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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.

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:

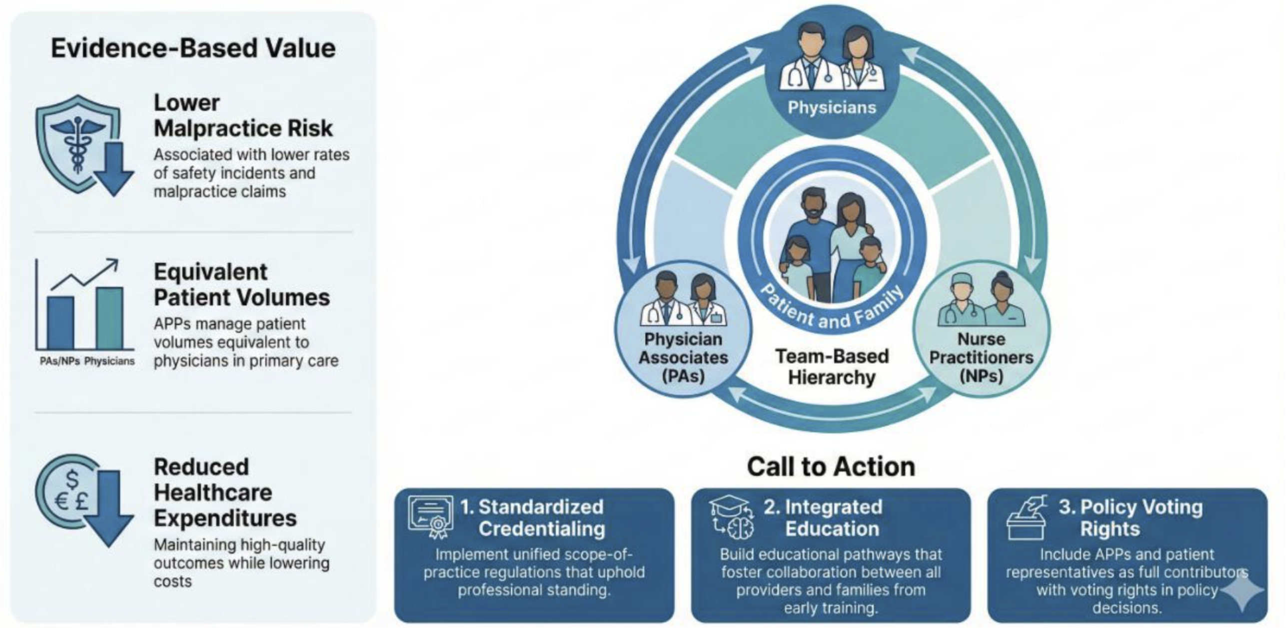
- Safety and malpractice—advanced practice providers are associated with lower rates of safety incidents and malpractice claims compared to traditional models, suggesting a high standard of patient safety and adherence to scope of practice [4].
- Cost and efficiency—meta-analyses of randomized controlled 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 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

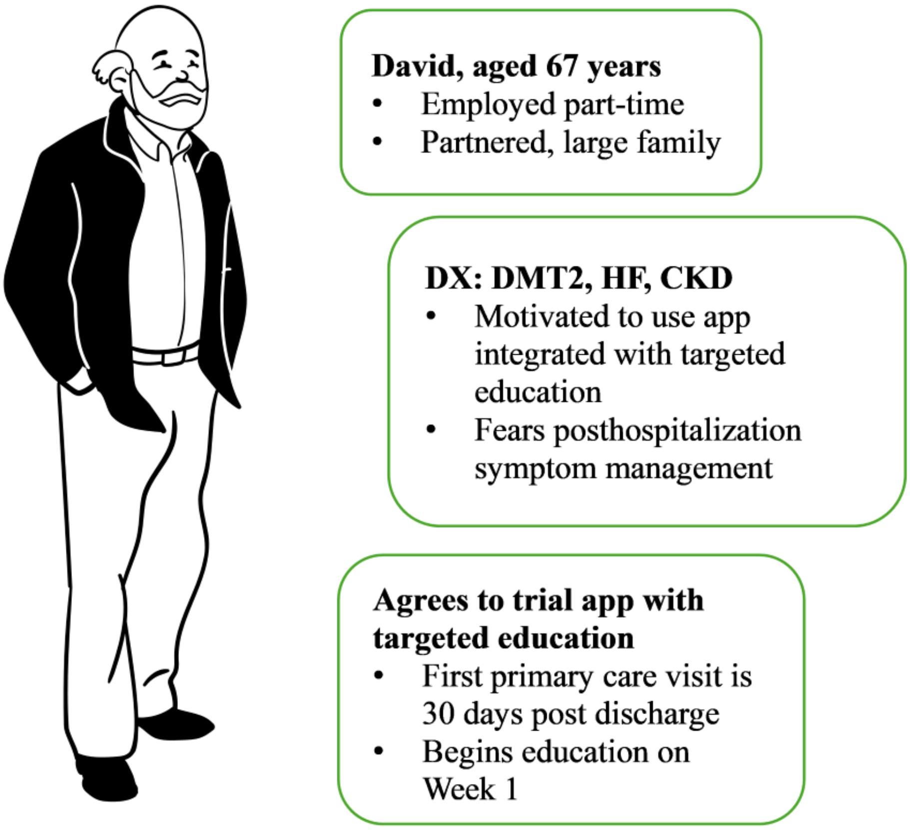
Care transitions from hospital discharge to follow-up with primary care are critical moments for patients that involve the transfer of vital information [1]. This process requires close collaboration among hospital care teams, primary care providers, specialists, patients, and family or caregivers [2,3] 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

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.



David, aged 67 years
- Employed part-time
- Partnered, large family

DX: DMT2, HF, CKD
- Motivated to use app integrated with targeted education
- Fears posthospitalization symptom management

Agrees to trial app with targeted education
- First primary care visit is 30 days post discharge
- Begins education on Week 1

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.

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

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 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.

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.

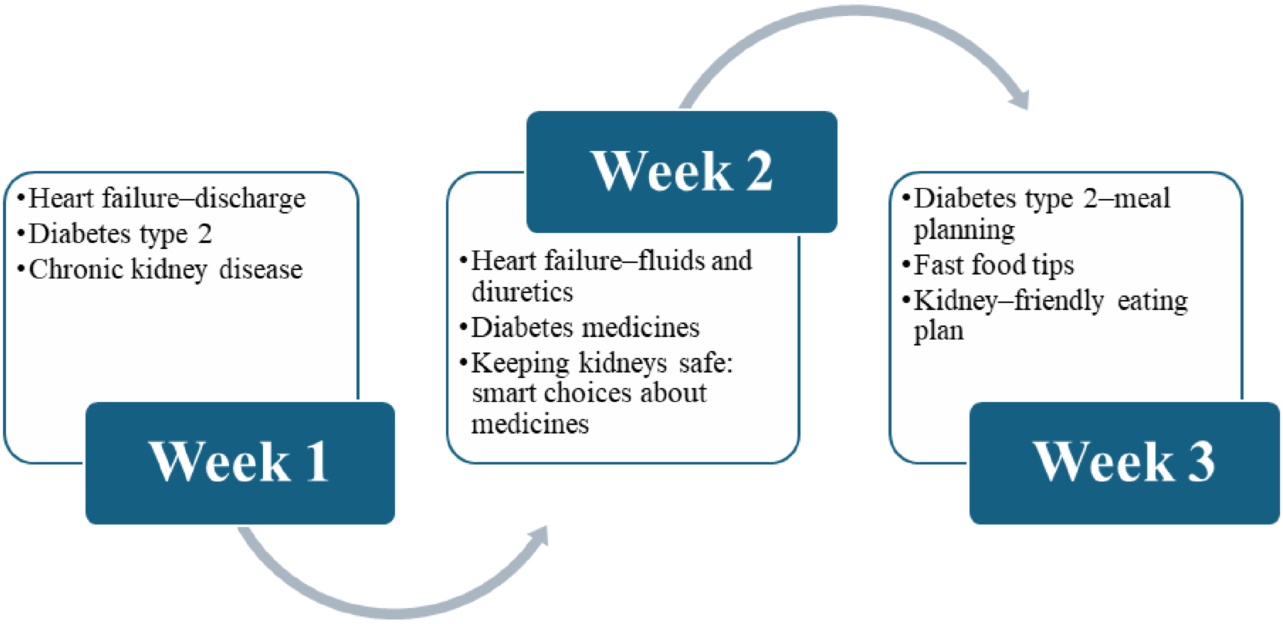
[b] HF: heart failure.

[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 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 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.

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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

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

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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

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 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.

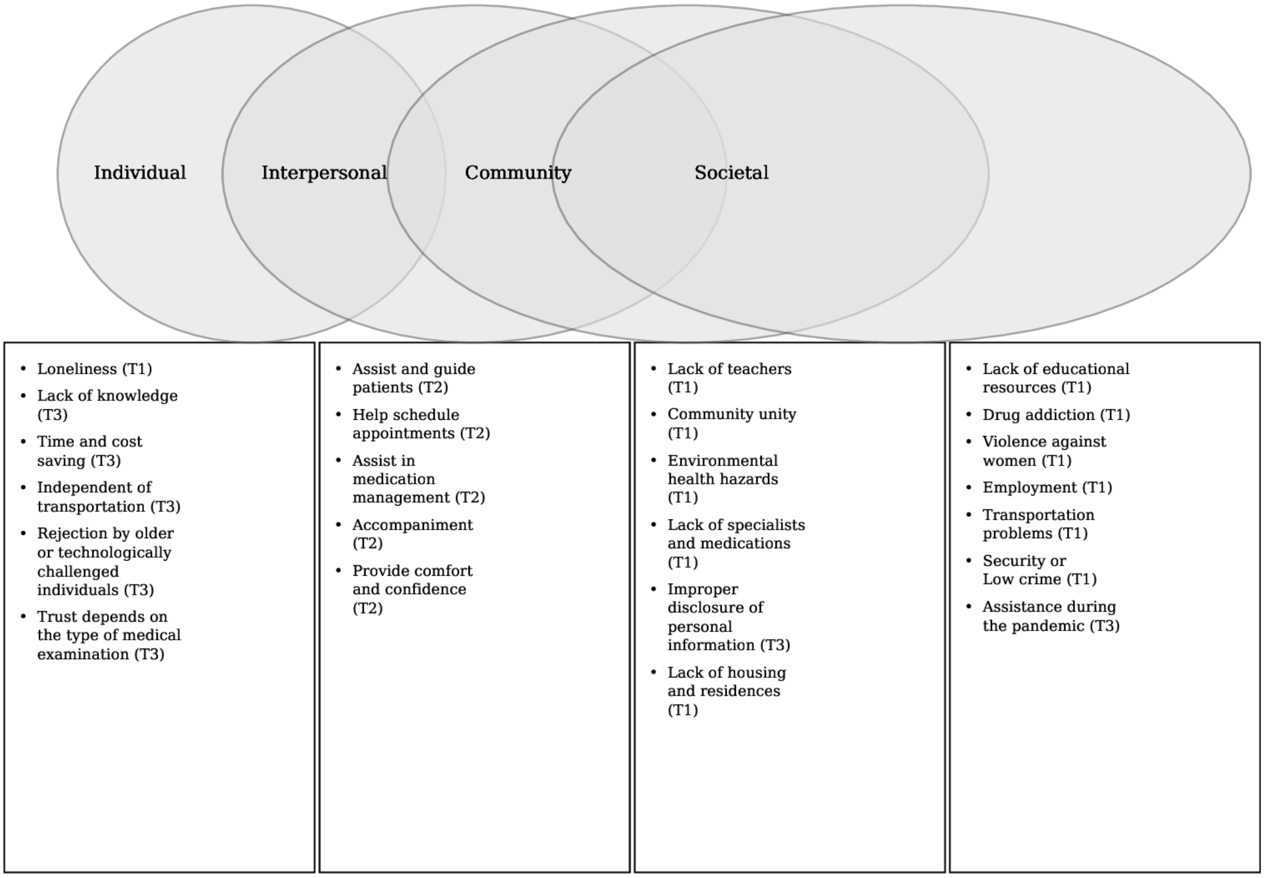
Interview data were examined iteratively using thematic analysis for patterns and themes, investigating community attitudes and perceptions toward THS systems and the CHW's model [20]. To ensure linguistic and cultural validity, themes and supportive quotes were translated and back-translated from Spanish 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.

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.

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.

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, 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

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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]

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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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 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.

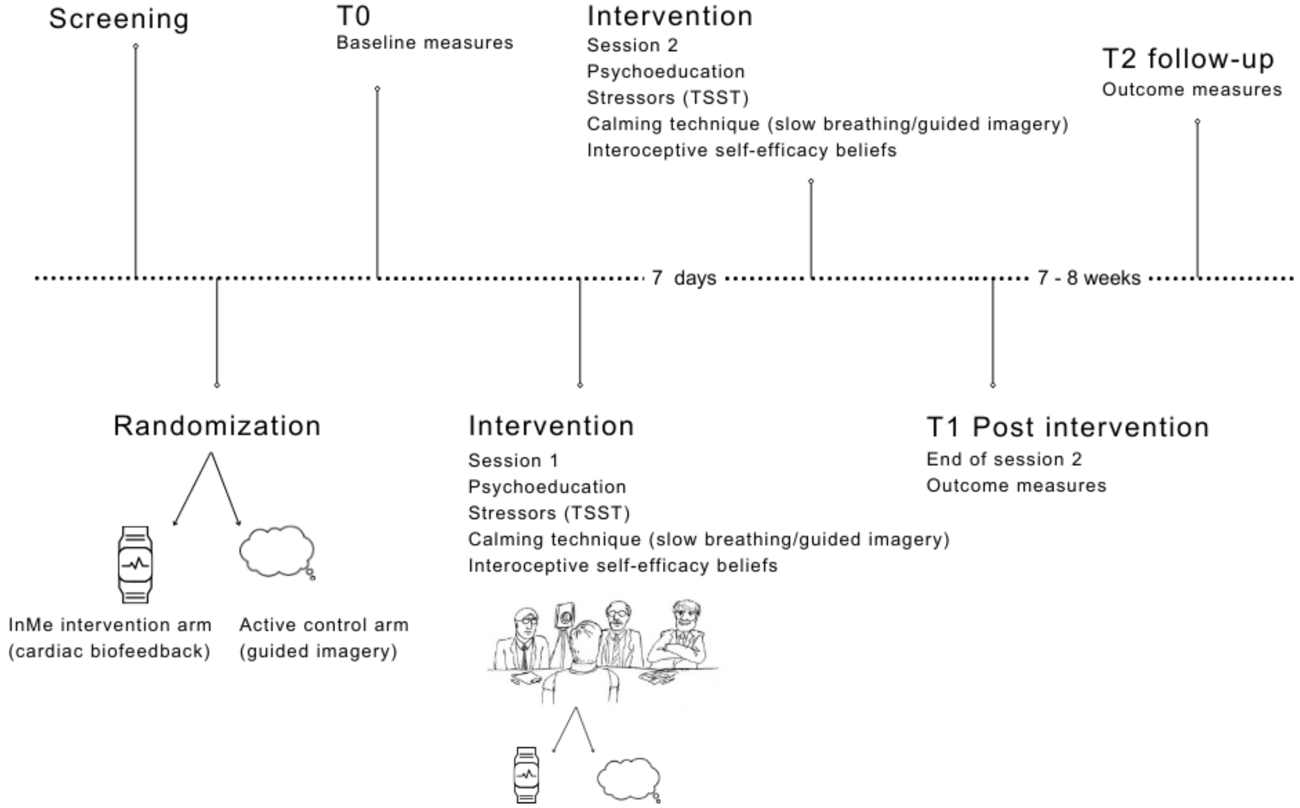
Intervention Background and Scope

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.

