerns about data privacy, security, and downstream use of information were also highlighted. Despite concerns, many endorsed the use of AI as an adjunct rather than a replacement for clinicians, noting potential benefits in symptom monitoring, preliminary information gathering, and support for administrative tasks, provided that human oversight is maintained.

Conclusions: Individuals with OCD expressed nuanced views on AI in mental health care, balancing cautious optimism with several concerns. While AI may improve efficiency, standardization, and symptom monitoring, participants highlighted risks related to deindividualization, accuracy, and erosion of human connection. These findings underscore the importance of patient-centered, ethically guided AI integration that preserves the therapeutic alliance while leveraging technological benefits.

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KEYWORDS

artificial intelligence; AI; large language model; LLM; chatbot; OCD; obsessive-compulsive disorder; patient experience; qualitative; thematic analysis

Introduction

Obsessive-compulsive disorder (OCD) is a chronic and often disabling psychiatric condition characterized by intrusive thoughts and repetitive behaviors that cause significant distress and functional impairment across occupational, academic, and interpersonal domains [1,2]. Lifetime prevalence estimates range from 1% to 3%, and patients often experience a waxing and waning of symptoms over time [3,4]. Modalities such as psychotherapy with exposure and response prevention (ERP)

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and pharmacotherapy with selective serotonin reuptake inhibitors are evidence-based and can produce meaningful symptom reduction [5]. Unfortunately, despite the existence of effective treatments, many individuals with OCD do not receive timely or adequate care [6].

Given the chronicity of OCD and gaps in access to evidence-based care, there is increasing interest in augmenting current treatment models with AI. AI has evolved from a largely theoretical concept in the mid-20th century into a rapidly advancing field with broad implications for health care delivery [7]. Improvements in computational power, widespread digitization of health information, and advances in algorithmic design have enabled AI systems capable of identifying complex patterns in large datasets [8], with applications including pattern recognition, prediction, and decision-making [9]. In medicine and mental health care settings, this includes supporting diagnosis, monitoring, and intervention. For instance, machine learning (ML) algorithms demonstrate promising accuracy in detecting psychiatric conditions and predicting outcomes [10]. AI-enabled clinical decision support systems have been developed that assist with medication selection and adjustment. Indeed, an AI-clinical decision support system used in the treatment of moderate major depressive disorder supported improvements in response and remission rates [11].

AI-driven conversational agents and chatbots have been used to augment psychotherapy by delivering components of cognitive behavioral therapy, providing psychoeducation, and offering real-time coping support [12]. Evidence indicates, particularly for adolescents and young adults, these tools can reduce depressive, anxiety, stress, and psychosomatic symptoms [13,14]. Such systems are often positioned as scalable adjuncts to therapy, extending support between sessions or to individuals without access to in-person care.

The successful integration of AI depends not only on technical performance but also on patient trust, acceptability, and lived experience. Understanding how patients perceive and interact with AI-enabled tools is critical to ensure these innovations promote equitable access, improve outcomes, and avoid unintended harms. Although research has begun to explore attitudes toward AI in mental health care, it remains limited and largely condition-agnostic. Survey studies indicate perceived benefits, such as improved access and efficiency, alongside concerns about privacy, accuracy, bias, and effects on the therapeutic relationship [15]. Research on digital mental health technologies more generally suggests that beliefs about credibility, personalization, and emotional understanding influence engagement [15]. However, little is known about how individuals with OCD perceive AI-enabled interventions, or how OCD symptomatology may shape these perceptions.

Given persistent treatment gaps and the growing role of AI in psychiatric care, condition-specific, patient-centered research is needed. Within a 2025 sample of 499 US adults with self-identified mental health conditions, nearly half reported using chatbots for psychological support last year [16]. Core features of OCD, such as intolerance of uncertainty and compulsive reassurance seeking, may uniquely predispose individuals with OCD toward maladaptive AI use [17]. Understanding how patients with OCD conceptualize these dynamics is a necessary precursor to designing safe and effective AI tools for this population. We conducted a qualitative study using a thematic analysis framework to explore how individuals with OCD perceive the use of AI in treatment, including benefits, risks, and conditions for acceptability. Given the existing literature described above and our clinical experience, we postulated that adults with OCD would have similarly varying perspectives on technology.

Methods

Study Design

This study sought to explore the attitudes of people with OCD toward the use of AI in their health care. We then used the approach of thematic analysis to interpret our data [18,19]. We used the COREQ (Consolidated Criteria for Reporting Qualitative Research) framework, a validated checklist for qualitative reporting, to guide and document important aspects of the research team, methodology, findings, and analysis (Checklist 1) [20].

Recruitment and Sample

Recruitment processes and participants were identical to Occhino-Moede et al [15]. Participants were recruited via convenience sampling from May to December 2024 through online spaces focused on OCD education, advocacy, and peer support, including platforms affiliated with the International OCD Foundation and OCD research registries maintained by our laboratory.

Recruitment posts described the study purpose, eligibility criteria, participation requirements, and compensation. Interested individuals contacted the research team and completed a REDCap (Vanderbilt University) screening survey. Eligible respondents were invited to a virtual onboarding session to verify submitted answers, review procedures, and provide informed consent.

Eligibility criteria included self-reported age ≥18 years and a diagnosis of OCD. Twenty-seven participants completed consent and an interview. Interviews were completed by personnel trained in OCD symptomatology; 3 were excluded due to concerns about eligibility (eg, unclear diagnosis or suspected repeat participation). Camera-on interviews and brief discussion of OCD symptoms were used to mitigate this risk. No participants withdrew after enrollment. Seven participants had prior contact with laboratory personnel through other studies. No repeat interviews were conducted. Sample characteristics are summarized in Table 1.

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Table . Participant demographics (N=24).

Characteristics	Values
Median age, years (range, IQR)	26.2 (20.1 - 63.6, 12.8)
Gender	
Man	7
Woman	16
Nonbinary	1
State	
California	14
Pennsylvania	3
Illinois	2
Ohio	2
Florida	1
Maryland	1
Virginia	1

Research Team and Procedures

The study was conducted by a multidisciplinary team, with formal educational levels ranging from undergraduate to medical student to board-certified psychiatrist; the team was led by the principal investigator (PI; ACF, MD/PhD, psychiatrist) (Multimedia Appendix 1). The PI has experience working with individuals with OCD in an outpatient clinical setting providing psychotherapy, medication management, and neuromodulation; additionally, the PI conducts quantitative and qualitative research in other studies with adults with OCD. While the interview guide did not exclusively focus on clinical or treatment-related applications of AI, given the PI's clinical background, these topics may be emphasized. All interviewers completed a structured 6-week qualitative training (eg, review of the interview guide, observation of senior interviewers, and postinterview debriefings) and participated in ongoing supervision. Interviewers were also trained in OCD symptomatology by the study PI; this included review of *Diagnostic and Statistical Manual of Mental Disorders, 5th Edition* (*DSM-5*) [21] criteria for OCD and review of diagnostic assessments used for OCD including the Yale Brown Obsessive Compulsive Scale (YBOCS) [22] and YBOCS symptom checklist, so that interviewers understood the breadth of experiences and symptoms that can be manifest in OCD. Some interviewers identified as having lived experience with OCD; others did not. All interviewers were familiar with commonly available forms of AI when interviews were completed, such as large language models (LLMs), chatbots, and text-to-image generating services. Some interviewers identified as consistent users of these AI services, and some identified as occasional users.

We used a semistructured interview guide to elicit participants' experiences with digital technologies used for health and health care, with a focus on OCD-related care. Participants were reminded of the study goals, and interviewers introduced themselves and their role in the project. Questions explored when and how participants began using various technologies, how these tools fit into their daily routines, perceived benefits and drawbacks, and how they related these tools to OCD symptoms, help-seeking, and treatment. This interview guide was used in Occhino-Moede et al [15], and while it included one specific question about AI, participant-initiated discussions about AI occurred outside of the context of this single question. A sample of the interview guide is provided in Multimedia Appendix 2.

Interviews were conducted remotely via Health Insurance Portability and Accountability Act (HIPAA)-compliant Zoom (Zoom Communications, Inc) between May 16, 2024, and December 20, 2024. With participant permission, sessions were audio- and video-recorded and auto-transcribed within Zoom. Research assistants reviewed transcripts for accuracy and deidentification. Interviews ranged from 35 to 65 minutes, with a median of 51 minutes.

Data Coding

Given the breadth of discussion of AI that occurred in interviews conducted in Occhino-Moede et al [15], we developed a new codebook for this manuscript. Codebook development was informed by Braun and Clarke's [18] 6-phase framework for thematic analysis. Two members of the research team (LO and EL) independently conducted open coding of the first five transcripts to generate an initial set of inductive codes related to participants' perspectives on AI. Analytic memos were maintained during this process to capture emerging interpretations and support reflexivity. The coders then met to compare codes and memos and used constant comparison to consolidate conceptually similar codes into broader candidate themes. Codes and their definitions were iteratively refined against the data set, and hierarchical relationships between parent and child codes were established. This recursive process produced the final codebook, which included global codes and nested thematic categories reflecting patterns identified in participant narratives. An excerpt of the final codebook is provided in Multimedia Appendix 3.

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All transcripts were imported into Dedoose, and the codebook was implemented in the software. Each interview was coded by two team members working independently. During coding, researchers identified and coded all AI-related content across the interview transcripts, including both responses to AI-specific interview questions and spontaneous references to AI that emerged during broader discussions of technology use in health care. Coder pairs subsequently met to reconcile differences through consensus.

During consensus, team members discussed whether any segments of text relevant to the research question had not been adequately captured by existing codes. These novel concepts were added to the existing codebook, and all previous transcripts were re-coded using the revised structure. Coding continued until code saturation was reached, defined as the point at which no new codes emerged from the data—reflecting the range of thematic issues identified across interviews [23].

Theory Development

Following consensus coding using the finalized codebook, the analytic team shifted from descriptive coding to interpretive theme development. Guided by the 4R's framework described by Naeem et al [24], researchers examined how codes combined to reflect broader patterns in participants' perspectives on AI in health care.

