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Viewpoint

# Data Sharing Goals for Nonprofit Funders of Clinical Trials

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## Abstract

Sharing clinical trial data can provide value to research participants and communities by accelerating the development of new knowledge and therapies as investigators merge data sets to conduct new analyses, reproduce published findings to raise standards for original research, and learn from the work of others to generate new research questions. Nonprofit funders, including disease

advocacy and patient-focused organizations, play a pivotal role in the promotion and implementation of data sharing policies. Funders are uniquely positioned to promote and support a culture of data sharing by serving as trusted liaisons between potential research participants and investigators who wish to access these participants' networks for clinical trial recruitment. In short, nonprofit funders can drive policies and influence research culture. The purpose of this paper is to detail a set of aspirational goals and forward thinking, collaborative data sharing solutions for nonprofit funders to fold into existing funding policies. The goals of this paper convey the complexity of the opportunities and challenges facing nonprofit funders and the appropriate prioritization of data sharing within their organizations and may serve as a starting point for a data sharing *toolkit* for nonprofit funders of clinical trials to provide the clarity of mission and mechanisms to enforce the data sharing practices their communities already expect are happening.

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## KEYWORDS

clinical trial; biomedical research; data sharing; patients

## Introduction

### Clinical Trial Data Sharing and the Role of Nonprofit Funders

Sharing clinical trial data can provide value to research participants and communities by accelerating the development of new knowledge and therapies as investigators merge data sets to conduct new analyses (eg, meta-analyses, statistical modeling), reproduce published findings to raise standards for original research, and learn from the work of others to generate new research questions.

Nonprofit funders, including disease advocacy and patient-focused organizations, play a pivotal role in the promotion and implementation of data sharing policies. Funders are uniquely positioned to promote and support a culture of data sharing by serving as trusted liaisons between potential research participants and investigators who wish to access these participants' networks for clinical trial recruitment. In short, nonprofit funders can both drive policies and influence research culture.

In the US Institute of Medicine (IOM) 2015 report, *Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk*, nonprofit funders were specifically identified as key stakeholders for advancing data sharing, while the important role of clinical trial participants, themselves, was additionally recognized [1]. As stated in the report, "the movement towards greater transparency is being further accelerated by trial participants...and a larger cultural shift already underway...in which the results of research are deemed a public good that can benefit society only when shared in a timely and responsible manner."

Despite arguments to the contrary, in many cases, clinical trial participants are indeed willing to share their data for a wide range of uses, assuming that adequate security safeguards are in place [2]. Patients may assume that data sharing is already taking place and could become frustrated when they learn that many nonprofit organizations and academic researchers are not actively implementing data sharing policies. Patient communities rightfully expect that the nonprofit funders who encourage them to enroll in studies would also take action to ensure that data resulting from these trials are shared.

### The Current State of Clinical Trial Data Sharing

Since the release of the 2015 IOM report, several efforts in the public sector have signaled that data sharing is increasingly regarded as a scientific responsibility rather than an optional activity [3-5]. For example, the bipartisan 21st Century Cures Act signed into law in December 2016 contains a number of provisions focused on advancing the responsible sharing of clinical trial data from government-funded research and improving public interfaces such as ClinicalTrials.gov [6]. ClinicalTrials.gov has since implemented changes to facilitate centralized access to and the discoverability of individual participant data (IPD) sharing plans and whether and where IPD and supporting information (eg, clinical study reports) are available after study completion [7]. In 2016, the FAIR Data Principles were published, providing guidelines for making scientific data FAIR—findable, accessible, interoperable, and reusable [8]. The GO FAIR Initiative was also established to help implement these guidelines, focusing on early developments in the European Open Science Cloud [9]. The International Committee of Medical Journal Editors also released policies requiring increased transparency and prioritization of data sharing among the manuscripts submitted to their journals. The Wellcome Trust released a policy on managing and sharing research outputs that include data, software, and materials [10-12].

More recently, for public comment, the National Institutes of Health (NIH) released an updated Draft NIH Policy for Data Management and Sharing, which would require NIH-funded grantees to submit a data management and sharing plan on how researchers intend to preserve and share their data [13-15]. In addition, clinical trial data sharing platforms such as Vivli, the Yale University Open Data Access Project, Supporting Open Access for Researchers, and ClinicalStudyDataRequest.com have enabled researchers and sponsors seeking share and access data from clinical trials [16-18]. Clinical trial data sharing workshops, such as the National Academies' recent 2019 workshop, *Sharing Clinical Trial Data: Challenges and a Way Forward*—have also helped advance the dialog by highlighting challenges, successes, and next steps in data sharing endeavors [19].