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).

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.

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

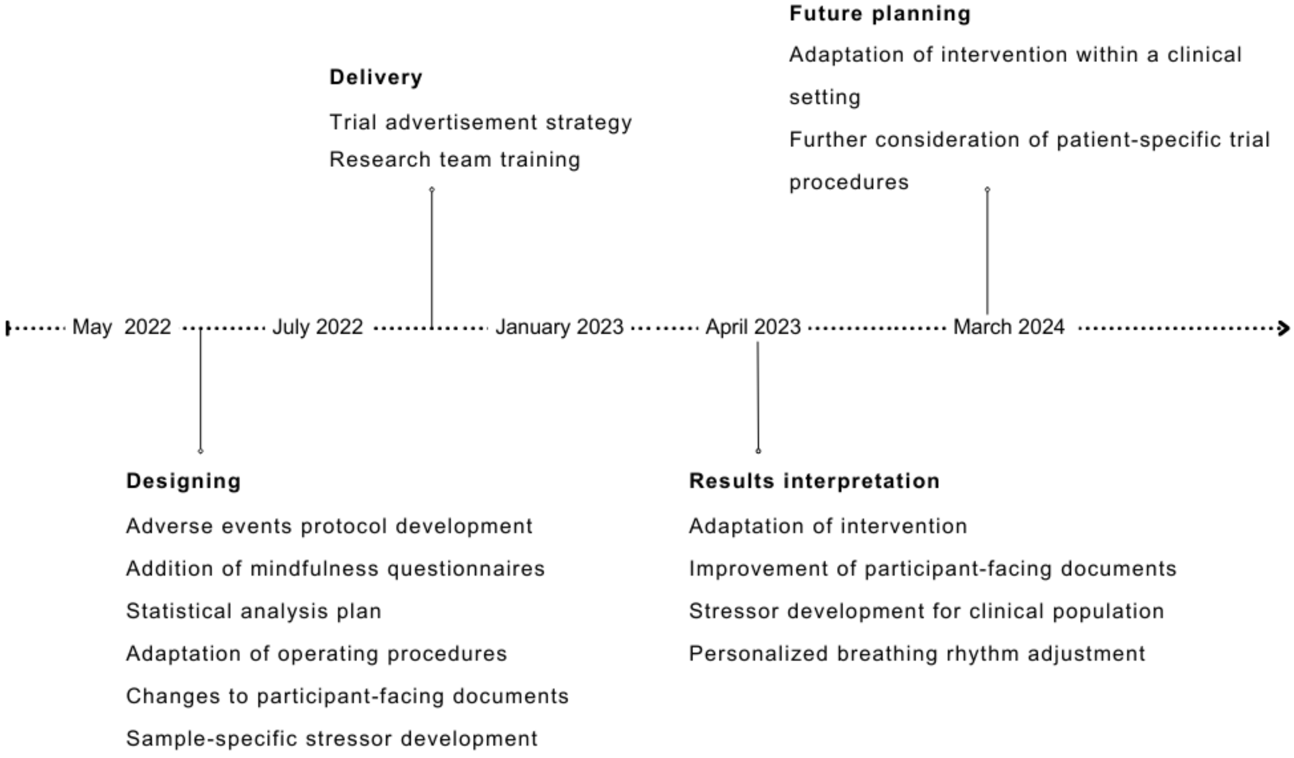
The lived experience advisory panel members (also referred to as "experts by experience") were selected based on their self-declared experience with somatic symptom disorders or EDs. Specifically, the lived experience advisory panel (n=5) was comprised of members with functional neurological disorder (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.

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 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.

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				

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.

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

InMe study

£37 reimbursement

Interoceptive insight & metacognitive efficacy beliefs

- Aged between 18–30 years
- No history of neurological or severe psychiatric disorder
- Not currently pregnant
- Available for 3 in person assessments

SCAN THIS →

1-19 Torrington Place, UCL, WC1E 7HB

STAYING IN LONDON OVER THE SUMMER?
LOOKING TO EARN EXTRA MONEY?

£ 37 PAY

We are looking for participants:

- Between 18 – 30 years
- No history of neurological or severe psychiatric disorder

If eligible you will be invited for 3 in person visits lasting each 1 - 1.5 hrs (computerised tasks and questionnaires)

UCL 1-19 Torrington Pl, London WC1E 7HB

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 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 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.

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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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 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.

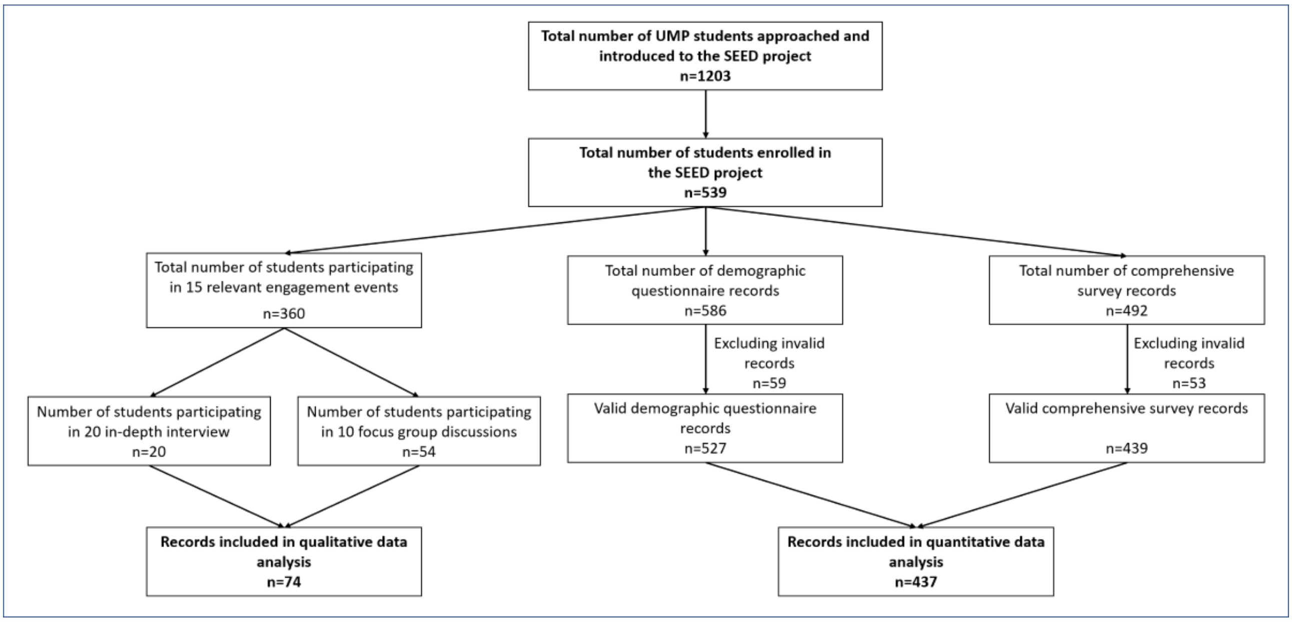
All qualitative data were audio-recorded, transcribed verbatim, and then uploaded into NVivo (version 12; Lumivero) software for management and analysis. Although the data from the FGDs and IDIs were transcribed and analyzed in Vietnamese, we used English codes to ensure accessibility for the full research 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 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].

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].

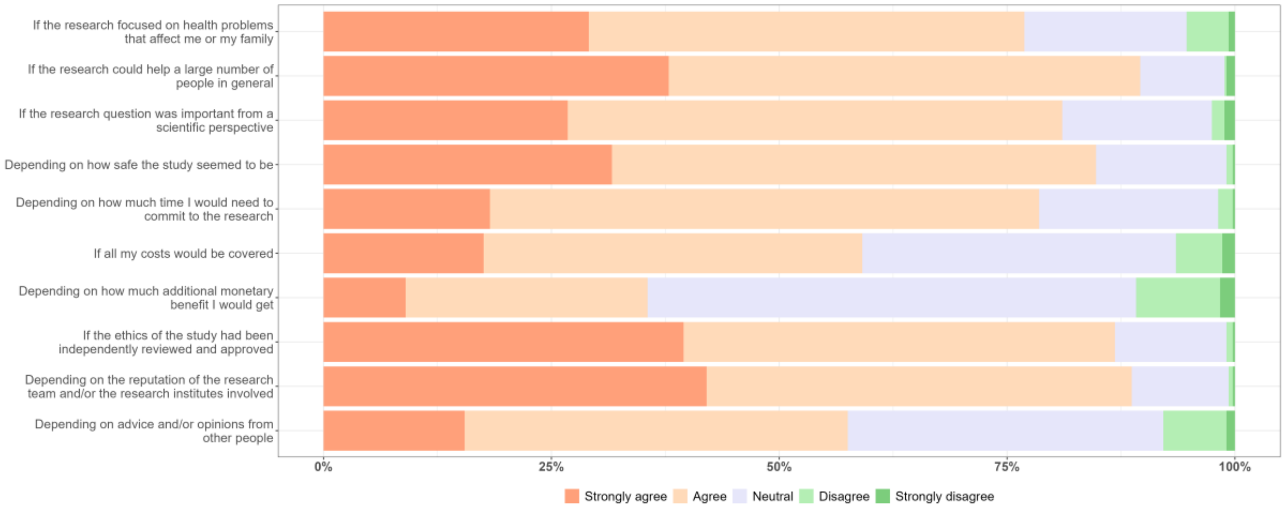
[d] Socioeconomic status refers to the students' personal assessment of their family's overall socioeconomic status within the Vietnamese context.

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 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.

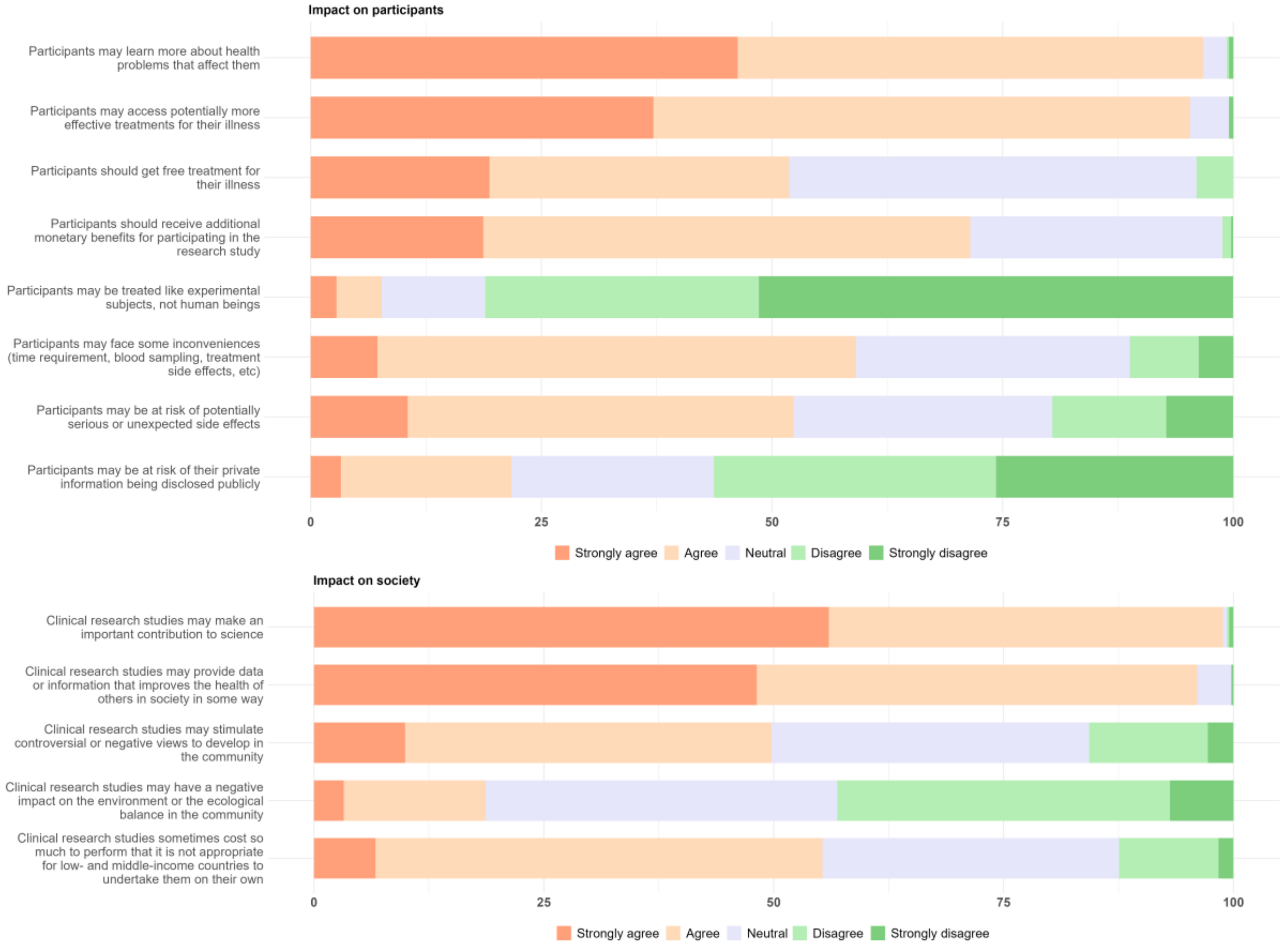


Motivation Driven by Perceived Social Value of Clinical Research

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.

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).

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*

> *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]

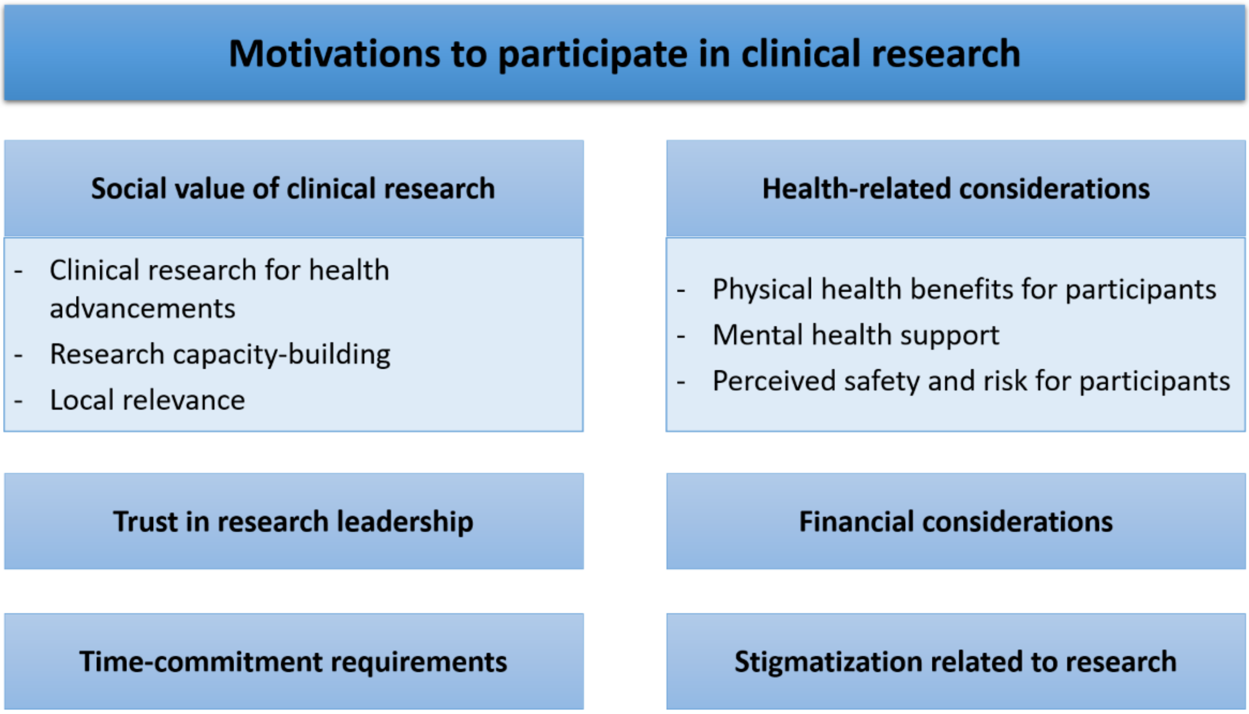
Participation Decision Fostered by Trust in Research Leaderships

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.