First, coded excerpts were reviewed across transcripts to ensure codes accurately reflected the underlying data and were applied consistently. The team then reflected on relationships among codes, using analytic memos and group discussion to explore how clusters of codes captured shared meanings within participants' narratives.

Candidate themes were subsequently refined through iterative team meetings in which codes were grouped into broader conceptual categories and evaluated for coherence and distinctiveness. Discordant cases were reviewed to ensure themes captured variation within the dataset. Negative cases are noted in the results, as these occurred in some themes [25]. Final themes were defined and named to represent the central patterns identified in participant narratives, with representative excerpts selected to illustrate each theme.

Ethical Considerations

All study procedures were approved by the University of Southern California Institutional Review Board (UP-23 - 01094). All study procedures involving human participants adhered to the ethical standards of the institutional review board and the 1964 Declaration of Helsinki and its subsequent amendments. Prospective participants received written information describing the study purpose, procedures, risks, benefits, and voluntary nature of participation. Study staff reviewed this information during a videoconference consent visit and answered questions prior to obtaining informed consent. Participants could decline any question or withdraw at any time without penalty. Interview data were deidentified before analysis and stored on secure, access-restricted servers. Participants received a US $50 Tango gift card after completing the interview.

Participants

A description of the participants (n=24) is provided in Table 1. No participants refused to participate in the study or withdrew their participation.

Results

Theme A: Inaccuracy and Inefficacy of AI in Health Care

Participants expressed concern that AI might generate inaccurate, fabricated, or misleading information. These inaccuracies, participants noted, could potentially lead to users feeling misunderstood at best, or at worst, engaging in dangerous behaviors.

Participants expressed specific concerns about AI's accuracy, such as worries about misattributed source information or LLM hallucinations, which are an established phenomenon in which LLMs identify nonexistent patterns, resulting in outputs that are incorrect or nonsensical [20]:

> *The degree to which it is erroneous in what it is saying is frustrating when it's a topic I know about, and have engaged with it. It's frustrating, again, because you can't see through that unless you know already. Like, it'll present it as though, like 'this is the quotation you're looking for', and you're like, no, that quotation is not from that.* [Participant 16]

> *AI produces what's called hallucinations, where it makes up stuff. And I've also experienced that when I've been using it personally. That it would say something that I knew was not correct. That's a recognized problem with AI.* [Participant 3]

With regard to OCD treatment, participants expressed concerns about AI's ability to understand the individual nature of the disorder and provide effective treatment recommendations, citing examples of how well-intentioned but misguided care can negatively affect outcomes:

> *Everyone has different obsessions and compulsions, so like, I think there would just have to be a lot that would have to like go into that before it (AI) could be like really, like effective and not harmful in the mental field in particular.* [Participant 19]

> *Treating it (OCD) as just kind of like anxiety … just makes it a lot worse. So even though it's not like someone acting in a harmful way, if it's not the correct treatment or thing to do … if someone is left feeling like they weren't helped, then that can just make it a lot worse and more isolating for them.* [Participant 19]

Some participants described concerns about the efficacy of AI in the context of mental health care more broadly. One individual stated:

> *I remember like, several months ago, reading something about AI, with either eating disorders, or a suicide hotline type of situation where it was like wildly ineffective… there's just like a lot of kinks there*

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> *to be worked out like if it were to ever be used for … helping people with … mental health concerns.* [Participant 19]

While a few participants were highly doubtful of the accuracy and efficacy of AI in treatment, most expressed feeling that they might be comfortable in the future, but didn't feel that the technology was quite developed enough yet. One participant succinctly stated:

> *I don't think that AI is quite there where it's like 100% trustworthy, and there's different mistakes that it can make.* [Participant 3]

However, not every participant shared this sentiment. When asked whether they had any concerns about AI and treatment, one participant acknowledged that mistakes were possible, but considered them unlikely:

> *Just giving the wrong diagnosis and just mak[ing] things worse. But I think that at the level where we are at, I think it shouldn't be an issue.* [Participant 19]

Concerns about LLM hallucinations, erroneous source information, weak algorithms, or poor quality, and even potentially dangerous outputs, decrease confidence in the ability of AI to generate helpful and accurate information for users with OCD.

Theme B: Clinical Decision-Making as a Contextual, Integrative, and Experiential Process

Participants emphasized the importance of clinical judgment in psychiatric care, describing it as a process grounded in contextual, interpretative, and experiential reasoning. Flexibility, nuance, and professional training were identified as central components, suggesting that effective psychiatric care depends on the ability to interpret complex and often ambiguous clinical presentations.

Participants described one component of effective psychiatric care as the ability of the clinician to detect subtle cues that extend beyond explicit symptom reporting. Clinical judgment was framed as requiring attention to tone, affect, and contextual signals that may not be directly verbalized. One participant noted:

> *A lot of psychiatry is more than just what the patient is saying… it's observations, listening, how they're saying it, trying to understand the bigger picture of their life, you know, what factors outside of what they're just talking about.* [Participant 9]

When asked if they had positive experiences with clinicians which would have been different with AI, one patient responded:

> *Oh my gosh, yeah, 100%... [my provider] looked holistically at my whole life story, and could understand what could be a trauma response, what could be a personal thing… sometimes you don't necessarily have the verbiage exactly to express, like what's going on, especially when you're new to the field of psychiatry.* [Participant 14]

Beyond recognizing cues, participants emphasized that psychiatric decision-making should be contextual and integrative, rather than linear and formulaic. Rather than relying on isolated symptoms, clinicians were described as integrating life history, social determinants, and situational factors. One participant commented that:

> *There's a reason, you know, it's not robots doing [medication adjustment or therapy]… with diagnosing and knowing the individual and the situation and the social determinants that are affecting it, there's more than just like the right answer.* [Participant 9]

Clinical reasoning was also described as requiring adaptability rather than rigid adherence to standardized patterns. One participant described their experience with rare medication side effects:

> *I'm that point less than point 1%. I have had a super rare side effect to everything that I've taken so I need to be able to interact with an actual human when adjusting things. If we mess something up or go up too high, I'll have a weird side effect. So I definitely would want a human that knows that and isn't just a computer and going off of a formula.* [Participant 24]

Their concerns suggest that participants viewed good clinical judgment as flexible and individualized, particularly when patients' experiences fell outside the norm.

Finally, participants linked legitimate clinical decision-making to formal training and credentialing. Decisions such as prescribing medication or modifying treatment plans were viewed as requiring education and supervised experience, not merely access to data. One participant stated:

> *A doctor, they go through so much training and education… they really possess the knowledge that is required to give the medication or prescription. The AI doesn't.* [Participant 12]

Although these perspectives predominated, one participant suggested that certain components of clinical reasoning, namely preliminary information gathering, could be appropriately delegated to AI. As they explained:

> *Being honest, I think AI will be helpful to some certain extent, like, let's say, the initial analysis… The AI can categorize me into some specific category of patient or something. And then, based on that, the doctors or anyone can come in after the initial analysis is done* [Participant 10]

Though they clearly saw the utility of AI in health care systems, it was important that clinicians retained responsibility for interpretation and final decision-making. This perspective suggests that participants distinguished between routine, structured aspects of clinical reasoning and the more complex interpretive processes they viewed as uniquely human.

Overall, participants distinguished human clinical reasoning from AI-generated outputs by emphasizing cue recognition, contextual interpretation, flexible clinical judgment, and credentialed expertise. In their accounts, effective psychiatric

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care was closely tied to these forms of clinical reasoning and difficult to replicate through automated systems.

Theme C: Therapeutic Alliance, Human Connection, and Trust

Participants emphasized that human connection is central to effective OCD care. Across interviews, trust, reassurance, relational nuance, and individualized understanding were described as important to symptom management and therapeutic progress. While part of this therapeutic alliance was observed to be a result of the providers' expertise and training as described in Theme B, another key theme emerged which displayed the importance of the human connection in itself.

Many participants described the human connection as uniquely reassuring, particularly during periods of symptom exacerbation. One participant reflected:

> *I found it very reassuring when I'm having an OCD flare to talk to someone who I know is an expert on this subject and he's treated people before who can say 'No, this doesn't mean that you're insane'...That can be very reassuring* [Participant 3]

Similar to Theme B, this participant also viewed clinical experience as important; however, the reassurance it provided was grounded not only in expertise, but in the relational presence of a clinician who could validate fears in real time.

The relational alliance between patients and providers was described as essential by many participants. This perspective framed therapy not merely as information exchange, but as an interpersonal process grounded in empathy. For instance, therapists who made a personal connection or shared an anecdote were seen as uniquely helpful. As one participant explained:

> *Also, I found it very reassuring or helpful when a therapist will help customize a therapeutic technique to my OCD. Or even I've had a therapist in the past who related stories about themselves in their battle with obsessive thoughts* [Participant 3]

Another stated:

> *Well, a therapist, I think, is meant to soothe you, listen to you individually and soothe you… You can't take away from the human aspect of a therapist.* [Participant 11]

AI was frequently positioned as incapable of replicating these relational dimensions. Therapeutic care was often viewed as part of broader human connectedness and community belonging. One participant expressed discomfort with replacing human interaction, stating:

> *It's just really icky to me that we're replacing these human interactions through AI…we need to feel part of the community…we're functioning with humans hopefully, so I feel like it's just not good to be kind of withdrawn from humanity.* [Participant 14]

Overall, participants framed therapeutic alliance, characterized by reassurance, personalization, empathy, and human touch, as indispensable to effective OCD care and not readily replaceable by AI systems.

Theme D: Data, Surveillance, Privacy, and Emotional Vulnerability

Participants described concerns regarding privacy, data security, downstream uses of personal data, and emotional vulnerability when considering the use of AI in health care. A central tension emerged between trust in human clinicians and uncertainty about whether AI systems could uphold comparable standards of confidentiality and privacy.