In 2015, following the publication of the IOM consensus study, *Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk*, Tudur Smith et al [20] published a set of *good practice*

*principles* for data sharing, which emphasized controlled and secure access, participant consent and confidentiality, and a multistakeholder approach for supporting the required resources [1]. Additional publications since this time have included the development of data sharing principles for specific diseases such as the Alzheimer disease, critiques of data access review policies, and proposed strategies for implementing protected cloud-based methods of clinical trial data sharing [21-23]. In a more comprehensive critique on data sharing and the reuse of individual participant-level data from clinical trials, Ohmann et al [24] published a number of principles and recommendations that resulted from a multistakeholder consensus process. Although these principles and recommendations are not necessarily targeted for nonprofit funders, there may be potential applications for funders, as is reflected in this data sharing paper.

Other recent publications have more specifically assessed and advised the practices of funders in data sharing. In one retrospective review published by Whitlock et al [25], clinical trial transparency policies were evaluated among the top 10 noncommercial US health researcher funders. The overall proportion of US funders with policies and practices to support transparency was found to be similar to that of larger international noncommercial funders. Terry et al [26] have additionally provided the following few key recommendations specific to funders to support the sharing of data: (1) funders should engage early with researchers to understand their concerns and more explicitly define the benefits for all stakeholders, (2) there should be a direct benefit to sharing data relevant to those people who collect and curate the data, and (3) a checklist of issues to be addressed should be developed for designing or revising data sharing resources.

### Challenges and Goals for Nonprofit Funders

Although data sharing has gained momentum, major challenges remain, including transparency of data access procedures, reuse of consent provisions (ie, policies that accommodate participant consent regarding the volume, nature, and timing for secondary use of clinical trial data for future scientific research), governance of data sharing policies, availability of affordable technical infrastructure, alignment on data standards, and a highly fragmented landscape of data repositories [27,28]. In particular, for nonprofit funders, data sharing can be a resource-intensive activity, requiring investment trade-offs between data sharing and other research priorities. In terms of bargaining power, nonprofit funders often have limited capability to enforce policies and contracts with individual investigators, despite having provided financial support for research projects.

The purpose of this paper is to detail a set of aspirational goals and forward thinking, collaborative solutions to data sharing for nonprofit funders to fold into existing funding policies. This paper was developed by the Sharing Clinical Trial Data Action Collaborative, an ad hoc activity associated with several forums at the National Academies of Sciences, Engineering, and Medicine: the Forum on Drug Discovery, Development, and Translation; the Roundtable on Genomics and Precision Health; the Forum on Neuroscience and Nervous System Disorders; and the National Cancer Policy Forum. The paper does not

necessarily represent the views of any one organization, the Forums or Roundtable, or the National Academies and has not been subjected to the review procedures of, nor is it a consensus study report or product of, the National Academies.

Throughout this paper, *nonprofit funders* refers to both traditional nonprofit funders (such as foundations and philanthropic organizations) and the full spectrum of nonprofit patient-focused and disease-advocacy organizations that fund or otherwise support clinical trials and *grantees* refers to those individuals, groups, institutions, and organizations who receive funding or other support for clinical trials. Clinical trial data may take many forms, including IPD (ie, raw data and the analyzable data set); metadata, or the information required to contextualize and understand a given data element; and summary-level data. Data may be identifiable or deidentified. *Data sharing* within this paper refers to the process of making clinical trial data—particularly IPD—available to secondary users, and *shared data* refers to any data accessed as a result of data sharing policies and processes. Recognizing that a range of contracting arrangements are possible, *grantees* refers to those receiving funds from nonprofit organizations and could be either (1) the research institution as a whole or (2) an individual researcher. Although this paper aims at data from prospective, interventional clinical trials, many of the goals and illustrative examples encompass clinical research more broadly.

## Sharing Clinical Trial Data Action Collaborative

To discuss and advise on the development of data sharing goals for nonprofit funders of clinical trials, an ad hoc group of individuals with relevant expertise representing nonprofit organizations and other stakeholders, including patient and disease advocacy representatives, researchers, regulators, and drug developers, was convened in July 2016 (n=9) and November 2017 (n=39) in Washington, DC, associated with the Sharing Clinical Trial Data Action Collaborative of the National Academies of Sciences, Engineering, and Medicine. Invited participants were identified by project coleaders, Sharon Terry (Genetic Alliance) and Timothy Coetzee (National Multiple Sclerosis Society), and with the research assistance of National Academies staff, to represent a subset of nonprofit funders of clinical trials interested in exploring and implementing data sharing policies. Over the course of planning for the 2016 and 2017 discussion meetings, 70 individuals were invited and 48 accepted and participated in either or both the 2016 and 2017 meetings.