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*

> *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 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 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)
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Methodology: EK (lead), JIVN (equal), CLP, VP-T, and HHTP (supporting)
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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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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].

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.

Figure 1. Overview of the i-Spero platform.

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 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

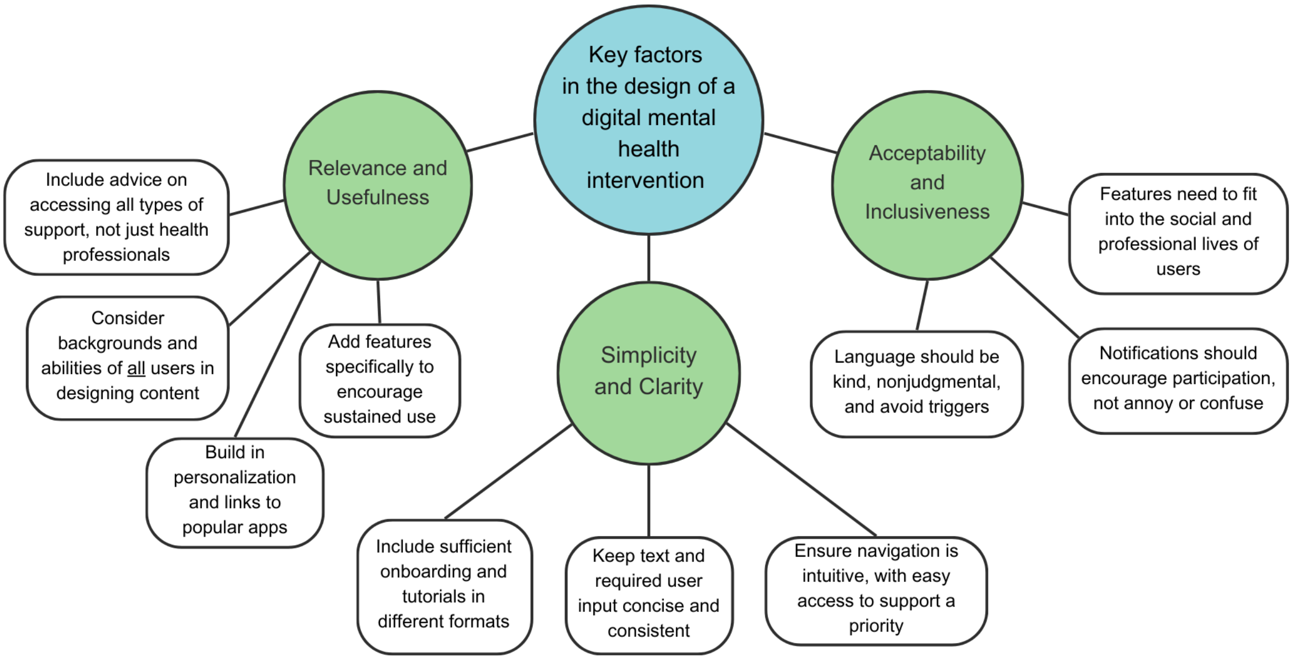
- All language suggestions for messages and notifications.
- Addition of student-designed questionnaires relevant to student issues.
- Changes to the color and layout of the interface.
- Addition and restructuring of well-being plans to enhance user experience.
- Addition of emojis and motivating messages.
- 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.

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.

> *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 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 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 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

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

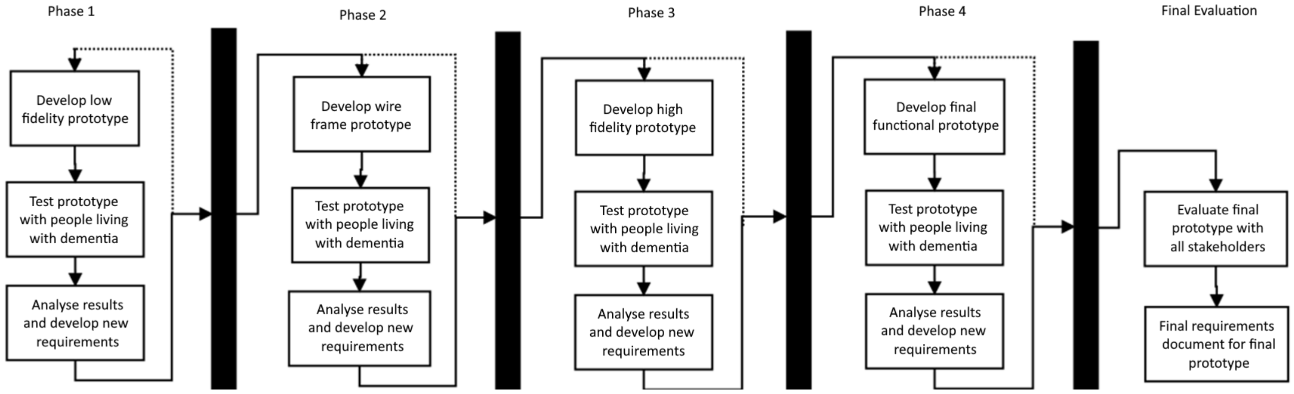
This iterative qualitative study invited people living with dementia and informal caregivers (ICs) to co-design and test prototypes for a novel application during 4 cycles of online workshops that developed a final functional prototype (FFP) before a final summative evaluation cycle involved all stakeholders 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, 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).

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.

Figure 2. Prototype development class chart. DEMQOL: dementia quality of life; QOL-AD: quality of life in Alzheimer's disease.

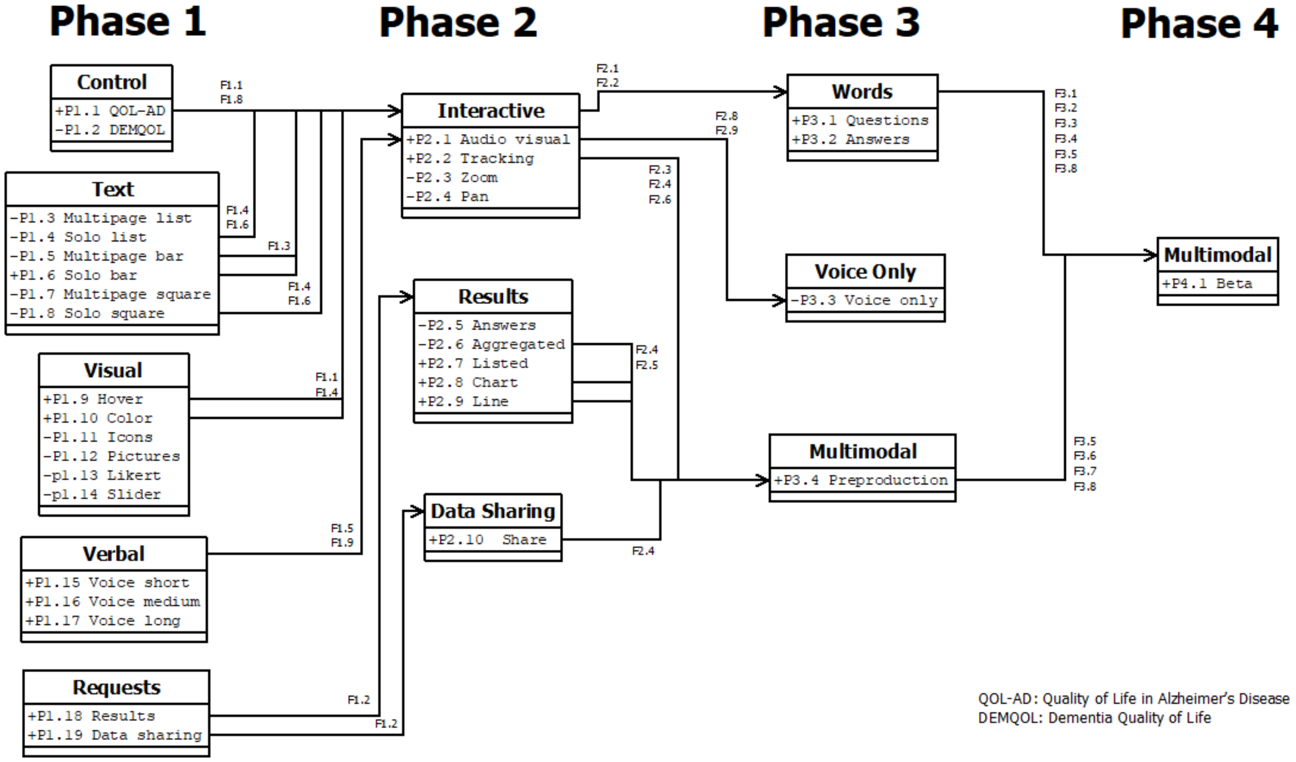


Table . Workshop 1 MoSCoW[a] results.

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.

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.

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 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.*

> ***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]

> *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

(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).

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.

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*

> *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.

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 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 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

PROM: patient-reported outcome measure
QoL: quality of life
QoL-AD: quality of life in Alzheimer disease
WFP: wireframe prototype

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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

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 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

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

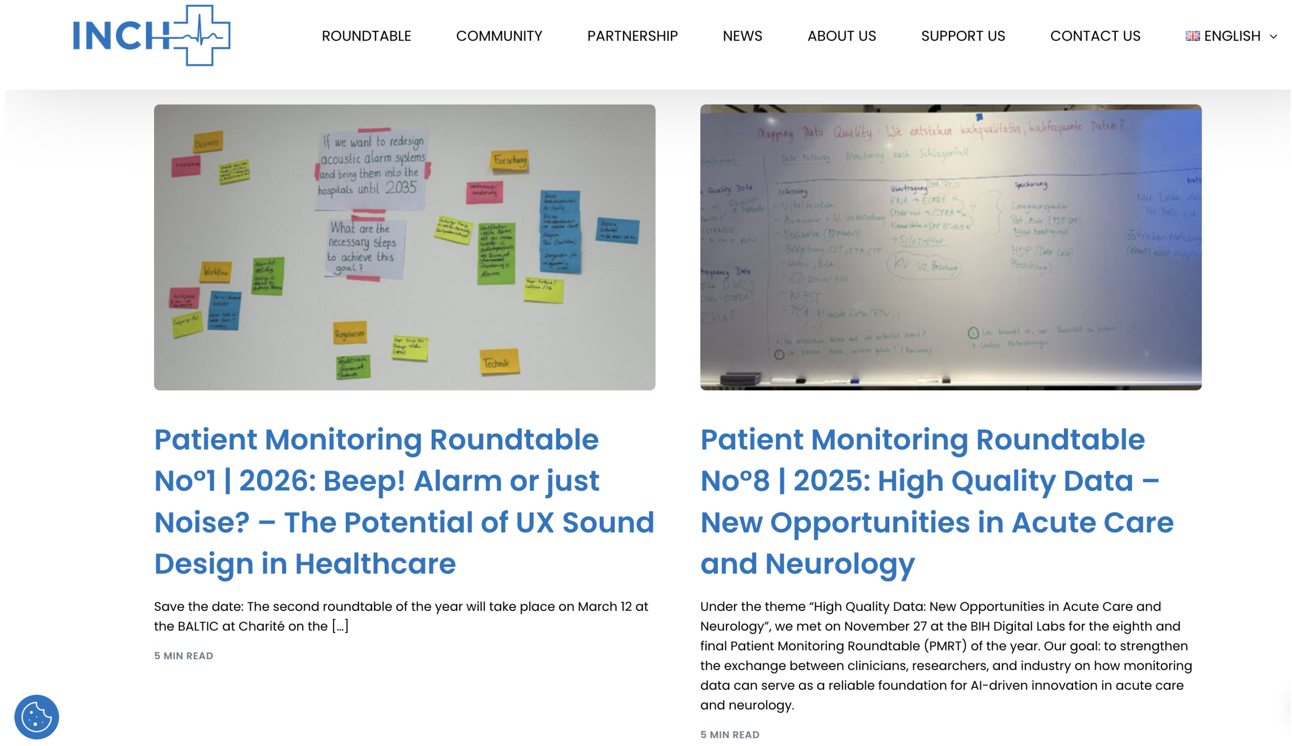
Topics and Participants' Interests

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].



Patient Monitoring Roundtable No°1 | 2026: Beep! Alarm or just Noise? – The Potential of UX Sound Design in Healthcare

Save the date: The second roundtable of the year will take place on March 12 at the BALTIC at Charité on the […]

Patient Monitoring Roundtable No°8 | 2025: High Quality Data – New Opportunities in Acute Care and Neurology

Under the theme "High Quality Data: New Opportunities in Acute Care and Neurology", we met on November 27 at the BIH Digital Labs for the eighth and final Patient Monitoring Roundtable (PMRT) of the year. Our goal: to strengthen the exchange between clinicians, researchers, and industry on how monitoring data can serve as a reliable foundation for AI-driven innovation in acute care and neurology.

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).

Agenda

6:00 pm Greeting by the PMRT team, introduction to the topic

6:10 pm Keynote speech by an expert

6:30 pm Workshops
→3 groups, 2 rotations, 20 min each

7:40 pm Large group discussion and fusion of results

8:00 pm Concluding words

8:10 pm Networking

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 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).

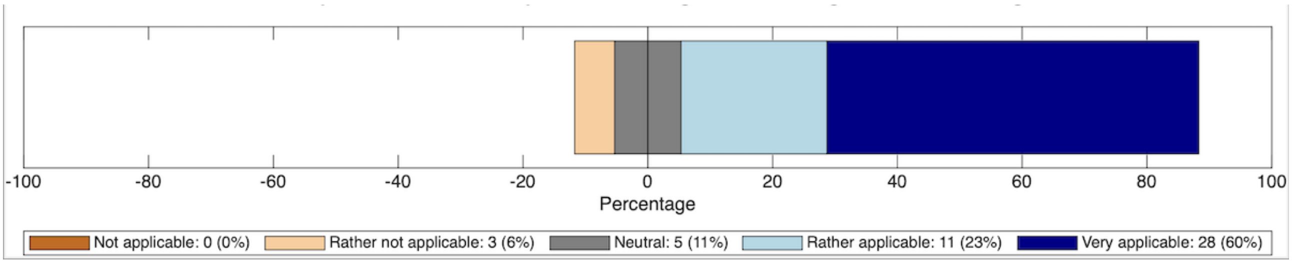
The majority of participants reported having experience in patient monitoring and/or other digital health technologies, with the median response to the statement, “I have experience in the field of patient monitoring and/or other digital health technologies,” being “very applicable” on a 5-point Likert 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.

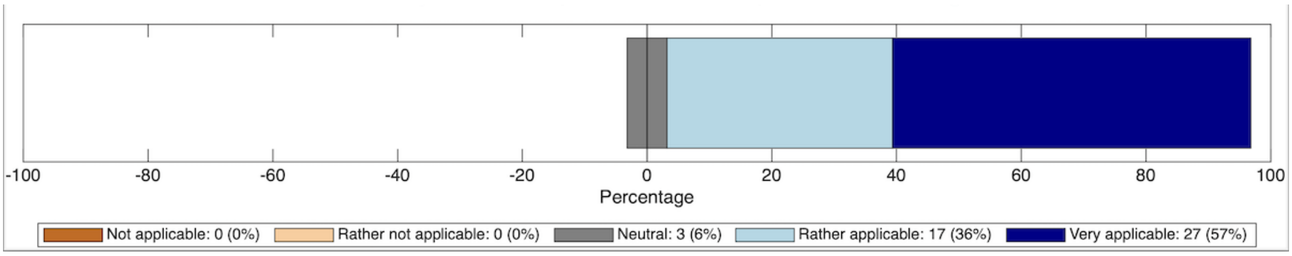


Engagement With PMRT Events

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.