Participants often raised concerns regarding privacy and security of sensitive information broadly. Several participants explicitly contrasted their confidence in health care providers with their hesitancy toward AI systems, expressing concern about the possibility of data breaches. One participant stated:

> *I totally trust health care providers to, you know, uphold HIPAA and um like health privacy, but the moment that AI is used- I don't know- I don't know how I can trust AI to maintain that same level of health security as like a doctor* [Participant 1]

Another participant explicitly stated:

> *I guess security is always a concern…data stealing from the therapy session would be a concern.* [Participant 3]

Participants also expressed concern about losing autonomy over their personal information once it is collected or processed by AI systems. One participant described involvement in a research study using AI and questioned how their recorded data would be handled:

> *I was doing another or currently am doing another research study where they're doing AI as well. And it's something about low back pain. So like I had to be recorded while I was doing different exercises and they said it was AI stuff and I was like, well, what, what are they going to do with this?* [Participant 20]

Another participant voiced fears of misuse and impersonation, stating:

> *I'm concerned that it, you know, that it's going to be abused…It's scary that way. I mean, it's like somebody could pretend to be me* [Participant 23]

Beyond technical concerns, participants distinguished emotional vulnerability as a separate and equally important issue. One participant highlighted discomfort with emotional disclosure to nonhuman systems:

> *Safety also, intimacy also. Someone might not be really comfortable in sharing these things with a Chatbot or any AI engine, because you never know how your data might get used or how it is interpreted.* [Participant 10]

Together, these accounts illustrate how concerns about AI in health care extend beyond technical data security to include autonomy, trust, emotional comfort, and the broader psychological implications of sharing sensitive information with artificial systems.

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Theme E: Participant Supported Uses of AI in Health Care

Participants generally endorsed the use of AI as a supportive clinical tool when implemented transparently, complementarily, and under human supervision. Rather than rejecting AI outright, many described conditional acceptance, particularly for functions that improve efficiency, organization, and symptom monitoring, as long as clinicians retain interpretive authority.

Several participants consistently emphasized that AI should assist rather than replace clinicians. However, one participant provided an example of potential dislike for AI that stood out from other cases:

> *I know that if it was AI that was helping to understand or confirm the evidence-based treatment, I would have no problem with that, as I would with the physician or therapists looking up information from any source. But I would dislike if the AI was answering me directly instead of the therapist.* [Participant 3]

Participants also described AI as potentially useful for initial analysis and administrative tasks, recognizing improvements in efficiency and standardization without supplanting clinician involvement. One participant explained:

> *I think AI will be helpful to some certain extent…The AI can categorize me into some specific category of patient…based on that, the doctors or anyone can come in after the initial analysis is done, so I feel that will save time as well.* [Participant 10]

When asked about potential positive uses of AI in health care, the same participant elaborated on the value of streamlining intake processes:

> *Especially…for therapy, or something like in the initial sessions, [with] the basic general questions…Those can be done via some, let's say, form…then it can be boiled down to something.* [Participant 10]

Participants also identified potential applications for AI in supporting evidence-based therapeutic interventions. One participant suggested that AI could assist with the development of ERP exercises while still operating within a structured clinical framework:

> *AI could probably be used well to kind of come up with ERP scripts and, like easy ready to go ERP scripts…AI with ERP would probably work really well…with ERP specifically, like, it's a pretty like, regimented thing that you could teach an AI to do.* [Participant 6]

Symptom tracking and early detection were also identified as potential advantages. One participant described openness to AI-driven monitoring tools contingent upon clinician involvement while rejecting the idea of a fully AI therapist:

> *If I had an AI bot that was my therapist I don't really know if I would like that, but…If I had maybe a piece of software on my phone that learned my habits…when I was starting to be manic and go crazy that would be very, very helpful.* [Participant 11]

These accounts illustrate that participants were open to AI when positioned as a transparent, clinician-supervised tool that enhances efficiency and monitoring, but expressed reluctance toward AI functioning independently or replacing human therapeutic relationships.

Discussion

Summary of Findings

This study explored the perspectives of individuals with OCD regarding the role of AI in health care using a qualitative thematic analysis framework. Several themes emerged: (1) inaccuracy and inefficacy of AI in health care, (2) the absence of clinical judgment and experiential reasoning in AI systems, (3) the potential loss of therapeutic alliance and human connection, (4) risks related to privacy, data security, and emotional variability, and (5) conditional acceptance of AI when used as a clinician-supervised tool that complements, rather than replaces, human care. Overall, participants favored a human-centered approach to AI integration in psychiatric treatment.

Algorithmic Rigidity Versus Human Clinical Reasoning

Participants highlighted a distinction between algorithmic pattern recognition and human clinical reasoning. While participants acknowledged that AI may be capable of processing large amounts of information and generating predictions, many questioned whether such outputs constitute true clinical judgment. Although ML systems are highly effective at identifying statistical patterns [26], most lack clear mechanistic reasoning [27]. Participants recognized this limitation, expressing concern that AI-generated answers do not provide transparent reasoning or contextual interpretation. Their reflections align with models of diagnostic reasoning that involve both pattern recognition and analytical processes, which clinicians shift between intuitively [28]. In contrast, participants described psychiatric clinical decision-making as an interpretive and narrative process. Clinicians were viewed as integrating multiple forms of information – patient history, tone of speech, affect, and broader life context – to construct a meaningful understanding of an individual's experience. Clinical literature describes this as a form of deliberate, analytical reasoning that extends beyond algorithmic classification and accounts for diagnostic uncertainty [29], and participants' valuation of flexible reasoning in atypical cases reflects this same principle. Several individuals described experiences with unusual medication responses or highly individualized symptom presentations, emphasizing the need for clinicians to consider possibilities outside statistical norms [28]. Although participants in our study did not raise concerns about biases in human clinical decision-making, it is important to recognize that clinicians are also susceptible to cognitive biases and diagnostic errors. Emerging evidence suggests that generative AI models may exhibit less trauma-related diagnostic overshadowing bias than mental health professionals in certain structured diagnostic

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tasks, underscoring that both human and AI decision-making have distinct strengths and limitations [30].

OCD symptomatology may further amplify these concerns. Core features of OCD include intolerance of uncertainty and heightened distress in response to ambiguous or potentially threatening information [31]. Within this context, the possibility that AI could generate inaccurate or misleading outputs may be particularly distressing for individuals with OCD. As a result, perceived reliability and transparency may be especially important factors influencing acceptance of AI technologies in this population. Additionally, the prominent emphasis on reassurance and validation presented in Theme E should be interpreted within the context of this population, as reassurance seeking is a well-recognized feature of OCD and may therefore have shaped participants' perspectives on the therapeutic role of human clinicians. Indeed, improvements in reassurance seeking track improvements in OCD [32] and excessive reassurance seeking can maintain OCD symptoms [33]. Increasingly, there is a recognition that the availability of generative AI to engage in the provision of reassurance may uniquely interact with OCD [34].

Data Security, Trust, and Emotional Vulnerability Through the Lens of OCD

Another finding was the distinction participants drew between traditional privacy concerns and broader issues of emotional vulnerability when interacting with AI systems. Participants expressed concerns regarding the security of sensitive mental health data, including fears of data breaches, unauthorized access, or misuse of personal information. These concerns reflect well-documented challenges related to data governance and cybersecurity within digital health systems, including increasing rates of health care data breaches, hacking, malware attacks, and unauthorized access to sensitive health records [35].

Participants also described a second dimension of concern that extended beyond technical privacy protections and reported discomfort with disclosing deeply personal thoughts, fears, and compulsions to an AI system. For these participants, emotional vulnerability was not solely a matter of data protection but also of emotional trust and relational security, a distinction that has led to hesitance when disclosing sensitive information [36]. Technical safeguards such as encryption and regulatory protections may address risks related to data security, though may not resolve concerns related to emotional vulnerability or perceived impersonality. Participants frequently contrasted their trust in clinicians, who are bound by professional ethics and regulatory frameworks, with their uncertainty regarding how AI systems store, process, or use personal data, a hesitance documented across systematic reviews of patient attitudes toward AI [37,38].

OCD-related cognitive features may further influence these concerns. Individuals with OCD often demonstrate heightened sensitivity to issues of control, responsibility, and potential harm, as well as increased vigilance in response to perceived threats [39]. Uncertainty regarding how personal information might be used or shared in AI systems may therefore be particularly salient for this population. Participants' emphasis on autonomy and transparency suggests that clear explanations of data storage, processing, and safeguards may be essential for fostering trust in AI mental health tools [40].

The Irreplaceable Role of Therapeutic Alliance in Psychiatric Care

Participants consistently emphasized that certain components of psychiatric care are inherently human-centric–such as empathy, reassurance, emotional attunement, and individualized understanding–and therefore difficult to replicate through AI systems. These findings align with psychotherapy literature demonstrating that the therapeutic relationship between patient and clinician is one of the strongest predictors of treatment outcomes across therapeutic modalities [41,42].

In the context of OCD treatment, these relational factors may be especially important. ERP, the gold-standard psychotherapy for OCD, requires patients to confront anxiety-provoking stimuli while refraining from compulsive behaviors [43]. This process often generates significant distress, and successful engagement frequently depends on a strong therapeutic alliance and trust in the clinician guiding the exposure exercises. This is especially true of individuals with OCD of a more fearful or anxious attachment style [44]. Overall, participants described reassurance, trust, and emotional presence as critical components of effective OCD care, particularly during periods of symptom exacerbation.

Participants also emphasized that clinicians bring experiential knowledge to treatment through training, prior clinical encounters, and in some cases shared personal experiences, which they viewed as inherently difficult for AI systems to replicate. This act of "self-disclosure" by therapists has been previously shown to correlate with positive and therapeutic patient outcomes [45]. These perceptions suggest that psychiatric care may be viewed by patients as less amenable to automation than some other areas of medicine.

Supported Roles of AI With Provider Supervision

While participants expressed concerns about AI's role in psychiatric care, they did not outright reject the use of technology. Instead, participants expressed interest in AI systems that automate administrative tasks or provide decision support. For instance, participants described AI as potentially useful for intake screening, triage processes, and the organization of clinical information [46]. Automated collection of baseline information or standardized symptom assessments were viewed as ways to streamline patient care and clinical workflows. In this sense, AI was perceived as a tool that could improve efficiency without replacing clinician judgment. In turn, these systems could ultimately allow clinicians to devote more time to direct patient interaction [47].