The 2016 meeting focused on gathering feedback on a draft set of data sharing principles for nonprofit funders drafted by Sharon Terry, Tim Coetzee, and National Academies staff working with Action Collaborative and drawn largely from themes in the 2015 IOM report, *Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk* [1]. On the basis of the 2016 discussion meeting, the principles were refined, including changing *principles* to *goals*, and presented to the larger group of stakeholders at the 2017 meeting. The 2017 discussion led to additional rounds of editing and refining by email among the meeting participants to reach the paper presented here. The

project coleaders made clear to meeting participants that all views—supportive or not—of data sharing were welcome throughout the process.

The National Academies provided a neutral venue for nonprofit funders to have a candid conversation about the opportunities and challenges of taking up formal data sharing policies within their organizations. Participants in this activity had an opportunity to share perspectives, sharpen questions, spark new ideas, and explore possible solutions. The participants did not cover a full representation of the nonprofit community. The goals included in this paper are not binding agreements but rather indications of support for advancing clinical trial data sharing among the nonprofit community.

### **Data Sharing Goals for Nonprofit Funders of Clinical Trials**

#### ***Goal #1: Encourage Co-Development of Data Sharing Policies With Patient and Lay Communities***

Patient communities and the lay public should have a voice in the development of data sharing policies regarding what and how data will be shared with others, including, but not limited to, IPD, participant-generated data (eg, patient-reported outcomes, patient data acquired from wearables), lay summaries, and resulting publications [29]. Members of the lay public should be codevelopers of all aspects of clinical research, including, but not limited to, clinical trial data sharing programs. The input and participation of patient communities and the lay public should infuse the entire process and be clearly stated in the informed consent process; it cannot be reverse engineered.

Embedded in this goal is the collective duty of nonprofit funders to prioritize educating patient communities about data sharing and build an informed public trust around the value of clinical trials and data sharing.

#### ***Goal #2: Incorporate Data Sharing Concepts and Policies as Early as Possible in the Clinical Trial Process***

Nonprofit funders should strive to prioritize data sharing in the earliest conceptions of a clinical trial. The ultimate utility of shared clinical trial data often hinges on the degree to which sharing was planned for from the beginning—a principle also endorsed by the multistakeholder task force on data sharing, as described by Ohmann et al [24]. When sharing is planned well in advance, researchers can ensure that data are collected and prepared in a way that enables effective sharing.

Nonprofit funders can incorporate data sharing principles into grant application policies. For example, grant provisions could require that the proposed clinical trials include a plan for how and when data from the trial will be shared and that clinical

trials be registered on a public data sharing platform (eg, ClinicalTrials.gov). In addition, nonprofit funders may set expectations for awardees to deposit clinical trial data in public databases and publish results of the trial regardless of the outcome.

#### ***Goal #3: Develop or Adopt Transparent and the FAIR Approval Processes for Data Access***

Nonprofit funders should work with grantees and patient communities to ensure that data access policies (1) facilitate the appropriate use of shared data, (2) enable research participants' data access preferences, (3) protect participant privacy, and (4) mitigate risks to the scientific integrity of investigators and sponsors that share data (ie, reducing the likelihood of misuse or misanalysis of shared data)—all without unduly restricting access to shared data. This goal echoes broader data sharing goals of making data access processes more explicit and transparent, and funder actions made to achieve this goal would additionally demonstrate support and alignment with FAIR principles [24,25].

Data access policies may vary based on the type of data being collected in a clinical trial and the preferences of the community. For instance, IPD with imaging and genetic information may warrant a third-party intermediary to review requests, as opposed to open access for anyone. It is difficult to make one-size-fits-all decisions on who should be authorized to have access to data, but variations are possible. For instance, platforms and technology exist to enable individuals to decide who should access their data.

Nonprofit funders could encourage or require grantees to provide the following information and respect the following policies as objective signals of the FAIR use and intent:

1. Establishing a plan or proposal that states the purpose of the data request (eg, to support hypothesis generation or protocol development)
2. Providing evidence via a standard biographical sketch of the qualifications of the requestor
3. Using data use agreements that may help ensure that data requesters follow the plan stated in the original request and do not attempt to use data in harmful or malicious ways, such as reidentifying participant data or using data for commercial or litigation purposes
4. Sharing clinical trial data, particularly of sensitive nature, in a way that it can be housed, accessed, and analyzed behind a firewall or other secure mechanism
5. Third-party review teams can vet data requests to provide an independent, transparent, accountable, and efficient data access review process (Textbox 1).