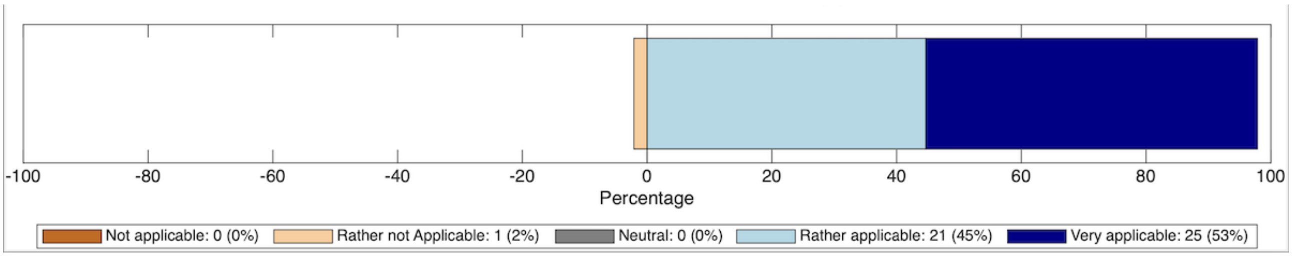


Figure 6. Distribution of participants' responses to the statement "The formats of the PMRT events (eg, small group discussions and workshops) effectively promote dialogue among participants" (n=46). Percentages indicate the proportions of answers given per Likert item (eg, "rather applicable"). Percentages may not sum to 100 due to rounding. PMRT: Patient Monitoring Roundtable.

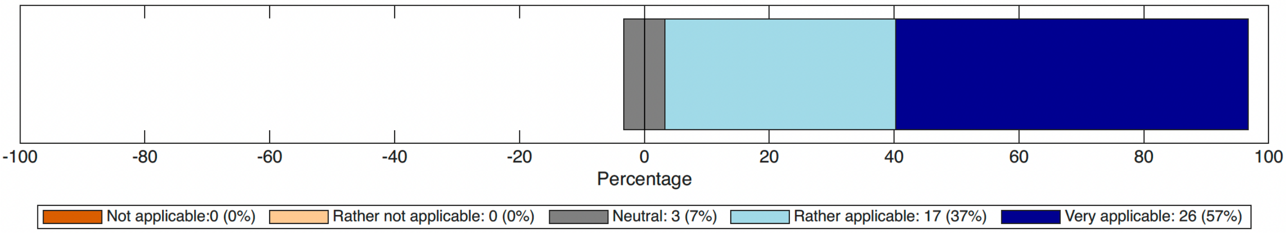
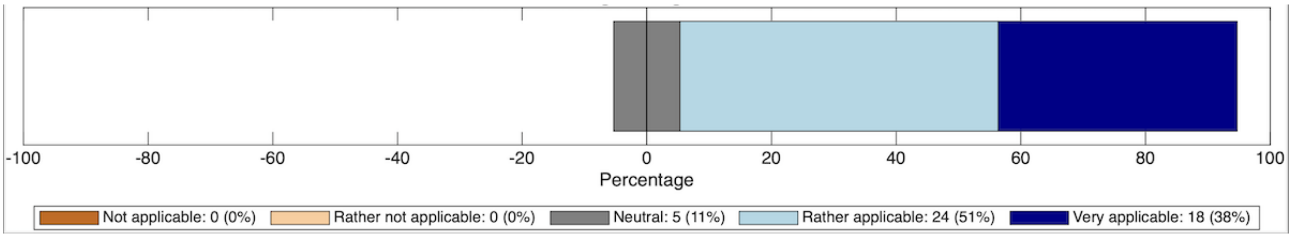


Figure 7. Distribution of participants' responses to the statement "Participating in the PMRT gives me the feeling of being part of a community of like-minded professionals in the field of patient monitoring and digital health" (n=47). Percentages indicate the proportions of answers given per Likert 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.

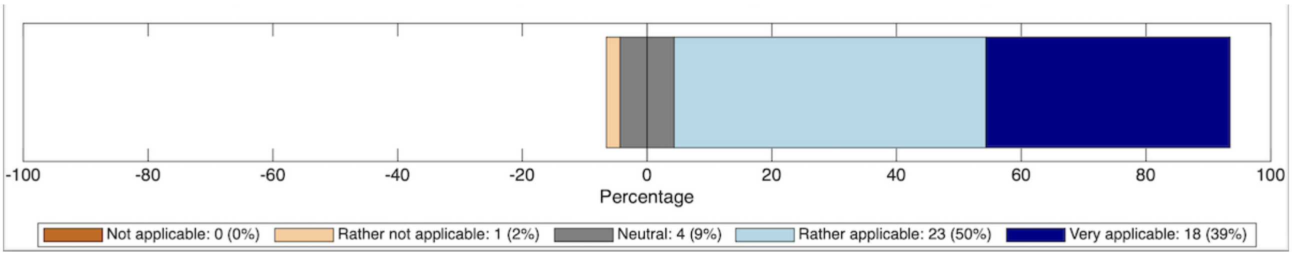
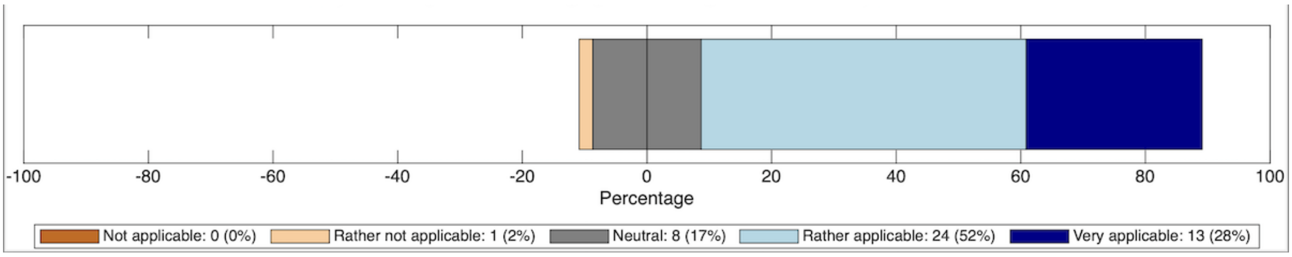


Figure 9. Distribution of participants' responses to the statement "I will apply new insights or knowledge gained through the PMRT in my professional work" (n=46). Percentages indicate the proportions of answers given per Likert item (eg, "rather applicable"). Percentages may not sum to 100 due to rounding. 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 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 (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.

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.

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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.

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

PMRT: Patient Monitoring Roundtable

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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

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.

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.

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)

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 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.

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.

> *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.

> *...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.”

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 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]

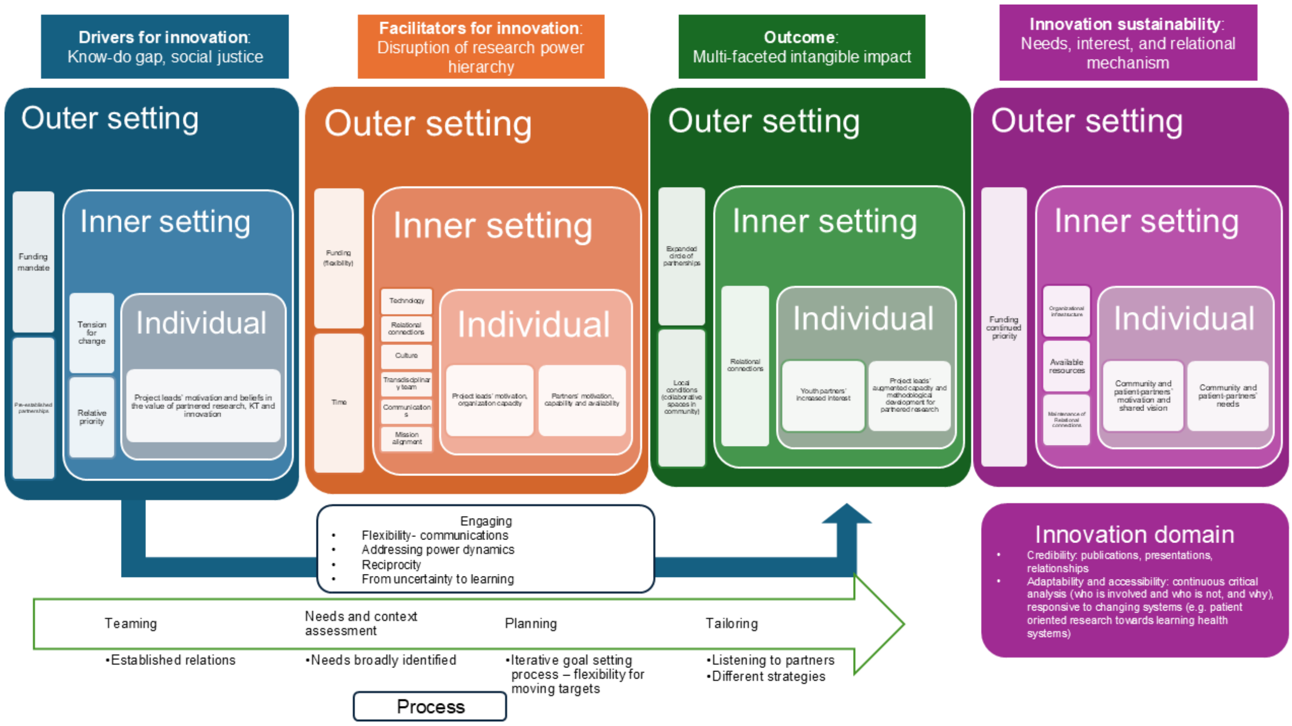
On the other hand, local attitudes in outer settings can be a potential barrier to the sustainable use of the KT product. The members of Project 3, who developed an online platform that provides resources and tools to people with autism in order to support their employment, noted that "we need to start challenging employers' perceptions of individuals with autism" by seeing them facing the structural barriers to employment. Furthermore, they also found that maintaining relational 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].

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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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.
[DOCX File, 16 KB - jopm_v18i1e77581_app1.docx]

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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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

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].

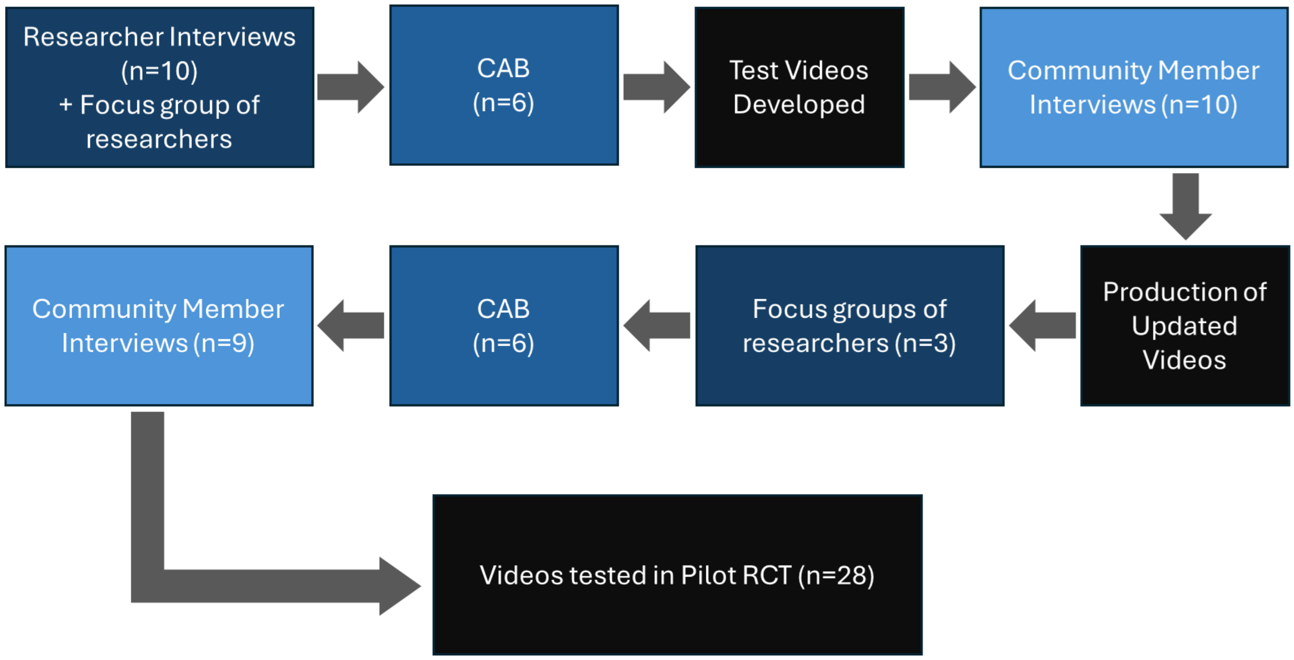
Ethical Considerations

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).

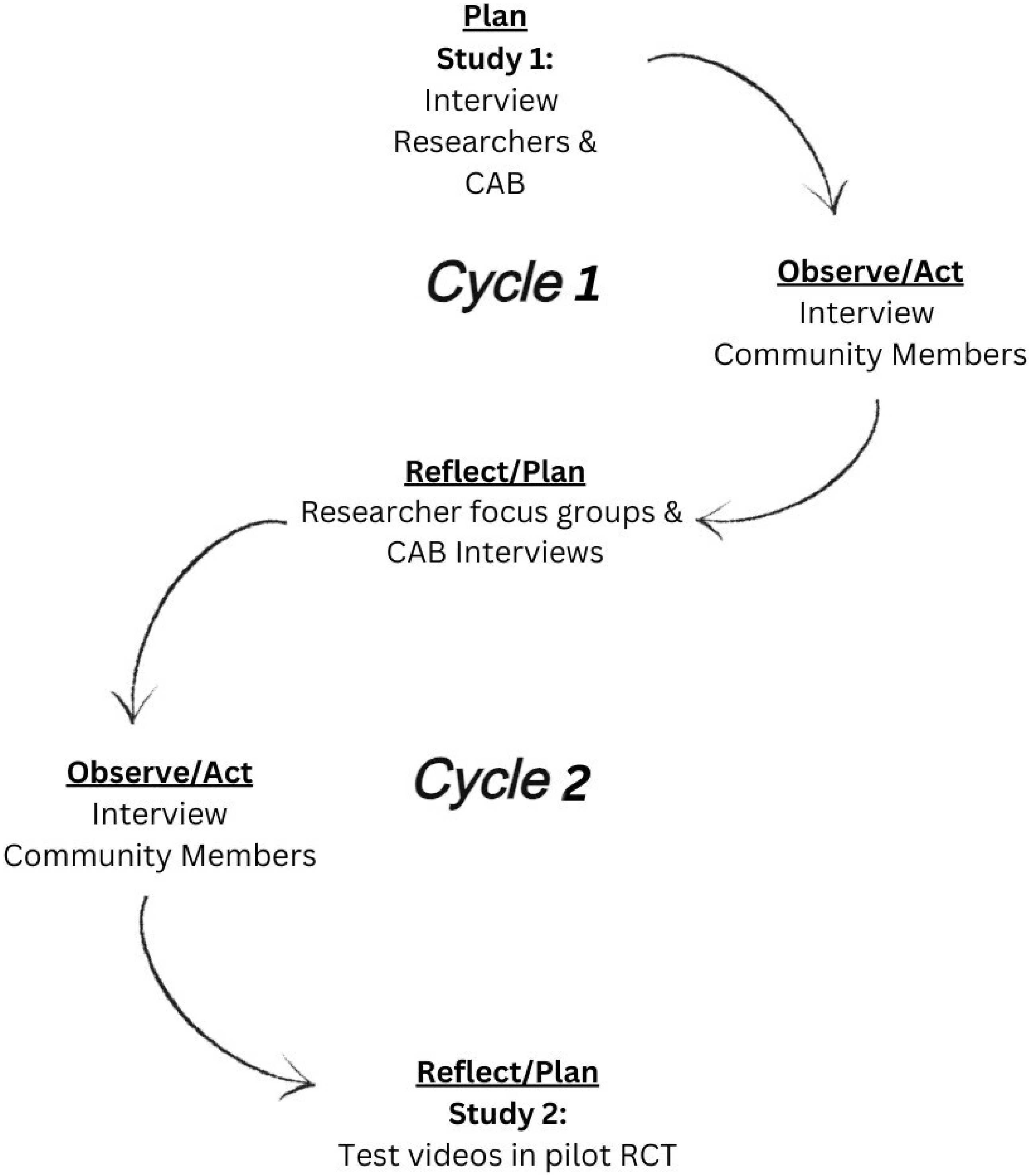
Figure 1. Participant involvement across studies. CAB: community advisory board; RCT; randomized controlled trial.