Participants also expressed openness to AI-enabled symptom monitoring and clinical decision support, describing interest in tools that could track behavioral patterns, detect early changes in symptom severity, or assist clinicians in reviewing research evidence and evaluating treatment options. However, participants consistently emphasized that final clinical decisions should remain under human supervision. This perspective aligned with broader discussions that position AI as augmenting rather than replacing clinician expertise [48]. Importantly,

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participants' conditional acceptance of AI appeared to reflect pragmatic openness rather than technological resistance. These findings suggest several practical considerations for the design of AI mental health tools. Developers could prioritize transparency, explainability, and clinician oversight when designing AI systems intended for psychiatric use. Safeguards for sensitive mental health data and mechanisms for personalization may also be important for addressing patient concerns and promoting trust.

Limitations

This study has several limitations that should be considered when interpreting its findings. First, the participant sample skewed relatively young and was geographically concentrated in California, which likely reflects our recruitment methods. Participants were recruited both through in-person studies conducted in Los Angeles and through online OCD advocacy networks. The younger age distribution may partially reflect online recruitment strategies, as younger adults tend to spend more time online than older adults [49], and similar age distributions have been reported in other studies using online recruitment methods [50-52]. As with most qualitative research, the goal of this study was to explore experiences and perspectives in depth rather than to produce findings that are statistically generalizable.

Second, participation required a baseline level of technological familiarity, as individuals needed to access digital recruitment materials and complete interviews via Zoom. As a result, the perspectives of individuals with lower digital literacy, limited technology access, or significant discomfort using digital tools may be underrepresented. In addition, participants likely varied in their familiarity with different forms of AI, and many may have used the term "AI" broadly rather than distinguishing between LLMs, clinical decision support systems, predictive algorithms, or other AI-enabled technologies. While the interview guide contained one question eliciting opinions on physicians or therapists using AI to guide treatment, the topic of AI arose organically throughout interviews. Because of this, some responses may reflect different conceptualizations of AI. Accordingly, findings should be interpreted as participants' perceptions of technologies they identified as AI rather than evaluations of any single AI modality.

Additionally, participants self-identified as having a diagnosis of OCD, and formal diagnostic assessments were not conducted. While self-reported diagnoses are commonly used in qualitative mental health research focused on lived experience and identity [53-56], some narratives may reflect overlapping symptoms with related conditions. To support credibility, research personnel reviewed transcripts for descriptions consistent with obsessive and compulsive experiences.

Relatedly, treatment history was not assessed. While diverse experiences may potentially impact attitudes toward the use of AI in treatment, prior research has found AI performance to be the biggest factor associated with trust of AI-assisted medical care, followed closely by the presence of a clinician [57].

An additional limitation is that the interview guide focused broadly on digital health technologies rather than AI specifically. While AI-related content was systematically identified across transcripts during coding, AI-focused questions represented only a small portion of the interview. Consequently, the themes identified should be interpreted as perspectives that emerged within a broader discussion of digital health technologies rather than as a comprehensive account of patient attitudes toward AI.

Finally, these findings should be interpreted as the perspectives of individuals living with OCD toward AI use in the context of mental health care. Some perspectives may generalize to broader populations and discussions of mental health care, while others may be more specific to individuals with OCD and their perspectives on OCD treatment.

Despite these limitations, this study provides novel insights into how individuals with OCD perceive the use of AI in health care and offers a foundation for future research examining patient-centered perspectives on emerging mental health technologies.

Conclusions

Further research should examine patient acceptance of AI-enabled mental health tools using quantitative methods to assess uptake and usage patterns for specific applications such as symptom monitoring, intake triage, and clinical decision support systems. Comparative studies across psychiatric conditions may also clarify whether attitudes observed in individuals with OCD reflect broader populations or disorder-specific concerns.

Additional research is needed to evaluate the clinical effectiveness of AI-supported interventions for OCD, particularly tools designed to augment ERP through symptom monitoring, behavioral tracking, or between-session support. Recent work has supported this role for AI within exposure therapy [58]. Investigating how specific OCD symptom dimensions influence technology acceptance may also provide insight into which patient groups are most likely to benefit from AI-enabled care.

Finally, future work should explore ethical frameworks and governance models for the integration of AI into mental health care, with particular attention to transparency, clinician oversight, data security, and patient autonomy. Incorporating AI into mental health care has shown promise, though ongoing efforts to develop and implement a framework for ethical usage are needed [59,60]. Developing systems that prioritize explainability and protect sensitive mental health data may be essential for promoting trust and responsible adoption.

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The authors declare the use of generative artificial intelligence (GenAI) in the research and writing process. According to the GAIDeT (Generative AI Delegation Taxonomy) 2025, the following tasks were delegated to GenAI tools under full human supervision: literature search and systematization; proofreading and editing; reformatting. The GenAI tools used were: GPT-4, GPT-4.5, GPT-5, Claude 4.6, OpenEvidence. These tools are all easily accessible to the general public, and they were not modified in any way. Responsibility for the final manuscript lies entirely with the authors. GenAI tools are not listed as authors and do not bear responsibility for the final outcomes. Declaration submitted by: 'collective responsibility'.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

Formal analysis, data curation, writing-original draft, writing – review and editing: DM, HW, ECG, DS
Methodology, investigation, formal analysis, writing – review and editing: LOM
Investigation, formal analysis, writing – review and editing: XL
Conceptualization, methodology, investigation, formal analysis, resources, writing – review and editing, supervision, funding acquisition: ACF

Conflicts of Interest

None declared.

Multimedia Appendix 1
Demographic and training characteristics of the research team members and their involvement in conducting qualitative interviews.
[DOCX File, 29 KB - jopm_v18i1e98822_app1.docx]

Multimedia Appendix 2
Sample interview guide.
[DOCX File, 1801 KB - jopm_v18i1e98822_app2.docx]

Multimedia Appendix 3
Codebook.
[DOCX File, 1799 KB - jopm_v18i1e98822_app3.docx]

Checklist 1
COREQ checklist.
[PDF File, 175 KB - jopm_v18i1e98822_app4.pdf]

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Abbreviations

COREQ: Consolidated Criteria for Reporting Qualitative Research
***DSM-5*:** *Diagnostic and Statistical Manual of Mental Disorders, 5th Edition*
ERP: exposure and response prevention
LLM: large language model
OCD: obsessive-compulsive disorder
PI: principal investigator
YBOCS: Yale Brown Obsessive Compulsive Scale

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Patient and Family Perspectives on Generative AI Tools in Rare Diseases: Exploratory Mixed Methods Online Survey

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Abstract

Background: Generative artificial intelligence (GenAI) tools are widely accessible to the public, who are engaging with them for a wide range of health care applications. Existing research has focused predominantly on clinician-facing adoption. Far less is known about how patients and family members use GenAI tools, particularly in rare disease contexts, where diagnostic delay, limited specialist access, and unmet informational needs are common.

Objective: This study aimed to examine the experiences and opinions of adult patients with rare diseases and parents or guardians of children with rare diseases regarding the use of GenAI tools.

Methods: Between November 2025 and January 2026, we conducted an exploratory mixed methods web-based survey using convenience sampling through rare disease community organizations in the United States. The survey included closed-ended items assessing prior GenAI use, purposes of use, perceived influence on medical decisions and diagnoses, trust, concerns, communication with clinicians, and experiences of harm, alongside open-text questions capturing qualitative reflections. Descriptive statistics were used to summarize quantitative data. Inductive qualitative analysis was applied to the open-text responses.

Results: A total of 115 respondents completed the survey. A majority of respondents were parents or guardians of a child with a rare disease (n=74, 64.3%), and the remaining respondents were patients with a rare disease (n=41, 35.7%). Slightly more than half of respondents (n=63, 54.8%) reported prior use of GenAI tools in the context of rare disease. Common purposes included exploring new treatments or clinical trials (n=53, 46.1%), interpreting medical tests or clinical notes (n=37, 32.2%), locating specialists or care centers (n=29, 25.2%), and suggesting possible diagnoses (n=28, 24.3%). Nearly one-third of respondents (n=37, 32%) reported some degree of influence of GenAI on their medical decisions. Nearly 10% (n=12) reported contributions of GenAI to a formal diagnosis. Concern about GenAI accuracy was widespread; 71 of 115 (61.8%) respondents reported moderate to extreme concern. Most respondents (n=90, 78.3%) had not discussed AI-generated information with a clinician. Few respondents (n=7, 6.1%) reported experiencing harm. Qualitative analysis identified 3 themes: (1) GenAI as a practical tool for augmenting patient and caregiver expertise and advocacy, (2) conditional trust and bounded use of GenAI with an emphasis on verification and human oversight, and (3) perceived risks, harms, and structural concerns, including inaccuracies, genetic misinterpretation, and privacy and commercialization issues.

Conclusions: In this exploratory study, patients and families affected by rare diseases were actively experimenting with GenAI tools to support information seeking, preparation, and advocacy while simultaneously expressing substantial caution and concern about the reliability, safety, and appropriate boundaries of use. Our findings contrast sharply with clinician concerns that patients lack the capacity to use GenAI tools judiciously. Notwithstanding, the sample was skewed toward highly educated participants. Future research should prioritize more representative samples to better capture the range of patient and caregiver experiences with GenAI in rare disease care.

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KEYWORDS

generative AI; general practice; primary care; large language models; education; training; online survey questionnaire; qualitative research

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Introduction

Background

Rare diseases collectively affect an estimated 10% of the global population, corresponding to approximately 500 million people worldwide [1]. Although individually uncommon, rare diseases constitute a large and heterogeneous group, with approximately 7000 distinct conditions currently described [2]. However, the distribution of cases is highly skewed: roughly 350 rare diseases account for around 80% of diagnoses, while thousands of additional conditions are classified as ultrarare [2]. Definitions of rarity vary internationally, with different taxonomic thresholds, including fewer than 1 in 2000 individuals in the European Union, fewer than 200,000 people in the United States, and fewer than 50,000 people in Japan [1,3]. In addition, genetic rare diseases differ across geographic regions, making the challenge of clinician diagnoses even greater in many cases. Together, these figures illustrate that rare diseases are neither exceptional nor marginal in aggregate, yet they remain structurally underrecognized within health care systems.