**Textbox 1.** Considerations for third-party teams reviewing data requests.

**Third-party review teams could consider the following criteria when reviewing requests for data:**

1. Can the data requested support the stated purpose of the requestor?
2. Does the request have a public health or health goal and address real patient needs?
3. What technology infrastructure is used to provide data access, and who is the data steward?
4. What data standards are used to share the final data set?
5. What data versioning processes does your data steward recommend?
6. What data variables and data types are shared and over what length of time?
  - What security measures are required for your shared data?
  - What is detailed in the data documentation (ie, data dictionary, schemas, example analyses, and use)?

***Goal #4: Promote the Development of a Sustainable and Feasible Data Sharing Infrastructure***

Requiring that data be shared but not providing a place to host shared data is an impractical mandate, and the recognition of the general need to properly structure and build a suitable and sustainable infrastructure for data sharing has remained an important recognition [24]. Consequently, an increasing number of platforms for data storage, curation, sharing, and archiving exist or are in development. For example, the Genetic Alliance established Promise for Engaging Everyone Responsibly (PEER) to help advocacy organizations, nonprofits, clinics, and sponsors establish data collection registries [30]. PEER enables participants to securely upload and store data (eg, electronic health records, health surveys, genomic and genetic information) and decide what data they will share. Companies and researchers can then access data to carry out study analysis with the appropriate embargos and mechanisms to release data back to the individuals and communities.

Many nonprofit funders acknowledge that developing and maintaining the technology to support a data repository is beyond their skill set. Thus, nonprofit funders will increasingly be looking to external platforms—and partnerships with technology companies—for hosting shared data. Nonprofit funders should work together to collectively form partnerships and provide support (eg, funding, guidelines, and requirements) for data sharing platforms in accordance with the needs and goals of their communities. Although each community will still have unique needs and expectations, there are significant similarities among the desired specifications of a data sharing infrastructure and much to be gained from ensuring that data are not unnecessarily siloed.

Within their organizations, nonprofit funders should develop and implement data sharing guidelines and/or policies that detail requirements for storage, curation, standards, documentation, sharing, and archiving of data produced by grantees. Nonprofit funders are encouraged to use the goals outlined in this paper as a framework for such guidelines or policies. When possible, nonprofit funders should support the training of grantees on the tools and methodologies for sharing and appropriately analyzing data.

***Goal #5: Promote and Support the Development and Adoption of Standards, Standard Language, and Common Data Elements***

Standards relevant to research data sharing encompass a number of types, including common data models; transport or exchange formats; metadata standards and analysis standards; data elements; terminologies and vocabularies, ontologies, and code lists. Organizations such as the Clinical Data Interchange Standards Consortium, TransCelerate, and the Critical Path Institute continue to develop and maintain the data standards, tools, and methods needed to support clinical trial data sharing [31-33]. Nonprofit funders should join other stakeholders to promote the use of standards during data collection, enabling easily discoverable, searchable, interoperable, and reproducible results [10]. Disease-specific nonprofit funders can lead to defining and promoting common data elements specific to their disease of interest but should also work across disease areas to find commonalities across diseases. The development of unique data elements for a particular disease has been the norm; however, unexpected connections across diseases and treatments have been found, and ensuring a level of interoperability and comparability can only increase the power of the data being collected. Common data elements typically present a question and valid answers to be recorded in a case report form and often specify the method to be used in collecting measurements. To enable comparisons of studies that apply the same measurement method, funders can also encourage the use of standardized protocols. Funding organizations may also issue manuals on exactly how a test should be conducted (eg, the Timed 25 Foot Walk in multiple sclerosis) in the context of a clinical trial.

***Goal #6: Include Incentives and Enforce Requirements in Grants, Contracts, and Other Funding Structures, Which Promote and Provide Accountability for Investigators to Share and Use Shared Data***

Nonprofit funders should, at a minimum, require that investigators have a data sharing plan in place before enrollment of the first participant that dictates when, what, with whom, how, and under what circumstances the data will be shared. Nonprofit funders can direct grantees to applicable guidelines for specific provisions of data sharing plans, in accordance with the needs of each nonprofit funders' organization, in general, and the clinical trial at hand, in particular [11-14]. For some

communities and trials, open access to data might be appropriate, whereas others will require more limited or tiered access.

The need to improve incentives has also been emphasized by others, and nonprofit funders are in a unique position to incentivize researchers by promoting the recognition of investigators who share their data [24,25]. Funders should encourage applicants to include shared data sets as part of the biographical sketch in a proposal. Furthermore, they should instruct reviewers of proposals to view a track record of shared data sets as a positive achievement, demonstrating research productivity.