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.

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?

- 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.

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.

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.

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.

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 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 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.

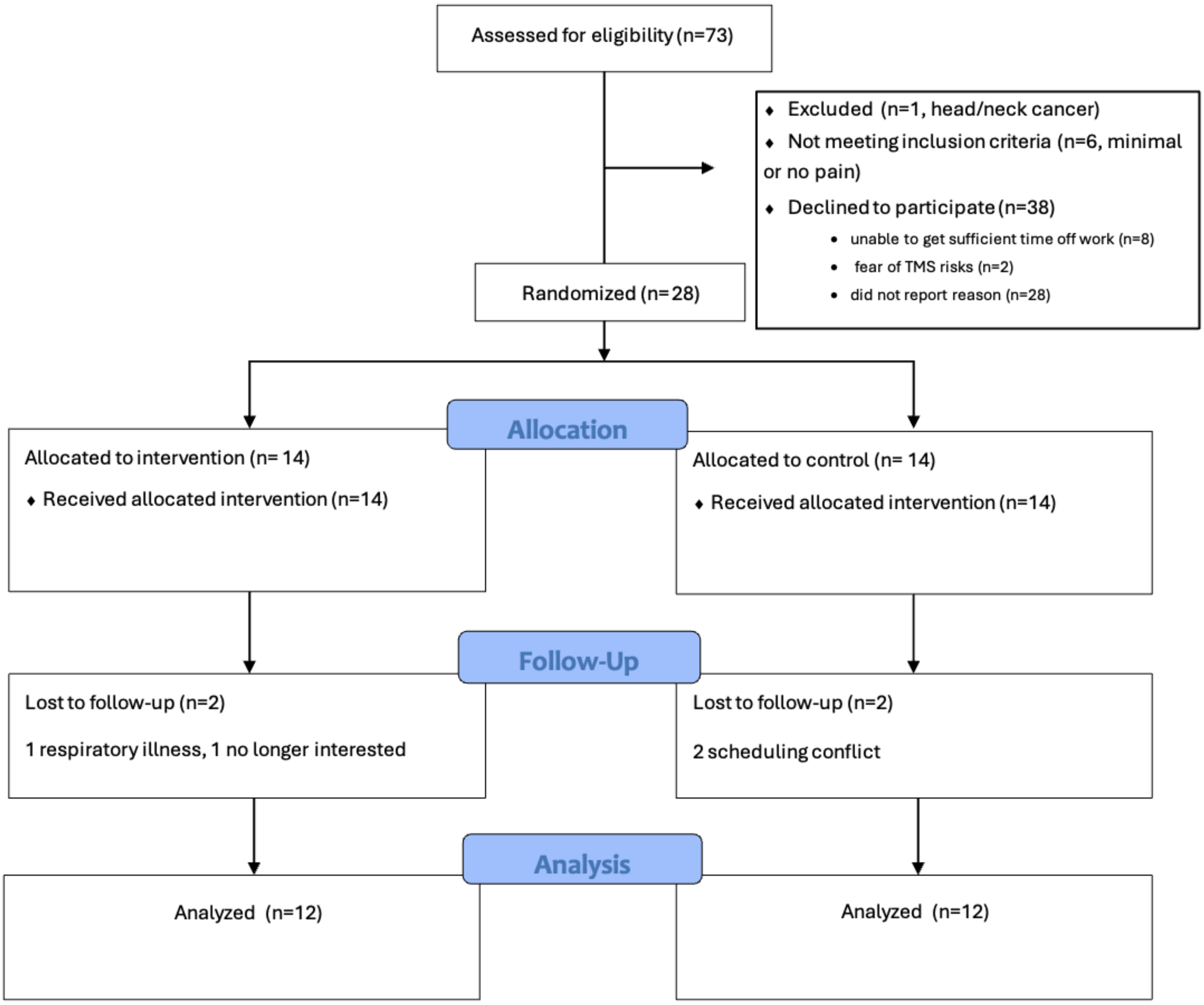
Brochures of the same video content were also produced, and participants were asked to provide feedback on their preference for learning about taVNS and TMS from the videos or brochures. Surprisingly, there were varied preferences. All 3 Spanish-speaking participants preferred learning from the video 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.

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).

Figure 4. Group differences in EXPECT scores. EXPECT: Expectations for Complementary and Alternative Medicine Treatments; taVNS: transcutaneous auricular vagus nerve stimulation.

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 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
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Formal analysis: MLW, CM, GG
Funding acquisition: MLW, LMM, MMT, FJP, EWN
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Methodology: MLW, CM, MMT, FJP
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Validation: MLW, CM
Visualization: MLW, CM, MMT
Writing – original draft: MLW, CM, GG

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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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 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 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.

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.

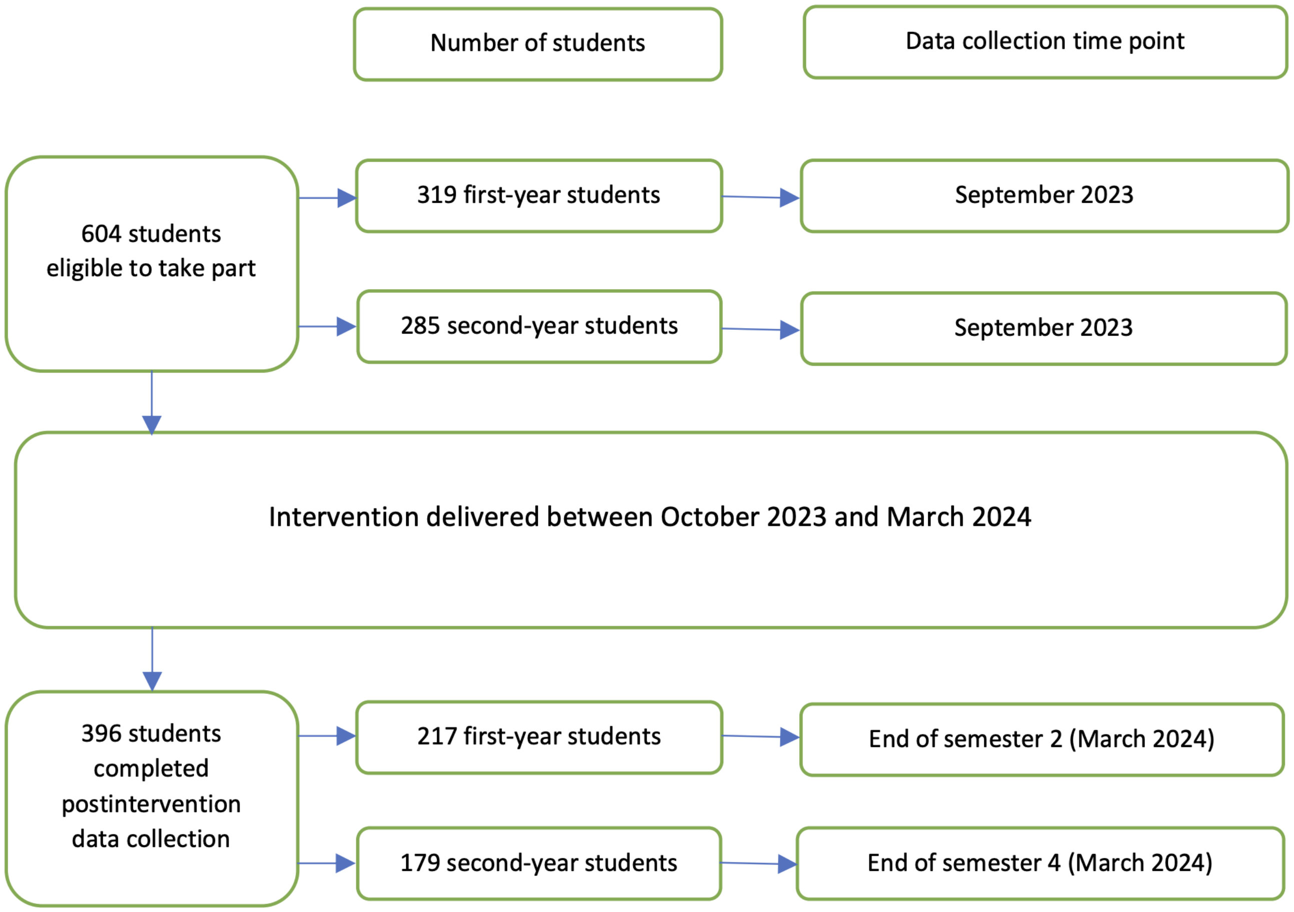
Table . Overview of the modules taking part in the initiative and patients hosted in the lectures.

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.

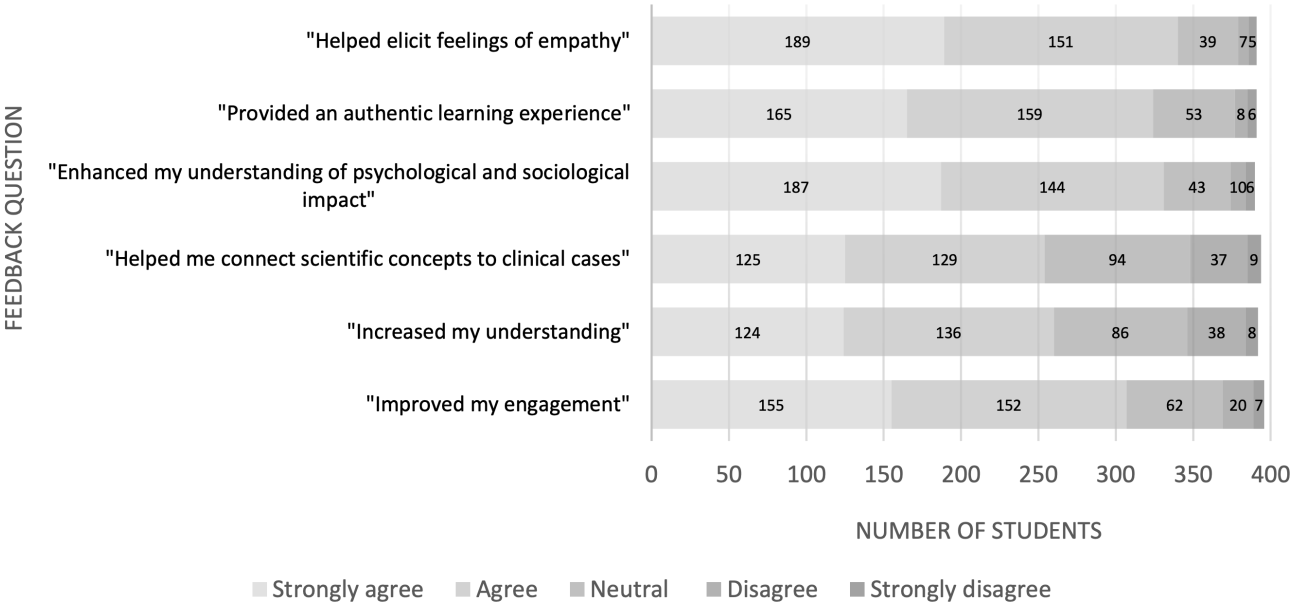
At the end of the year, all students were invited to complete the feedback questionnaire. A total of 396 students completed the evaluation (396/604, 65.6% response rate), with 217 (54.8%) first-year students and 179 (45.2%) second-year students taking part. In total, 1.5% (6/396) of the students did 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.

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 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.

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 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

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 .

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).

Methods

Ethical Considerations

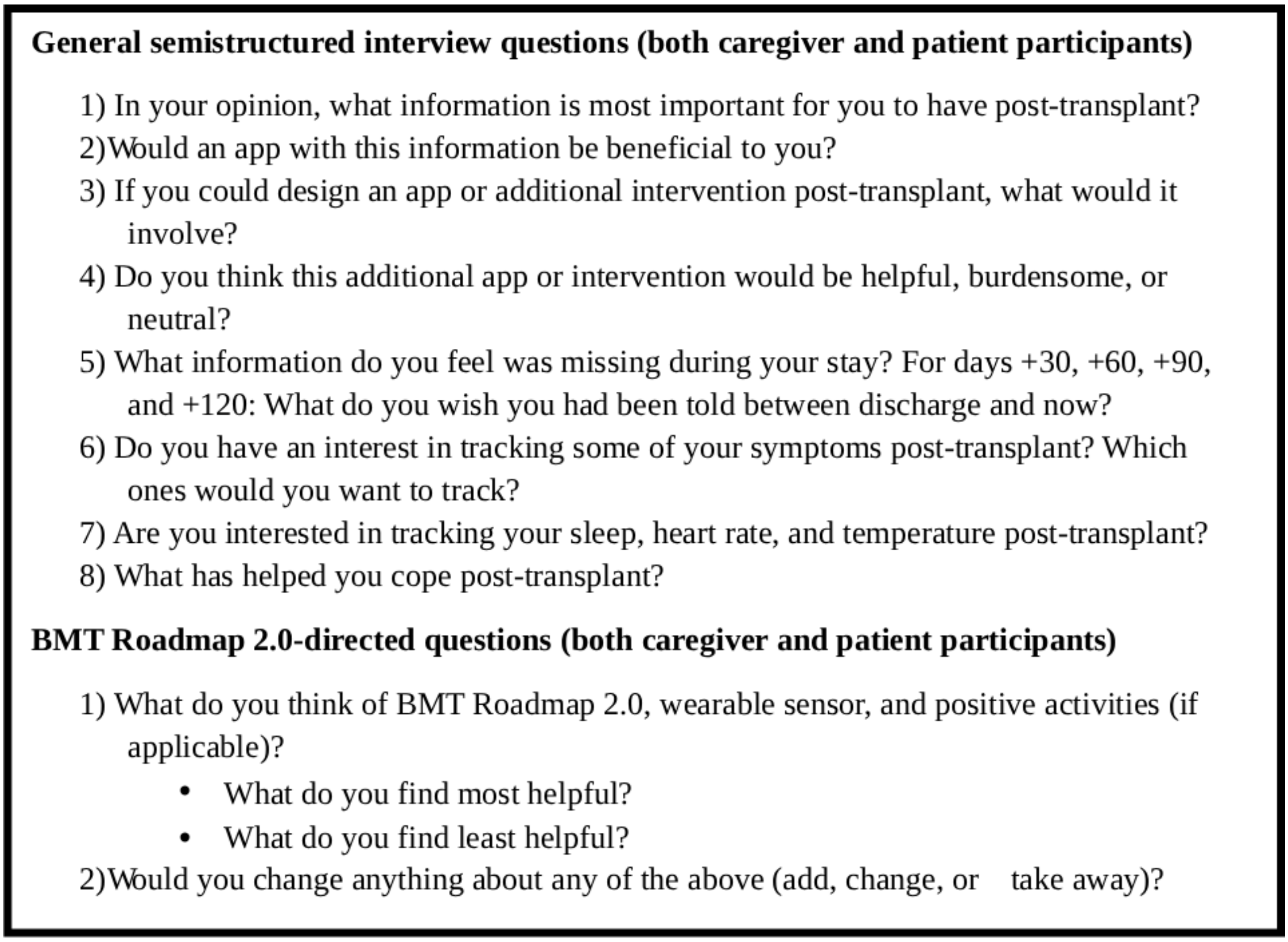
Institutional review board approval was granted at OHSU and oversight approval granted at the University of Michigan, which served as the central or single institutional review board (HUM00176584). The risks and benefits of the study were explained and informed consent was obtained prior to the conduction 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)?