People with rare diseases frequently experience prolonged and complex diagnostic pathways. Substantial delays between symptom onset and correct diagnosis are common. A study in Australia found that approximately 30% of individuals waited between 5 and 30 years for a definitive diagnosis [4]. In the United States, another study reported that around 50% of patients and caregivers attribute diagnostic delays to limited clinician awareness of their condition [5]. These challenges occur within a clinical environment characterized by the rapid expansion of biomedical knowledge. In addition to thousands of existing rare diseases, approximately 250 new rare diseases are described each year, accompanied by the continual refinement of gene-disease associations and molecular subtypes [2]. Under these conditions, it has been argued that maintaining up-to-date familiarity across rare disease domains is not realistically achievable for individual clinicians [6].

Even when an accurate diagnosis is achieved, therapeutic options are often limited. Fewer than 10% of rare diseases currently have an available disease-modifying treatment, and approximately 95% lack a US Food and Drug Administration–approved therapy [2]. Evidence generation is constrained by small patient populations, fragmented research efforts, and high rates of trial noncompletion or nonpublication [7,8]. As a result, patients and families commonly engage in sustained self-directed information seeking, including monitoring emerging research, identifying potential clinical trials, and synthesizing highly technical biomedical information to support care decisions [9].

In parallel, rare disease care has long challenged conventional assumptions about where medical expertise resides. In part, because of knowledge deficits among clinicians and diagnostic delays, patient-researchers argue that people living with chronic and rare conditions often develop deep, experience-based expertise and may actively contribute to research, innovation, and care improvement rather than merely receiving it [9,10]. However, health care systems frequently struggle to recognize patient and caregiver knowledge. Philosophers describe this problem as one of "epistemic injustice"—a "wrong done to someone in their capacity as a knower," in which patients' accounts tend to be granted less credibility than professional perspectives [11,12]. In clinical settings, this can manifest as "testimonial injustice" (patients not believed) or "hermeneutical injustice" (patients' experiences not fitting existing medical categories), phenomena closely related to what patients often describe as medical gaslighting [11,13]. Set against these concerns, the rapid public availability of large language model (LLM)–powered chatbots has burgeoned when it comes to health-related searches [14,15]. The use of consumer generative artificial intelligence (GenAI) tools, such as ChatGPT, Gemini, and DeepSeek, and a range of other models has created new possibilities for processing health information. Public access to consumer GenAI tools is a recent phenomenon. ChatGPT, the first widely available LLM chatbot, was released by OpenAI in November 2022. This prompted the rapid release of competing tools, including Google's Gemini (2023) and Anthropic's Claude (2023), among others. GenAI tools are, therefore, readily available but are susceptible to producing inaccurate or fabricated outputs and may encode or amplify existing biases, including those related to race, gender, and disability, with potential consequences for equity in health care [16]. In addition, the widespread availability of consumer-facing GenAI tools, coupled with their highly interactive conversational interfaces, raises concerns about privacy, data security, and the handling of sensitive personal health information [17,18].

To date, empirical research on GenAI in health care has primarily examined clinician adoption of both consumer and medical-grade applications for a range of clinical tasks, including documentation support, clinical reasoning, and treatment recommendations [19]. In contrast, far less is known about how patients and family members use GenAI tools [19-22]. This gap is particularly consequential for rare disease communities, where informational needs are persistent and clinical expertise is unevenly distributed [20]. However, one US survey found that households with rare diseases were twice as likely to use GenAI tools compared with other households [23].

Moreover, even before GenAI, people affected by rare diseases were established users of online resources—both to manage the chronic uncertainty of conditions with life-limiting potential, such as cancer predisposition syndromes and degenerative disorders [24-26], and to connect with peers and advocacy organizations for social support [27-30]. Consumer GenAI tools thus enter an information ecosystem in which these communities are already highly engaged online.

Notably, parents in rare disease communities have a documented history of being early adopters of novel and at times controversial technologies [31], suggesting that engagement with emerging GenAI tools is consistent with longstanding patterns of technology uptake in this population. This study takes epistemic injustice as its theoretical framework, asking how patient and caregiver GenAI use intersects with the credibility deficits and interpretive gaps common among patients with rare diseases, many of whom wait decades to be diagnosed [4,5].

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Objective

Against the theoretical framework of epistemic injustice and the research gaps related to patient use of GenAI, the objective of this mixed methods study was to examine the experiences and opinions of adult patients with rare diseases and parents or guardians of children with rare diseases regarding the use of GenAI tools. Specifically, we asked the following questions: *How do patients and family members in rare disease communities use GenAI tools? What purposes do these tools serve? What benefits and concerns are perceived? To what extent do participants report that AI-generated information influences health care decisions or interactions with clinicians?* We addressed these questions using a convenience sample recruited through rare disease networks and community organizations in the United States, combining quantitative survey data with open-text qualitative responses.

Methods

Study Design and Ethics

This study used an exploratory mixed methods cross-sectional survey design to examine the experiences and opinions of patients with rare diseases and parents or guardians of children with rare diseases regarding the use of GenAI tools in the context of rare disease care. A mixed methods approach was selected to enable descriptive quantification of patterns of use alongside qualitative exploration of concerns and contextual experiences. Given the limited existing patient-centered evidence in this area, an exploratory design was considered appropriate.

Ethical Considerations

The study received ethics approval and was deemed exempt from the human participants research requirements of 45 CFR 46 by the Boston Children's Hospital Institutional Review Board (approval ID IRB-P00051505). Electronic informed consent was obtained from all participants prior to survey initiation. Participation was voluntary, and respondents could withdraw at any time before submitting the survey. In addition, no compensation was provided for completing the survey.

Survey Development

An original survey instrument was developed by the study team to address the study objectives. Survey content was informed by prior literature on patient information-seeking behaviors, emerging scholarship on GenAI in health care, and consultation with rare disease community stakeholders [23,32,33]. We distinguish here between our patient partner (CEB), who contributed to survey co-design, and the survey respondents (N=115), who participated anonymously. Specifically, our patient partner (CEB) with lived experience of a rare disease contributed to item development, wording, and assessment of relevance. Draft versions of the survey were reviewed by contacts within participating rare disease networks to assess clarity, accessibility, and face validity, and the instrument was timed to ensure feasibility of completion within approximately 5 minutes.

The final survey comprised 19 primary items, including multiple-choice, Likert-type, and checkbox questions, together with 4 standalone open-text free-response questions (items 10a, 16a, 17a, and 18). Open-text questions did not accompany every closed-ended item; rather, item 10a invited respondents to specify other purposes of GenAI use, whereas items 16a, 17a, and 18 invited extended reflection on experiences of harm, factors influencing cautious or nonuse, and final reflections on rare disease care and the potential role of GenAI tools, respectively. The 3 additional reflection questions were as follows:

- 16a. Please briefly describe the harm or negative outcomes you experienced from generative AI advice or information.
- 17a. Please describe other factors that have influenced your decision not to use generative AI tools or to use them more cautiously.
- 18a. Is there anything else you would like to share about your experiences with rare disease care, or your perspectives on the potential role of generative AI in this area?

All questions were optional. Because the study did not aim to examine identity-based differences and sought to reduce the collection of potentially sensitive personal data, gender was not included among the demographic items. The full survey instrument and informed consent materials are provided in Multimedia Appendix 1. The study adhered to the CHERRIES (Checklist for Reporting Results of Internet E-Surveys) guidelines [34] (Checklist 1).

Participants and Recruitment

Participants were eligible if they were aged 18 years or older and self-identified as either a patient with a rare disease or a parent or guardian of a child with a rare disease. No additional exclusion criteria were applied. Recruitment used convenience sampling through the established rare disease networks and community organizations COMBINEDBrain [35] and EveryLife Foundation [36]. Based in the United States, both are umbrella networks of rare genetic disease communities with validated patient and family member contacts. Members of these organizations were invited by email to distribute an anonymous survey link through their email lists and closed-network newsletters, and with 2 reminder emails requested during the recruitment period. To intentionally reduce the risks of bot contamination, duplicate participation, and unverifiable eligibility, the survey team and contacts were requested not to share the survey link on any open social media platforms.

Data Collection

The survey was hosted on REDCap (Vanderbilt University), which is a secure web-based data capture platform. Data collection occurred between November 1, 2025, and January 10, 2026. No personally identifiable information, including names, email addresses, or IP addresses, was collected, and responses were anonymous. In addition to fixed-response items, as noted previously, participants could provide open-text responses describing other purposes for GenAI use, experiences of harm or negative outcomes, additional factors influencing cautious use or nonuse, and any further reflections on rare disease care or the potential role of GenAI tools. To reduce the risk of reidentification, particularly given the rarity of some conditions and the potential for triangulation with demographic

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information, we did not share row-level raw data. Instead, we provided the full aggregated and tabulated responses in Multimedia Appendix 2.

Data Analysis

Quantitative data were analyzed using descriptive statistics, including frequencies and percentages, to summarize respondent characteristics, prior use of GenAI, purposes of use, perceived influence on medical decisions, trustworthiness, concerns, and communication with health care professionals. Given the exploratory nature of the study and the limited expected sample size, no inferential statistical analyses were planned.

Qualitative thematic analysis was restricted to the 3 reflective free-response items (items 16a, 17a, and 18). Responses to item 10a (other purposes of use) consisted of brief specifications that supplemented the quantitative data on purposes of use and were not subjected to thematic analysis. Open-text responses were analyzed using a qualitative descriptive approach with inductive thematic coding, allowing patterns and concepts to be identified directly from the data rather than from pre-existing frameworks [37,38]. However, given the concise nature of many responses and the frequent use of brief phrases or sentence fragments, the data were not suited for in-depth interpretive thematic analysis [39]. Prior to analysis, responses indicating no substantive content (eg, “none,” “not applicable,” or “no comment”) were removed. The remaining responses were imported into an Excel file for data management and coding.