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

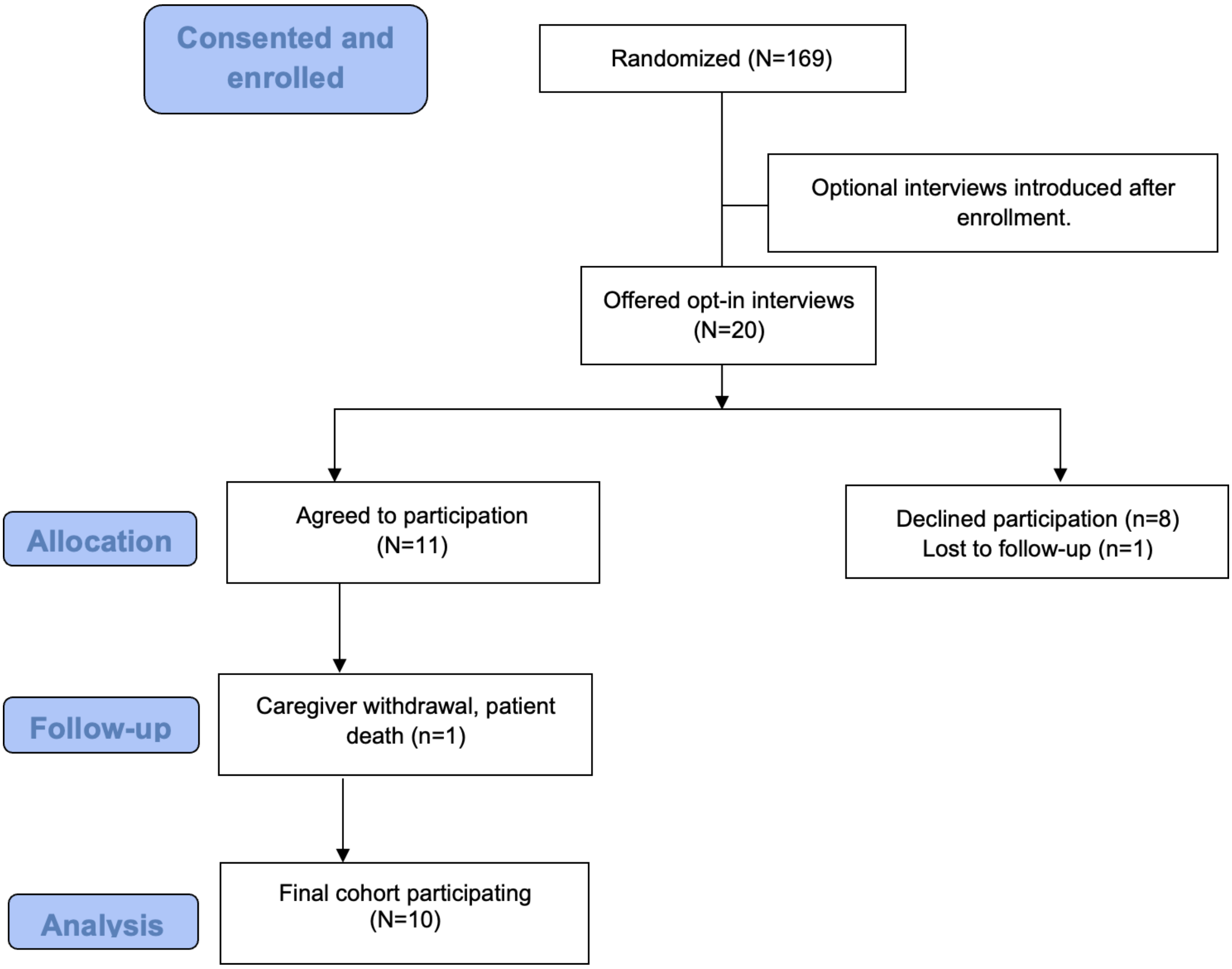


Table . Patient and caregiver demographics.

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.

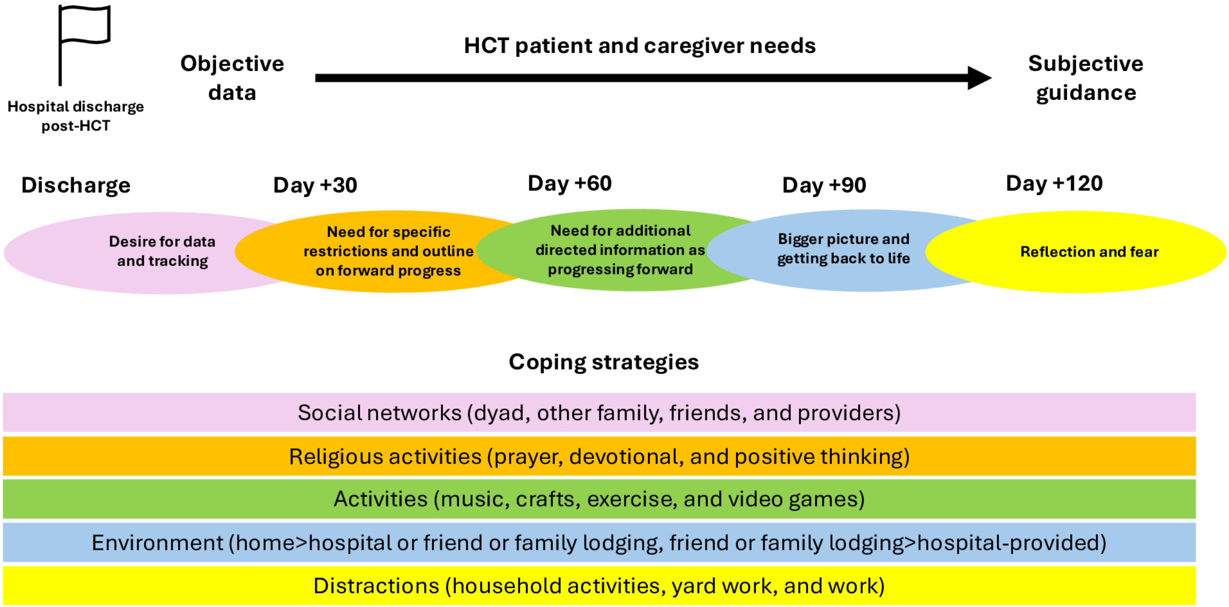
[b] MDS: myelodysplastic syndrome.

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.

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.

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*

> *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*

> *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 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
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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

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.

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

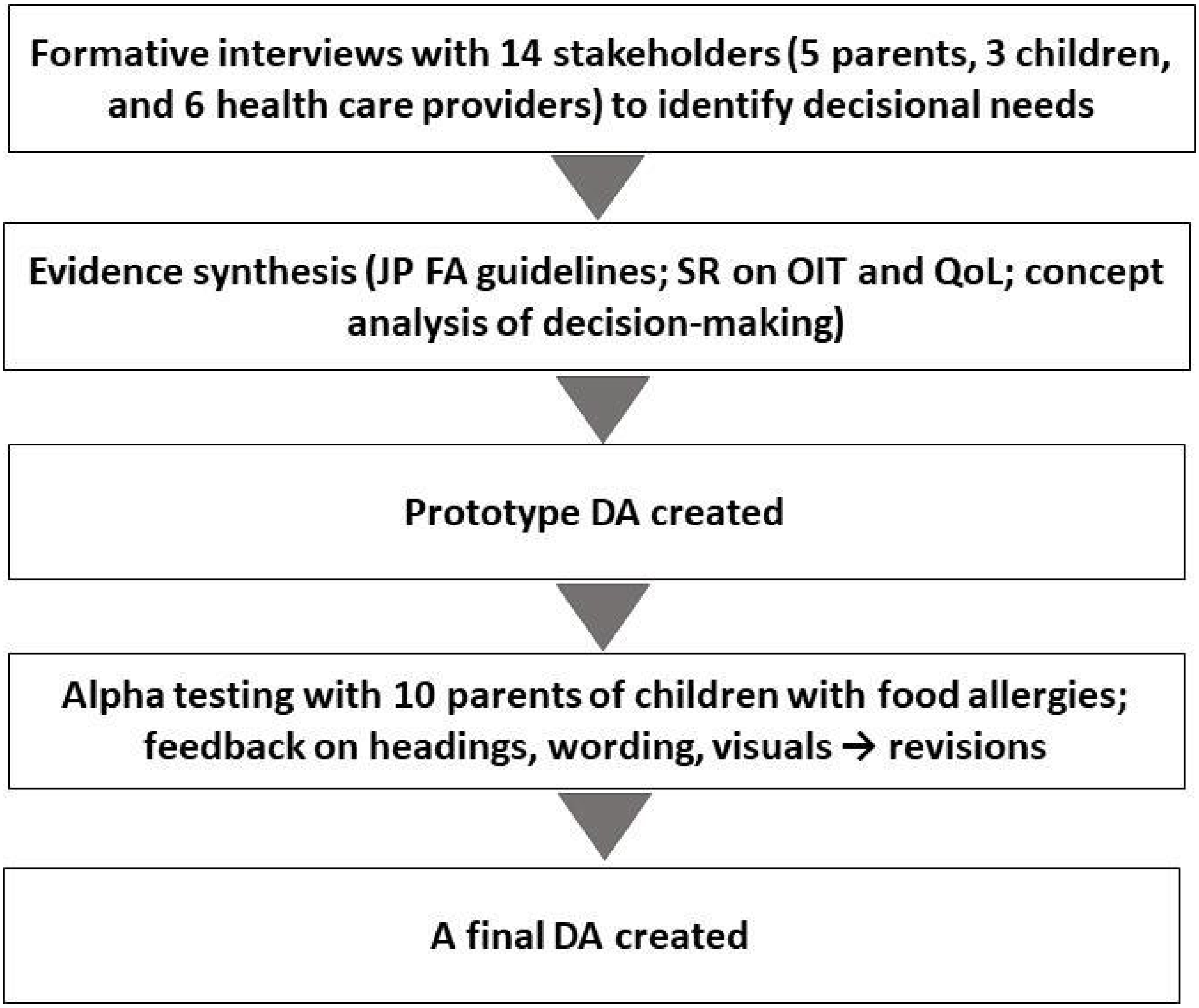
Formative interviews were conducted with 14 stakeholders, 5 parents, 3 children, and 6 health care providers, by purposively sampling families that had previously considered OIT (proceeded vs continued elimination; approval number 19R-272). Children expressed a desire to learn about options and to be 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.

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 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.

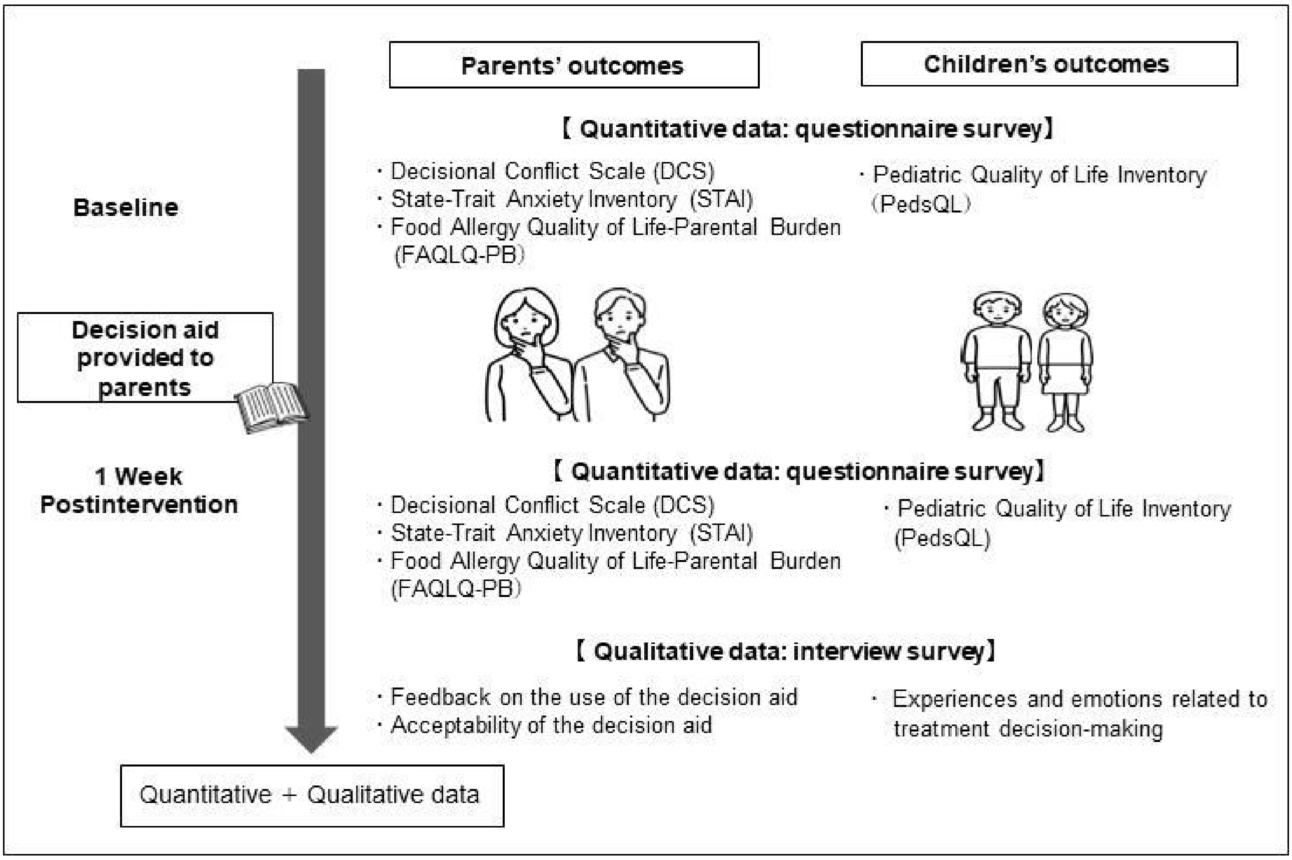
One Week Postintervention

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].

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).

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).

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.

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.

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 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 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 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

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.

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.

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)

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.

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.

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 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.