Two members of the research team (CB and CEB) independently reviewed the responses multiple times to develop familiarity with the dataset. CB is a philosopher, ethicist, and informaticist, and CEB is her twin sister, a government worker, who lives with a rare illness. An inductive coding strategy was then applied, whereby short descriptive codes were assigned to capture the central idea expressed in each response. Responses that conveyed more than one idea were assigned multiple codes. Coding was iterative, with ongoing comparison of codes to identify areas of convergence and divergence. CB and CEB met to discuss coding decisions, resolve only minor and trivial discrepancies, and refine the coding framework. Given the short and often fragmentary nature of the open-text responses, formal intercoder reliability statistics and thematic saturation were not appropriate because these techniques presuppose richer narrative data than this instrument was designed to elicit. Final codes were subsequently grouped into higher-order categories based on conceptual similarity, generating a structured summary of participant perspectives. Again, this approach is entirely consistent with the limitations of the dataset [39] and has been undertaken in previous analyses by the study team [40]. Owing to the online survey format and the limited responses, we were unable to establish thematic saturation.

Results

Sample Characteristics

A total of 115 respondents completed the survey. The majority of respondents (n=74, 64.3%) identified as parents or guardians of a child with a rare disease, whereas the remainder (n=41, 35.7%) identified as patients with a rare disease (Table 1). Participants were predominantly adults, with 61.7% (n=71) aged between 35 and 54 years. Educational attainment was high, with 75.7% (n=87) reporting a university or postgraduate degree. Most respondents resided in the United States (n=98, 85.2%). A breakdown of the results by respondent group is further presented in Multimedia Appendix 3.

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Table . Respondent characteristics (N=115).

Characteristic	Total, n (%)
Age (y)	
18-24	2 (1.7)
25-34	18 (15.7)
35-44	35 (30.4)
45-54	36 (31.3)
55-64	16 (13.9)
65 or older	8 (7)
Highest attained education	
Secondary school	1 (0.9)
College or vocational training	27 (23.5)
University degree	41 (35.7)
Postgraduate degree	46 (40)
Country	
United States	98 (85.2)
United Kingdom	4 (3.5)
Australia	3 (2.6)
Canada	2 (1.7)
Colombia	1 (0.9)
Hungary	1 (0.9)
Israel	1 (0.9)
Lithuania	1 (0.9)
Pakistan	1 (0.9)
Spain	1 (0.9)
Turkey	1 (0.9)
Missing	1 (0.9)

Diagnostic Journey

Respondents reported consulting a mean of 7.3 (SD 12.0) health care professionals prior to receiving a correct diagnosis (Table 2). Diagnostic timelines were frequently prolonged, with 43 of 115 (37.4%) reporting a wait of 3 years or longer, including 16 of 115 (13.9%) who reported delays exceeding 10 years. Among the participants, 22 of 115 (19.1%) reported receiving an official rare disease diagnosis since 2023.

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Table . Diagnoses and time to diagnosis (N=115).

Characteristic	Total, n (%)
Diagnosis[a]	
Tuberous sclerosis complex	31 (26.1)
Stiff person syndrome	13 (11.3)
Leber hereditary optic neuropathy	9 (7.8)
SYNGAP1-related disorder	6 (5.2)
Angelman syndrome	5 (4.3)
Okur-Chung syndrome	2 (1.7)
DYNC1H1-related disorder	2 (1.7)
Hao-Fountain syndrome	2 (1.7)
SLC6A1-related disorder	2 (1.7)
Epilepsy (Grand Mal)	2 (1.7)
Other single-entry diagnoses	41 (35.7)
Missing	1 (0.9)
Time to diagnosis (y)	
Less than a year	45 (39.1)
1-2	26 (22.6)
3-5	15 (13)
6-10	12 (10.4)
More than 10 years	16 (13.9)
Missing	1 (0.9)

[a]Multiple diagnoses could be reported; the total count will exceed the number of participants. All reported diagnoses can be found in Multimedia Appendix 2.

Use of GenAI Tools

Slightly more than half of the respondents (63/115, 54.8%) reported some prior use of GenAI tools for rare disease–related purposes, whereas 52 of 115 (45.2%) respondents reported never using such tools (Table 3). Among users, the most commonly reported purposes were exploring new treatments or clinical trials (53/63, 84.1%) and interpreting medical tests or clinical notes (37/63, 58.7%). One-third of respondents (37/115, 32.2%) reported additional uses, including summarizing scientific publications and supporting insurance appeals or advocacy.

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Table . Use of generative artificial intelligence (GenAI) tools (N=115).

Characteristic	Total, n (%)
Prior use of GenAI tools	
Never	52 (45.2)
Occasionally	21 (18.3)
Once or twice	17 (14.8)
Regularly	25 (21.7)
Reasons for using GenAI tools[a]	
Exploring new treatments or clinical trials	53 (46.1)
Interpreting medical tests or notes	37 (32.2)
Finding specialists or care centers	29 (25.2)
Suggesting possible diagnoses	28 (24.3)
Emotional or social support or advice	18 (15.7)
Preparing questions for health care visits	17 (14.8)
Other	37 (32.2)

[a]Multiple reasons could be reported; the total count will exceed the number of participants.

Influence of GenAI on Medical Decisions and Diagnosis

As shown in Table 4, most respondents reported minimal or no influence of GenAI tools on medical decisions (77/115, 67.0%). However, nearly one-third of respondents (37/115, 32.2%) reported that GenAI had influenced their medical decisions to some degree, including 10 (8.7%) respondents who reported a strong influence. Direct contributions of GenAI to formal diagnoses were uncommon (11/115, 9.6% reporting any contribution), and most respondents reported that GenAI had not shortened their diagnostic journey (93/115, 80.9%).

Table . Influence of generative artificial intelligence tools on medical decisions and diagnoses (N=115).

Characteristic	Total, n (%)
Influence on medical decisions	
Minimal or no influence	77 (67.0)
Somewhat	27 (23.5)
Strongly	10 (8.7)
Missing	1 (0.9)
Contribution to formal diagnosis	
Did not help	90 (78.3)
Somewhat helpful	7 (6.1)
Critical contribution	4 (3.5)
Unsure	13 (11.3)
Missing	1 (0.9)
Shortened diagnostic journey	
Not noticeably	93 (80.9)
Moderately	8 (7.0)
Significantly	3 (2.6)
Unsure	9 (7.8)
Missing	2 (1.7)

Trust, Concerns, and Communication With Clinicians

Perceived trustworthiness of AI-generated health information was mixed: of 115 respondents, 45 (39.1%) respondents rated it as less trustworthy than traditional sources, while 33 (28.7%) rated it as equally trustworthy (Table 5). Concern about accuracy was widespread, with 71 (61.7%) respondents reporting moderate, very high, or extreme concern. Notably, most

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respondents (n=90, 78.3%) had not discussed AI-generated information with a health care professional.

Table . Trust, concerns, and communication regarding generative AI tools (N=115).

Characteristic	Total, n (%)
Perceived trustworthiness of AI-generated health information compared to traditional sources	
Less trustworthy	45 (39.1)
Equally trustworthy	33 (28.7)
More trustworthy	7 (6.1)
Unsure	30 (26.1)
Concerns with accuracy of AI-generated medical information	
Extremely concerned	18 (15.7)
Very concerned	22 (19.1)
Moderately concerned	31 (27.0)
Slightly concerned	31 (27.0)
Not concerned	12 (10.4)
Missing	1 (0.9)
Discussions of AI-generated information with health care provider	
Not discussed	90 (78.3)
Health care provider was skeptical	9 (7.8)
Health care provider was supportive	14 (12.2)
Missing	1 (0.9)

Experience of Harm

Few respondents reported experiencing harm or negative outcomes related to GenAI use (7/115, 6.1%; Table 6). When considering factors that dissuade respondents from using GenAI tools, most cited uncertainty about accuracy (75/115, 65.2%), followed by privacy concerns (36/115, 31.3%) and lack of trust (35/115, 30.4%).

Table . Experience of harm or negative outcomes related to generative artificial intelligence (GenAI) tools (N=115).

Characteristic	Total, n (%)
Experience of harm or negative outcomes from GenAI advice or information	
Yes	7 (6.1)
No	105 (91.3)
Missing	3 (2.6)
Factors that influence the decision not to use GenAI tools or to use them more cautiously	
Uncertainty about accuracy	75 (65.2)
Privacy concerns	36 (31.3)
Lack of trust	35 (30.4)
Technological comfort or skill	11 (9.6)
Lack of awareness or access	10 (8.7)
None, use without hesitation	21 (18.3)
Other	7 (6.1)

Qualitative Component

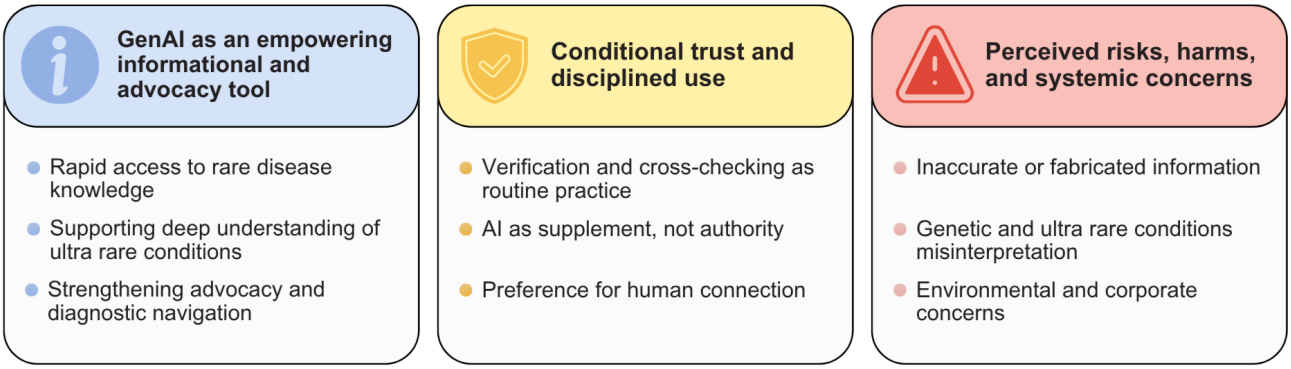
Overview of Qualitative Findings

A total of 66 respondents provided substantive open-text comments across 3 survey items addressing GenAI tools in relation to experiences of harm (item 16a), additional factors influencing cautious or nonuse of GenAI tools (item 17a), and final reflections on rare disease care and the potential role of GenAI tools (item 18). As a result of using an inductive thematic coding, 3 overarching themes and associated subthemes were identified (Figure 1), which are presented below with illustrative quotations. Parenthetical numbers indicate individual participant identifiers; also indicated are age group and whether respondents

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reported being a patient with a rare disease or a parent or guardian of a child with a rare disease.

Figure 1. Themes and subthemes. GenAI: generative artificial intelligence.



Theme 1: GenAI as an Empowering Informational and Advocacy Tool

Overview

Participants frequently described GenAI as a practical resource for navigating complex rare disease information, supporting learning, and strengthening medical self-advocacy or caregiver-advocacy. Crucially, these accounts position GenAI as a response to a structural deficit—scarce expertise and limited clinical time—rather than as a substitute for professional judgment.

Subtheme 1.1: Rapid Access to Rare Disease Knowledge

A recurring emphasis in participants' accounts was the speed and accessibility of information that GenAI provided—particularly in contexts where clinical time is limited and rare disease expertise is scarce:

> *AI helps to find extra information really fast.* [#41, 45-54 years, Parent/Guardian]
>
> *It's been helpful for asking a million questions the doctors don't have time for.* [#92, 35-44 years, Parent/Guardian]

The second account is especially revealing: it locates GenAI's value not in replacing the clinician but in absorbing the questions that the clinical encounter cannot accommodate. Against our finding that respondents consulted a mean of 7.3 (SD 12.0) clinicians before diagnosis, this points to GenAI filling the interstitial spaces of fragmented care pathways.

Several respondents underscored the value of rapid access in contrast with their own diagnostic histories, expressing regret that these tools had not been available to them earlier:

> *My son was diagnosed before AI in 2018. But I would have used AI if it were available back then to try and find the answers.* [#4, 35-44 years, Parent/Guardian]
>
> *At the time of my daughter's diagnosis, this was not available. But I am also a rare disease patient,...and do see the value when looking for quick information.* [#12, 35-44 years, Parent/Guardian]

Subtheme 1.2: Supporting a Deep Understanding of Ultrarare Conditions

Beyond rapid retrieval, several respondents described GenAI as enabling qualitatively deeper engagement with genetic and mechanistic detail—knowledge ordinarily gated behind specialist channels:

> *Generative AI has taught me about the gene, the related pathway, other genes/disorders associated with the pathway and has helped me identify a gap in care...* [#7, 45-54 years, Parent/Guardian]
>
> *Generative AI has a great potential to democratize scientific knowledge to parents and caregivers (NotebookLM for example does a great job of breaking down dense research papers)...* [#37, 35-44 years, Parent/Guardian]

These accounts suggest that GenAI functioned less as a search engine and more as a translation layer between specialist literature and lay expertise. The reference to identifying "a gap in care" is notable: the participant is not merely consuming information but is using it to audit the adequacy of care, an act of epistemic agency that the framework of epistemic injustice predicts patients are often denied the standing to perform.

Subtheme 1.3: Strengthening Medical Self-Advocacy and Caregiver-Advocacy and Diagnostic Navigation

A few respondents reported that GenAI had directly supported diagnostic reasoning or advocacy:

> *I use AI almost every day and in virtually every facet of my life, including for rare disease care management, research, and advocacy activities.* [#99, 35-44 years, Parent/Guardian]
>
> *I entered all my past medical labs and notes from docs. ChatGPT was able to pinpoint my disease and was correct when I finally found a specialist that knew my disease.* [#63, 45-54 years, Patient]
>
> *AI wasn't around when we were seeking a diagnosis for my son…I would've been able to push harder against the doctors who were dismissing his symptoms.* [#40, 35-44 years, Parent/Guardian]

The final quotation is the clearest articulation of GenAI as epistemic scaffolding—resources that can help patients to articulate and validate observations that might otherwise be

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dismissed: the participant frames it not as a source of answers but as a source of *standing*—the confidence and evidentiary footing to contest clinical dismissal. This directly engages with the testimonial dimension of epistemic injustice, where patients' accounts are given diminished credibility by clinicians [12,41,42]. Here, GenAI is imagined as a counterweight to that asymmetry, although the same accounts also caution that such confidence must be calibrated against the reliability concerns documented in Theme 3.

Theme 2: Conditional Trust and Disciplined Use

Overview

If Theme 1 describes the reach of GenAI use, Theme 2 describes its limits, and these limits were self-imposed and explicit. Participants did not describe trust as a binary but as a conditional, effortful stance that had to be earned through verification and was bounded by clear rules about where the GenAI tool's authority ended.

Subtheme 2.1: Verification and Cross-Checking as Routine Practice

Respondents described verification not as an occasional safeguard but as standard operating procedure:

> *Important to include sources for AI responses and then check those sources. I also use two or more AI tools as cross reference and frequently ask for clarifications or restatements.* [#38, 65 years or older, Parent/Guardian]

> *I always ask for links or references to verify what it is telling me is accurate.* [#3, 35-44 years, Parent/Guardian]

> *Ask for sources and cross reference and challenge.* [#18, 65 years or older, Parent/Guardian]

These are not the practices of uncritical users. The recurrence of triangulation, source-checking, and adversarial questioning ("challenge") indicates a working approach among participants whereby GenAI output is treated as a hypothesis to be tested rather than a conclusion to be accepted. This directly counters deficit framings that assume lay users absorb AI output passively. It is notable, however, that the verification described here may operate within a closed informational loop: participants reported triangulating across multiple AI systems and sought online sources and references, rather than cross-checking GenAI output against real-world sources such as clinicians. Whether they raised informational queries in a more clandestine way with clinicians, however, is a possibility.

Subtheme 2.2: AI as Supplement, Not Authority

Participants drew a firm line between informational support and clinical authority:

> *I would not trust my child's healthcare to AI and would not trust a provider who used AI as anything more than a source of an idea to consider.* [#17, 45-54 years, Parent/Guardian]

> *I will never trust generative AI as a source when so many wonderful research summaries are available that are written by human scientists.* [#16, 55-64 years, Parent/Guardian]

The first quotation is striking for extending the boundary to clinicians themselves—the participant polices not only their own reliance on GenAI but their providers' as well. This suggests that, for at least some participants, the appropriate role of GenAI is a settled normative question, not an open one.

Subtheme 2.3: Preference for Human Connection

Human interaction remained central to several participants' conceptions of care:

> *I feel the human interaction is the best way to receive care. Human touch is key to connection. It's genuine, not artificial.* [#88, 45-54 years, Patient]

Here, the limit on GenAI is about what it cannot offer. This participant values human care for its own sake. This suggests that, for some participants, GenAI use and the clinical relationship need not be in competition.

Theme 3: Perceived Risks, Harms, and Systemic Concerns

Overview

The caution evident in Theme 2 was grounded in concrete experience, as further elaborated in Theme 3. Participants' concerns ranged from specific encounters with errors to structural critiques of the technology's social costs.

Subtheme 3.1: Inaccurate or Fabricated Information

Several respondents reported direct encounters with errors, including hallucinated references and incorrect clinical content:

> *It has generated nonexistent references mixing authors and titles and journals, etc.* [#36, 45-54 years, Parent/Guardian]

> *Provided incorrect information about therapy option.* [#5, 35-44 years, Parent/Guardian]

> *AI seems to be giving me the information that is popular, but not accurate.* [#72, 55-64 years, Patient]

The final observation—that GenAI may prioritize prevalence over precision—is particularly pertinent in rare disease contexts, where conditions are, by definition, underrepresented in training data.

Subtheme 3.2: Genetic and Ultrarare Misinterpretations

A subset of participants with genetic expertise described technically sophisticated errors that nonspecialists could not easily detect:

> *It has given incorrect information for example the number of exons in the MED13L gene or it has read a genetic report that was a frameshift and deemed it a nonsense.* [#10, 35-44 years, Parent/Guardian]

> *When using it to research ultrarare diseases and specifically genetic variants, I have come across several inaccuracies.* [#58, 35-44 years, Parent/Guardian]

This subtheme reveals a basic problem: GenAI may be least reliable for exactly the rare conditions where patients most need

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accurate information. Moreover, the errors are hard to detect. These participants identified them only because they had unusual technical expertise; most users might not have done so. This is what makes the verification practices in Theme 2 necessary, and it tempers the more optimistic picture in Theme 1.

Subtheme 3.3: Environmental and Corporate Concerns

A minority of respondents raised broader ethical objections:

> *The environmental impact of the data centers. Making billionaires even richer.* [#63, 45-54 years, Patient]
>
> *They are destroying the environment and contributing to environmental racism.* [#113, 35-44 years, Patient]

Although raised by few respondents, these accounts indicate that GenAI was, for some, evaluated against a wider ethical horizon than individual accuracy. That such critiques surface in a rare disease sample is itself notable: communities already attuned to systemic inequity in health care appear to extend that scrutiny to the political economy of the tools they nonetheless use—a further marker of the critical, nonnaive engagement that characterizes the dataset.

Discussion

Principal Findings

Currently, there is very little research on patient use of GenAI tools, particularly among people affected by rare diseases, a historically marginalized population that must often navigate care amid limited clinician expertise. In this convenience sample, mixed methods survey (N=115), just over half of the respondents (n=63, 54.8%) reported using GenAI for rare disease-related tasks, most commonly exploring treatments or trials (n=53, 46.1%), interpreting medical tests or notes (n=37, 32.2%), identifying specialists (n=29, 25.2%), and considering possible diagnoses (n=28, 24.3%). Qualitative responses indicated these activities functioned as extensions of caregiving and medical self-advocacy—helping participants understand complex genetic information and prepare questions—rather than as attempts to replace clinicians.

Participants used GenAI cautiously and strategically. Most reported minimal or no influence on medical decisions (n=77, 67.0%), formal diagnostic contributions were uncommon (n=11, 9.6%), and concern about accuracy was widespread (n=71, 61.8%). Few had discussed AI outputs with clinicians (n=90, 78.3%), and harms were rarely reported (n=7, 6.1%). Against a backdrop of prolonged diagnostic effort (clinicians consulted: mean 7.3, SD 12.0; n=43, 37.4% waiting ≥3 y), GenAI primarily served as a cognitive support for navigating fragmented care and potentially constrained access to expertise—enabling preparation, verification, and self-advocacy in medicine while maintaining reliance on human clinical oversight.