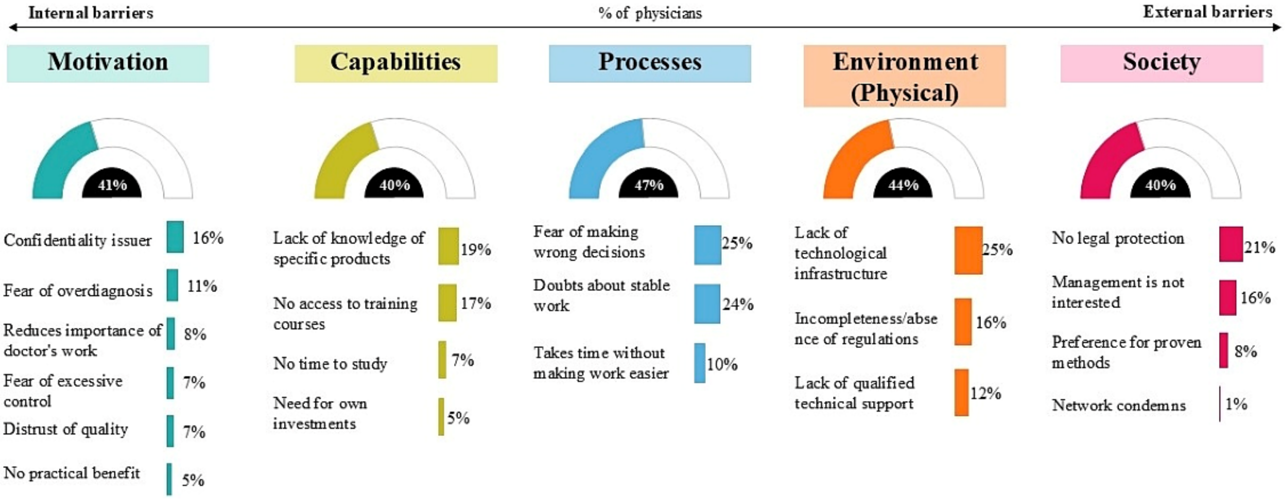
An important issue for physicians remains legal security (17.5%) when using this group of technologies. Physicians also noted a lack of trust in the quality of technology (10.7%), a feeling of excessive control over their professional activities (9.8%), and a decrease in the significance of the role 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).

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.

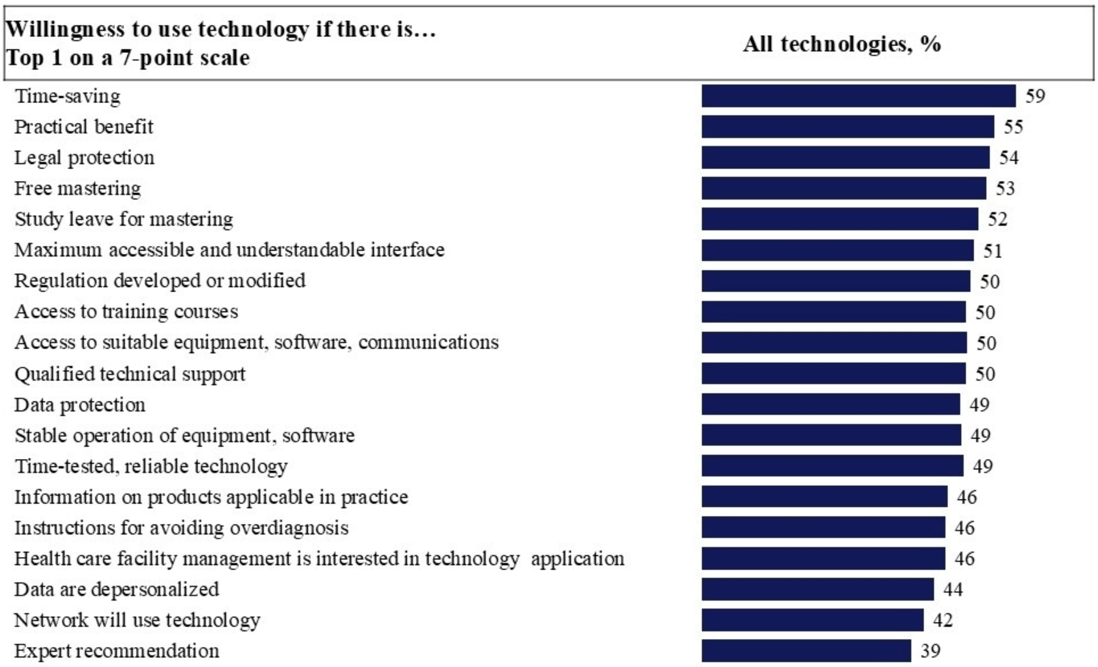
[b] Based on the answers to the question: "How likely is it that you would start using/more actively use the following technologies when implementing the ideas on a scale from 1 to 7?" The table shows the percentage of respondents who chose 7 points for this answer (a physician would definitely start 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.

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 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.

"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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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].

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 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

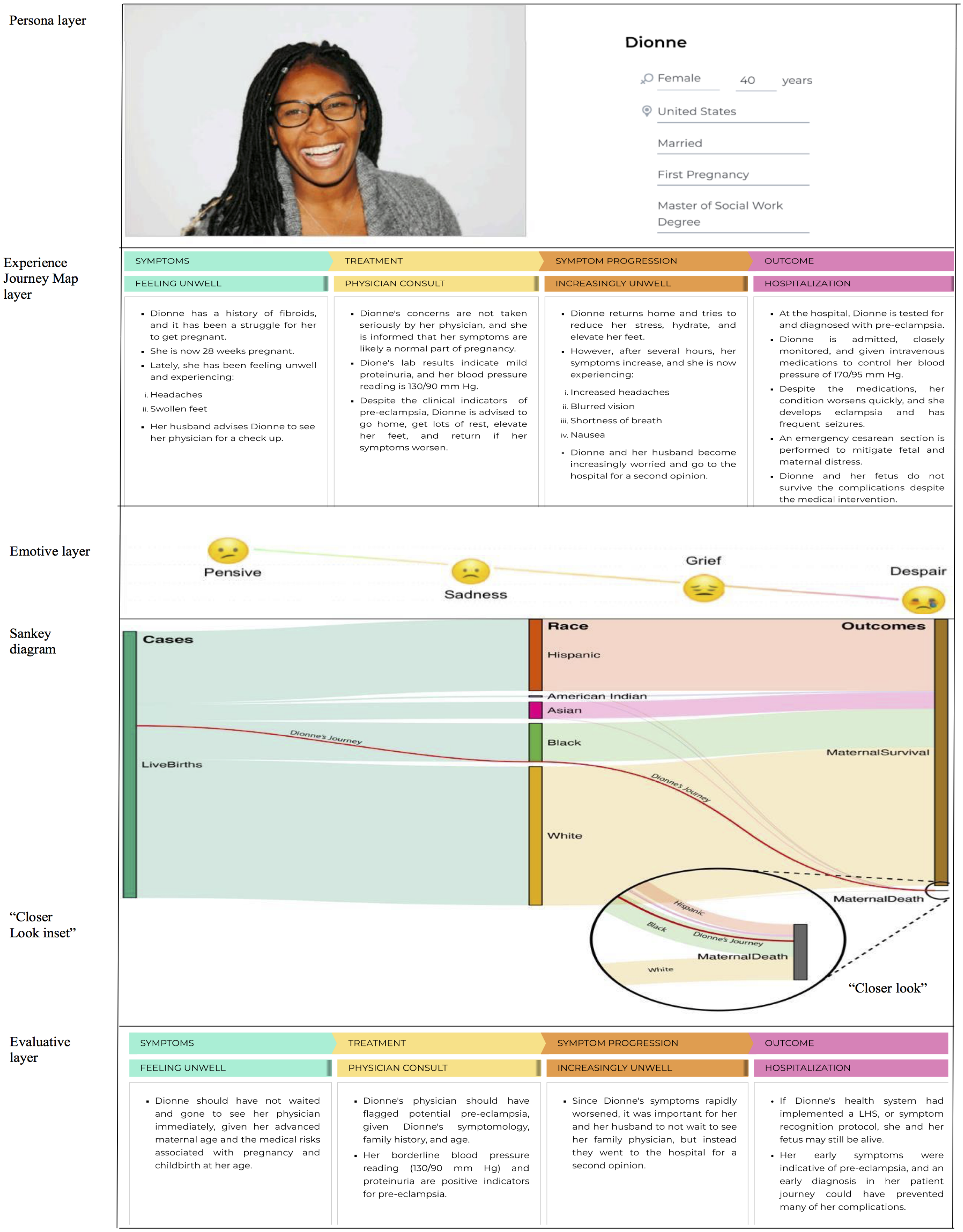
The qualitative data for the persona and Experience Journey Map were synthesized from cases documented from the Goldsmiths Prized ProPublica *"Lost Mothers"* series [7,77]. The *"Lost Mothers"* investigative journalism project was selected as a data source, as it provided detailed narratives of maternal 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.

Figure 1. Visualized Combined Experience diagram illustrating Dionne’s trajectory compared with the maternal health outcomes of other population groups. LHS: learning health system.



Experience Journey Map layer

SYMPTOMS — FEELING UNWELL

- Dionne has a history of fibroids, and it has been a struggle for her to get pregnant.
- She is now 28 weeks pregnant.
- Lately, she has been feeling unwell and experiencing:
  - i. Headaches
  - ii. Swollen feet
- Her husband advises Dionne to see her physician for a check up.

TREATMENT — PHYSICIAN CONSULT

- Dionne's concerns are not taken seriously by her physician, and she is informed that her symptoms are likely a normal part of pregnancy.
- Dione's lab results indicate mild proteinuria, and her blood pressure reading is 130/90 mm Hg.
- Despite the clinical indicators of pre-eclampsia, Dionne is advised to go home, get lots of rest, elevate her feet, and return if her symptoms worsen.

SYMPTOM PROGRESSION — INCREASINGLY UNWELL

- Dionne returns home and tries to reduce her stress, hydrate, and elevate her feet.
- However, after several hours, her symptoms increase, and she is now experiencing:
  - i. Increased headaches
  - ii. Blurred vision
  - iii. Shortness of breath
  - iv. Nausea
- Dionne and her husband become increasingly worried and go to the hospital for a second opinion.

OUTCOME — HOSPITALIZATION

- At the hospital, Dionne is tested for and diagnosed with pre-eclampsia.
- Dionne is admitted, closely monitored, and given intravenous medications to control her blood pressure of 170/95 mm Hg.
- Despite the medications, her condition worsens quickly, and she develops eclampsia and has frequent seizures.
- An emergency cesarean section is performed to mitigate fetal and maternal distress.
- Dionne and her fetus do not survive the complications despite the medical intervention.

Evaluative layer

SYMPTOMS — FEELING UNWELL

- Dionne should have not waited and gone to see her physician immediately, given her advanced maternal age and the medical risks associated with pregnancy and childbirth at her age.

TREATMENT — PHYSICIAN CONSULT

- Dionne's physician should have flagged potential pre-eclampsia, given Dionne's symptomology, family history, and age.
- Her borderline blood pressure reading (130/90 mm Hg) and proteinuria are positive indicators for pre-eclampsia.

SYMPTOM PROGRESSION — INCREASINGLY UNWELL

- Since Dionne's symptoms rapidly worsened, it was important for her and her husband to not wait to see her family physician, but instead they went to the hospital for a second opinion.

OUTCOME — HOSPITALIZATION

- If Dionne's health system had implemented a LHS, or symptom recognition protocol, she and her fetus may still be alive.
- Her early symptoms were indicative of pre-eclampsia, and an early diagnosis in her patient journey could have prevented many of her complications.

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 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

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 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 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 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 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].

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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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, 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, 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.

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.

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).

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 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 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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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.

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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 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

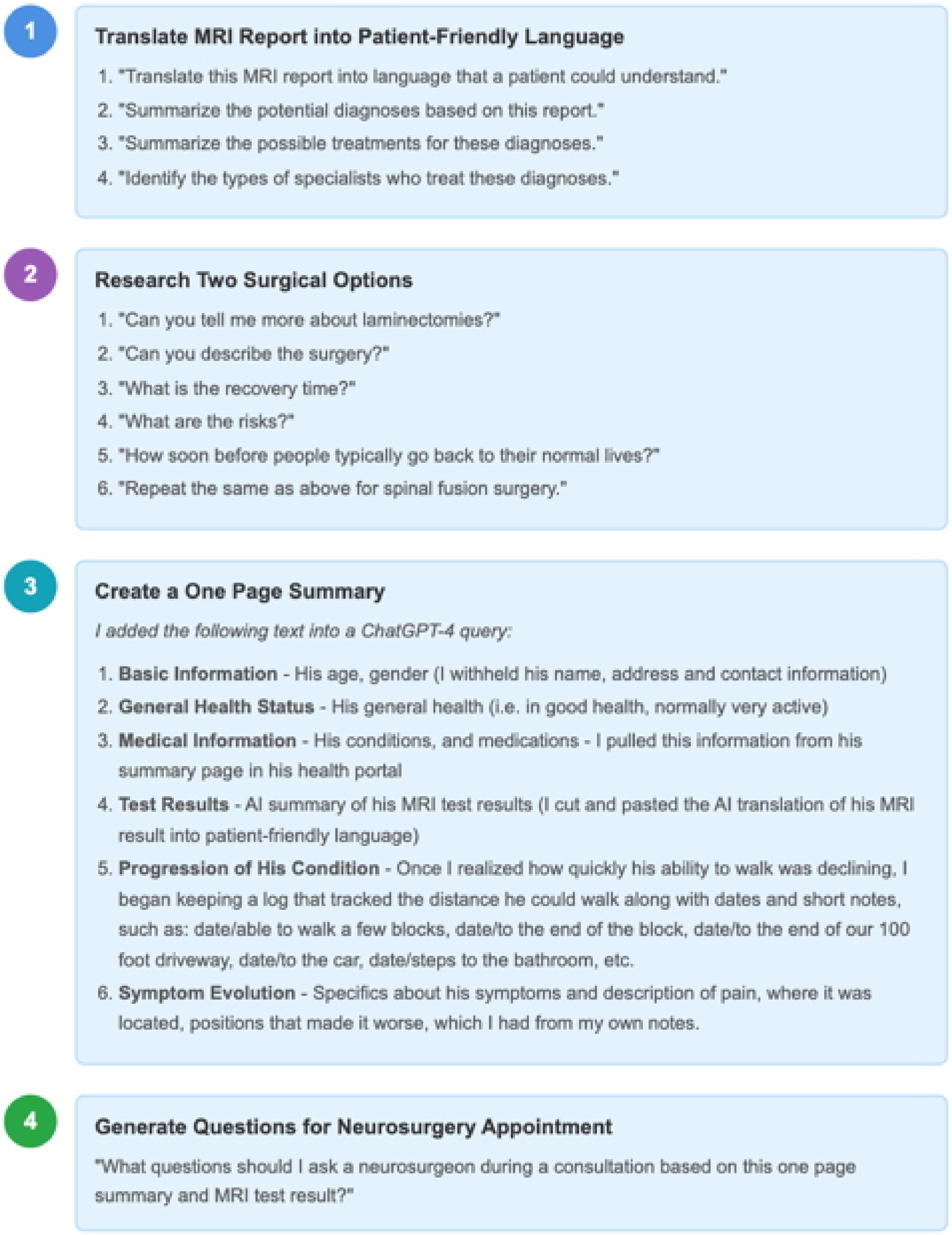
MBS discovered that starting with AI to translate MRI results into patient-friendly language and then gradually conducting deeper research led to a greater understanding of the situation. By taking things step by step over several days—each new question adding to her understanding—she steadily built 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].

Figure 1. Approach used with generative artificial intelligence by the family caregiver in the case presented. MRI: magnetic resonance imaging; AI: artificial intelligence.



Translate MRI Report into Patient-Friendly Language

1. "Translate this MRI report into language that a patient could understand."
2. "Summarize the potential diagnoses based on this report."
3. "Summarize the possible treatments for these diagnoses."
4. "Identify the types of specialists who treat these diagnoses."

Research Two Surgical Options

1. "Can you tell me more about laminectomies?"
2. "Can you describe the surgery?"
3. "What is the recovery time?"
4. "What are the risks?"
5. "How soon before people typically go back to their normal lives?"
6. "Repeat the same as above for spinal fusion surgery."

Create a One Page Summary

I added the following text into a ChatGPT-4 query:

1. **Basic Information** - His age, gender (I withheld his name, address and contact information)
2. **General Health Status** - His general health (i.e. in good health, normally very active)
3. **Medical Information** - His conditions, and medications - I pulled this information from his summary page in his health portal
4. **Test Results** - AI summary of his MRI test results (I cut and pasted the AI translation of his MRI result into patient-friendly language)
5. **Progression of His Condition** - Once I realized how quickly his ability to walk was declining, I began keeping a log that tracked the distance he could walk along with dates and short notes, such as: date/able to walk a few blocks, date/to the end of the block, date/to the end of our 100 foot driveway, date/to the car, date/steps to the bathroom, etc.
6. **Symptom Evolution** - Specifics about his symptoms and description of pain, where it was located, positions that made it worse, which I had from my own notes.

Generate Questions for Neurosurgery Appointment

"What questions should I ask a neurosurgeon during a consultation based on this one page summary and MRI test result?"

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]

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.

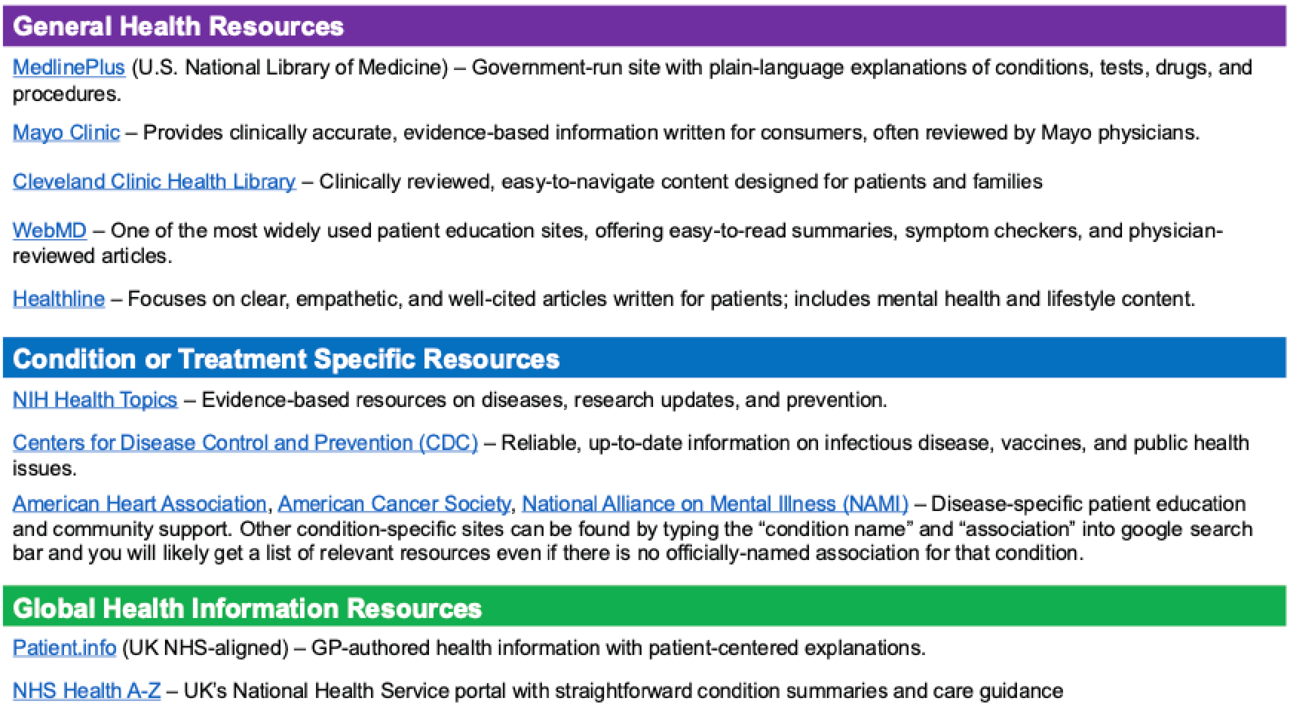
Balancing AI's Potential With Its Risks

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

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.



General Health Resources

MedlinePlus (U.S. National Library of Medicine) – Government-run site with plain-language explanations of conditions, tests, drugs, and procedures.

Mayo Clinic – Provides clinically accurate, evidence-based information written for consumers, often reviewed by Mayo physicians.

Cleveland Clinic Health Library – Clinically reviewed, easy-to-navigate content designed for patients and families

WebMD – One of the most widely used patient education sites, offering easy-to-read summaries, symptom checkers, and physician-reviewed articles.

Healthline – Focuses on clear, empathetic, and well-cited articles written for patients; includes mental health and lifestyle content.

Condition or Treatment Specific Resources

NIH Health Topics – Evidence-based resources on diseases, research updates, and prevention.

Centers for Disease Control and Prevention (CDC) – Reliable, up-to-date information on infectious disease, vaccines, and public health issues.

American Heart Association, American Cancer Society, National Alliance on Mental Illness (NAMI) – Disease-specific patient education and community support. Other condition-specific sites can be found by typing the “condition name” and “association” into google search bar and you will likely get a list of relevant resources even if there is no officially-named association for that condition.

Global Health Information Resources

Patient.info (UK NHS-aligned) – GP-authored health information with patient-centered explanations.

NHS Health A-Z – UK’s National Health Service portal with straightforward condition summaries and care guidance

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.

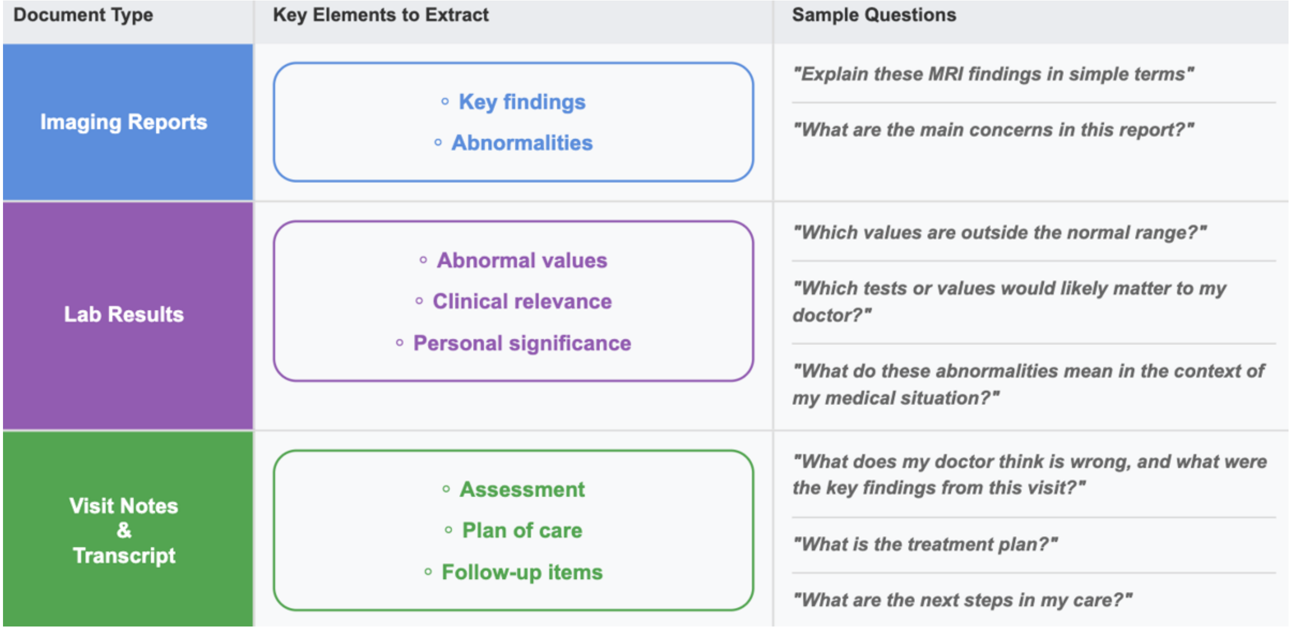
Transforming complex medical language into accessible information is powerfully illustrated in MBS’s case, but AI translation extends beyond imaging reports. Laboratory results, often presented as a series of numbers and technical terms, can be transformed into meaningful insights. When reviewing a comprehensive 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.

Figure 3. Strategies for patients and caregivers to use artificial intelligence to understand medical documentation. MRI: magnetic resonance imaging.



Document Type	Key Elements to Extract	Sample Questions
Imaging Reports	◦ Key findings ◦ Abnormalities	*"Explain these MRI findings in simple terms"* *"What are the main concerns in this report?"*
Lab Results	◦ Abnormal values ◦ Clinical relevance ◦ Personal significance	*"Which values are outside the normal range?"* *"Which tests or values would likely matter to my doctor?"* *"What do these abnormalities mean in the context of my medical situation?"*
Visit Notes & Transcript	◦ Assessment ◦ Plan of care ◦ Follow-up items	*"What does my doctor think is wrong, and what were the key findings from this visit?"* *"What is the treatment plan?"* *"What are the next steps in my care?"*

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.

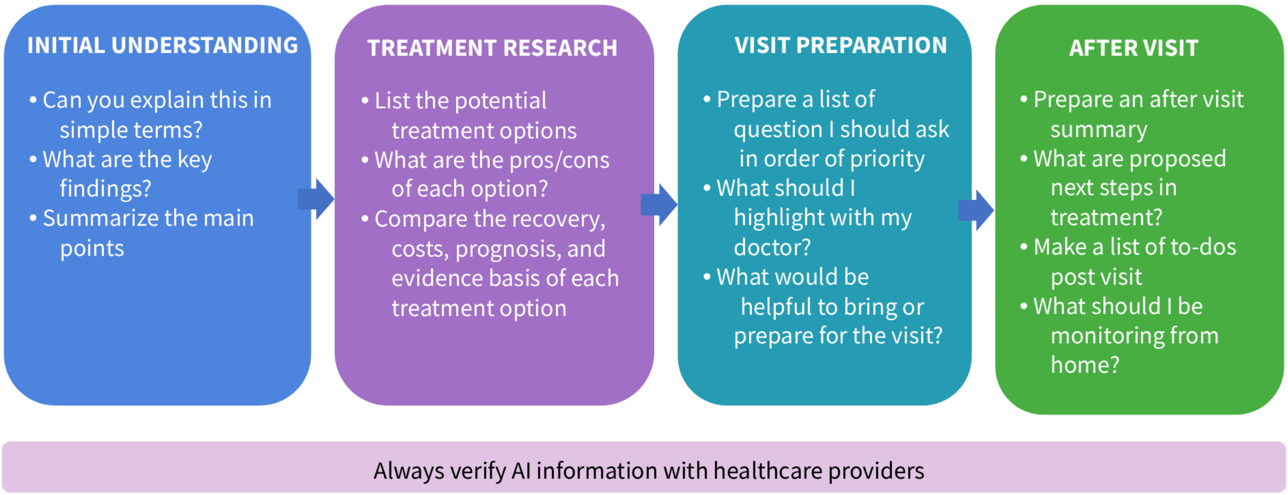
Figure 4 shows examples of research that patients can conduct using ChatGPT or other LLMs, with some sample questions showcasing several areas where patients might find AI helpful in researching their own medical conditions.

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.

Figure 4. Sample prompts and queries to research patient health data and medical information.



INITIAL UNDERSTANDING

- Can you explain this in simple terms?
- What are the key findings?
- Summarize the main points

TREATMENT RESEARCH

- List the potential treatment options
- What are the pros/cons of each option?
- Compare the recovery, costs, prognosis, and evidence basis of each treatment option

VISIT PREPARATION

- Prepare a list of question I should ask in order of priority
- What should I highlight with my doctor?
- What would be helpful to bring or prepare for the visit?

AFTER VISIT

- Prepare an after visit summary
- What are proposed next steps in treatment?
- Make a list of to-dos post visit
- What should I be monitoring from home?

Always verify AI information with healthcare providers

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

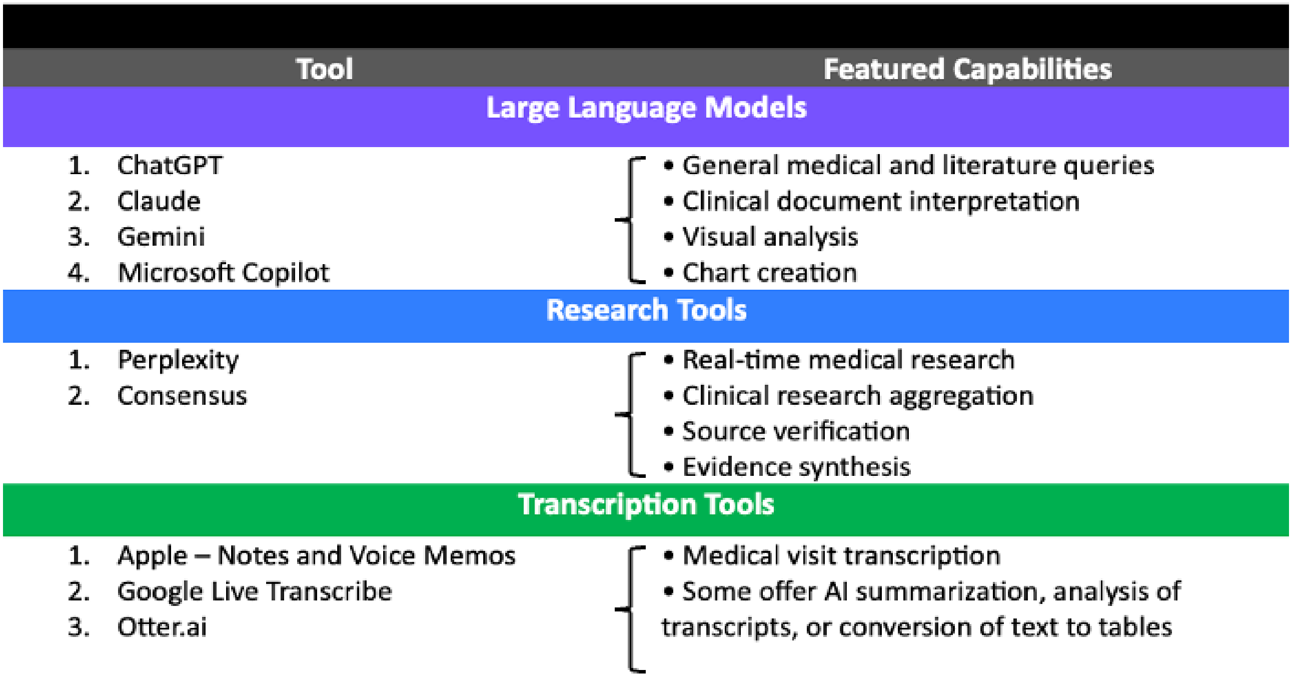
Visit preparation represents another area where AI can significantly improve patient care. When patients arrive at visits with a basic understanding of their condition and well-researched questions, clinicians can focus on the more complex and personalized aspects of care. Patient and symptom summaries 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.

Figure 5. Sample artificial intelligence tools for patient and caregiver empowerment that may help a health care journey.



Tool	Featured Capabilities
Large Language Models	
1. ChatGPT 2. Claude 3. Gemini 4. Microsoft Copilot	• General medical and literature queries • Clinical document interpretation • Visual analysis • Chart creation
Research Tools	
1. Perplexity 2. Consensus	• Real-time medical research • Clinical research aggregation • Source verification • Evidence synthesis
Transcription Tools	
1. Apple – Notes and Voice Memos 2. Google Live Transcribe 3. Otter.ai	• Medical visit transcription • Some offer AI summarization, analysis of transcripts, or conversion of text to tables

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].

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.

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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