A large probability-based US survey conducted earlier in 2025 found that people in households with members having a rare disease were disproportionately early adopters of digital tools, with 38% reporting the use of AI tools to learn about a condition or treatment options [23]. However, that study characterized adoption at the population level and did not examine how patients use AI, how they judge its reliability, or how it may shape clinical decision-making. This study complements and extends those findings by showing that engagement is not merely uptake but invokes reflective and structured practice: participants described verification strategies, bounded trust, and selective incorporation of GenAI into advocacy and preparation rather than replacement of clinicians.

Conversely, compared with our convenience sample, the probability sampling of the earlier national survey provides stronger population representativeness. However, by integrating quantitative patterns with qualitative accounts, this study demonstrates that AI use in rare disease contexts may function subtly in patient adoption, rather than merely as simple technological enthusiasm. Together, these studies suggest that rare disease communities may be early adopters and careful interpreters of GenAI.

This study contrasts with the narratives presented in other highly cited studies. For example, recent experimental work using standardized vignettes suggests that access to LLM tools does not automatically improve lay diagnostic or triage accuracy [43]. However, these findings should be treated with caution and should not be interpreted as evidence that patients "believe misinformation." Rather, such findings may reflect limitations of one-shot vignette paradigms and the difficulty of translating conversational suggestions into a single committed decision, especially when users are not living with symptoms over time. Our study survey adds important nuance: participants reported more cautious and critical GenAI use than is often assumed in clinical and academic commentary. These results underscore the importance of avoiding deficit framings that inadvertently discount patient expertise [42,44].

The study findings should also be read in light of the sample composition. Most respondents were already diagnosed, and many—particularly parents and guardians—were reflecting retrospectively or on a child's diagnostic pathway, often during a period when GenAI tools were not yet available. The finding that GenAI was not perceived to have shortened the diagnostic journey may, therefore, reflect the timing and structure of the participants' experiences rather than a limitation of GenAI's potential to do so—an open question that prospective studies of undiagnosed patients are better placed to address. Future studies designed to capture time since diagnosis directly, and powered for subgroup analysis, could valuably examine whether GenAI use is prompted by diagnoses. Similarly, future work should be powered to explore patient or caregiver age, gender, and education level to explore demographic differences in the adoption of GenAI tools.

The study findings also align with the literature on epistemic injustice in health care [11,12]. Participants used GenAI not to replace clinicians but to translate genetic reports, prepare arguments, and support advocacy during prolonged diagnostic pathways. In this sense, GenAI tools appeared to function as a form of informational support: resources that helped patients to articulate and validate observations that might otherwise be dismissed. However, further qualitative research is needed to substantiate this claim in depth (eg, interviews).

Prior work has emphasized listening to patient concerns as a prerequisite for meaningful clinical recommendations and

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highlighted how "spetspatients" (expert patients) can reshape health care through knowledge production [9,10]. The study results suggest GenAI may increasingly mediate this process, potentially reducing but also revealing epistemic asymmetries in rare disease encounters. Yet clinicians in rare disease care also operate under genuine, often irreducible, uncertainty [6,45]. Read against this, patient GenAI use can be understood not only as a corrective to epistemic injustice but as a parallel response to a shared epistemic predicament—reframing it as a resource for collaborative management of uncertainty rather than a challenge to clinical authority [46].

It is important to note that the expert role rare disease patients and families take on is often less a chosen empowerment than a burden of necessity, undertaken in the absence of accessible clinical expertise or established evidence. Combined with the epistemic injustice they may encounter if their resulting knowledge is dismissed [12,42,47], rare disease patients and caregivers are placed in a structurally difficult position: they are required to acquire and interpret specialist information, yet may be denied standing as credible knowers when they do so [13,42]. Patient and caregiver use of GenAI should, therefore, be read against this dual pressure, as a tool taken up to manage a burden that the health care system has, in many cases, failed to relieve.

Our findings also align with an established literature documenting the expertise that patients with rare diseases and caregivers develop through both offline networks (such as advocacy organizations and patient registries) and online communities, where peers exchange clinical experiences, navigate uncertainty, and contribute to research agendas [27,48]. Our data extend this picture by showing that GenAI is now being layered onto this existing expertise infrastructure. The conflict this surfaces is not new but is sharpened by GenAI's reach—patients and caregivers continue to perform substantial epistemic labor that is often unrecognized by health systems, even as the tools available to them become more powerful. This underscores the need for explicit recognition of patient and caregiver expertise in the design and governance of rare disease care, including GenAI's role within it [20].

Of particular note, the participants in our exploratory survey were cautious about the present use of GenAI, with few reporting harms, yet many believed that these tools could have helped them during earlier stages of rare disease diagnosis. These findings are not contradictory but reflect timing. As noted, GenAI became publicly available only in late 2022, whereas most respondents (93/115, 80.9%) were diagnosed earlier and could not have used it during their diagnostic journey. The retrospective belief that GenAI might have helped therefore reflects unmet need rather than an evaluation of its actual contribution. Given the lengthy diagnostic pathways reported in this study, and for rare disease patients, these attitudes may reflect an adaptive response to unmet clinical need. The nuanced reflections on uptake also challenge dominant narratives that frame patient use of GenAI mainly as a safety concern.

Strengths and Limitations

This study has several limitations. First, we used a nonprobability convenience sample, which limits generalizability. Participants were recruited through web-based rare disease networks and community organizations, and it is likely that respondents who chose to participate were more digitally literate and more interested in digital tools or GenAI than nonrespondents. Responses were likely biased in favor of highly engaged patients and caregivers who had affiliated with these rare disease networks for information and peer support. Notably, network membership in this context reflects community engagement rather than an advocacy role, and the sample should not be read as composed of designated patient advocates. This is, however, the population in which patterns of early GenAI use are most visible and most relevant for informing emerging patient-facing guidance. Recent national data indicate that rare disease households are disproportionately early adopters of these tools [23], suggesting that our sample represents the leading edge of community uptake rather than an isolated subgroup.

Notwithstanding, and second, our sample was highly educated and based mostly in the United States, and the sample size was modest and not powered to examine associations between respondents' demographic characteristics and outcomes. In addition, it was not possible to establish thematic saturation due to the limitations of the dataset. Third, to minimize respondent burden and limit the collection of potentially sensitive personal data, the survey included a restricted set of demographic variables and did not collect information on gender, precluding analysis of potential gender-based differences. Fourth, although the qualitative data provided important contextual insights, open-text responses were typically brief, limiting the depth of interpretation and precluding more nuanced qualitative analyses. For example, items such as the use of GenAI for emotional or social support could have been interpreted either as using chatbots for therapy bots, or as seeking out information about services to support patients and caregivers. Furthermore, more targeted interviews or focus groups could disambiguate differing interpretations.

These limitations should be considered alongside important strengths. To our knowledge, this study represents one of the first in-depth patient-centered and family-centered surveys to examine experiences and opinions regarding GenAI use in health care, which focuses specifically on rare disease communities. In addition, when it came to reported rare diseases, our sample was highly heterogeneous. Recruitment was conducted exclusively through validated patient and family networks, rather than open social media platforms, reducing risks of contamination, ineligible participation, and automated or duplicate responses. That said, we acknowledge that 87% of respondents did not state where they learned about the survey; this was an optional question, however, and it may have been perceived as redundant by our participants. The mixed methods design enabled the integration of quantitative patterns with qualitative perspectives, providing a more comprehensive picture of how GenAI tools are currently being used and perceived outside clinical settings.

Taken together, these findings provide early, exploratory evidence of a growing but largely unexamined layer of patient-facing GenAI use. More robust research is needed, including studies using larger and more representative samples,

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longitudinal designs, and in-depth qualitative methods, such as interviews or focus groups, to better understand patient experiences, potential benefits, risks, and implications for clinical practice and policy. Furthermore, translation of these early findings to wider populations will require complementary work, including plain-language patient guidance, peer-led informational resources distributed through rare disease networks, and clinician communication training, alongside larger and more representative survey samples.

Conclusions

This study reveals a largely invisible layer of patient-facing GenAI use occurring outside clinical oversight. Patients with rare diseases and their caregivers were not replacing clinicians but were using AI to interpret information, prepare questions, and support advocacy developed through prolonged diagnostic uncertainty.

Although the findings are limited by a modest, highly educated convenience sample and therefore not broadly generalizable, the study provides timely and original insight into how a historically marginalized patient population is engaging with emerging technologies. Rather than overreliance, participants demonstrated cautious and critical use while recognizing AI's potential to reduce diagnostic delays and informational scarcity. GenAI, therefore, does not merely introduce new risks into rare disease care; it also exposes longstanding epistemic gaps within it and suggests that future governance and clinical practice should be organized around partnership with informed patients rather than re-enacting justifications for paternalistic protectionism.

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Data Availability

The raw data supporting the findings of this study are available as Multimedia Appendix 2.

Authors' Contributions

Conceptualization: CB, JJ, KDM
Data curation: JJ, KDM
Formal analysis: CB, CEB, AK, CGS
Funding acquisition: CB, KDM
Investigation: CB, JJ, KDM
Methodology: CB, KDM
Project administration: CB, JJ, KDM
Supervision: CB, KDM
Writing – original draft: CB
Writing – review & editing: KDM, CEB, AK, CGS

Conflicts of Interest

None declared.

Multimedia Appendix 1
Informed consent and survey.
[PDF File, 51 KB - jopm_v18i1e93720_app1.pdf]

Multimedia Appendix 2
Anonymized data.
[DOCX File, 1846 KB - jopm_v18i1e93720_app2.docx]

Multimedia Appendix 3
Results by respondent group.

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[DOCX File, 31 KB - jopm_v18i1e93720_app3.docx]

Checklist 1
CHERRIES guidelines.
[DOCX File, 19 KB - jopm_v18i1e93720_app4.docx]

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Abbreviations

CHERRIES: Checklist for Reporting Results of Internet E-Surveys
GenAI: generative artificial intelligence
LLM: large language model

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