**Textbox 2.** Mechanisms for nonprofit funders to incentivize data sharing or the use of shared data sets in new research.

**To incentivize data sharing or using shared data sets in new research, nonprofit funders could:**

1. Publish a list of top data sharers and shared data users for usage analytics, either within their organization or in partnership with other organizations.
2. Highlight the success stories of data sharing or the use of shared data by grantees in articles in high-impact publications.
3. Provide credit and/or rewarding grantees who share data and use shared data.
4. Engage in open science efforts that incentivize the use of publicly available data, crowdsource challenges in medicine, and share the data and insights gleaned from the work (eg, DREAM Challenges) [15].
5. Educate both patient and research communities on the benefits of data sharing to create an expectation of data sharing in clinical research.

**Goal #7: Provide Funding for Data Sharing and Include This Activity as a Line Item in Grants and Contracts**

Implementing data sharing involves costs, but the precise cost is often a challenge to unearth. Nonprofit funders face difficult decisions, including whether to prioritize and pay for data sharing, thereby funding fewer new grants for research. Nonprofit funders could include, as a provision in grants and contracts, the allocation of funds to support sharing the data produced by the funded research. This could entail a line item dedicating a set amount of funding, or a percentage of overall funding, to data sharing efforts. Even if they do not provide the full funding for a particular trial, organizations may use their leverage to insist on such terms in grants and contracts before promoting trials to their networks. Organizations are broadly encouraged to incorporate data sharing costs into their respective funding models, maintaining a diverse, mission-aligned portfolio. If practical, and conducive to the organization's policies, charging a fee for access to data could help defray the cost of data sharing.

Mechanisms by which nonprofit funders could *enforce* the adoption of data sharing agreements in grants and contracts or the use of shared data sets in research design could include:

1. Withholding a portion of the allocated funding until certain benchmarks of data sharing plans are realized
2. Including a neutral third party as an honest broker to administer the sharing of data in a responsible manner
3. Promoting the clinical trial to the nonprofit funder's patient or disease advocacy networks contingent on inclusion of language stipulating a data sharing plan
4. Requiring a data sharing plan as part of any funding request, which includes an appropriate level of detail demonstrating specific steps to comply with the funder's data sharing requirements

Data are valuable and often one of the greatest assets a nonprofit organization has. However, nonprofits are encouraged to maintain a clear focus on their mission and resist the temptation to unnecessarily keep data internal to their organization. Nonprofit funders should consider how to incentivize grantees to use externally authored shared data sets to improve the proposed clinical research design (eg, to better estimate the effect size of the proposed treatment; [Textbox 2](#)). This reuse of existing data sets further emphasizes the above goals of technical infrastructure, standards, common data elements, and sufficient documentation for grantees to integrate and reproduce results.

In addition, nonprofit funders may facilitate the adoption of data sharing agreements by offering examples of organizations providing funding to support data sharing, such as NIH (eg, NIH grantees are permitted to charge the salaries of administrative and clerical staff as a direct cost to help investigators meet their responsibilities under the NIH policy on reporting research results) [7].

**Goal #8: Incorporate Previous Data Sharing as a Measure of Impact When Making Decisions on Whether to Fund or Support Clinical Trials**

As part of the decision-making process surrounding funding or support of clinical trials, nonprofit funders should request that prospective grantees with a history of sharing data provide evidence and impact of previous data sharing and, to the extent possible, invite grantees to provide evidence of the impact of earlier data sharing. Such evidence could include new collaborations, publications, novel analysis or findings, or the evidence that emerges from secondary monitoring of usable spaces to see who is active in the community and contributing to knowledge generation. Nonprofit funders might consider conducting pilot projects to evaluate the feasibility and identify the challenges of including prior data sharing as an impact measure.

## Discussion

The goals in this paper convey the complexity of the opportunities and challenges facing nonprofit funders and seek to provide a starting point for a data sharing *toolkit* for nonprofit funders to provide the clarity of mission and mechanisms to enforce data sharing practices their communities already expect are happening. Simply requiring data sharing by grantees would be insufficient—nonprofit funders and the communities they represent expect high-quality sharing efforts that go beyond

*check-the-box* exercises. A *toolkit* for nonprofit funders might include guidance, templates, general information, and other additional resources that might be of benefit to nonprofit funders—all of which could be informed, in part, by the goals in this paper.

There are costs associated with data sharing activities; therefore, it will be important to ensure that the aspirational goals expressed in this paper do not create an undue burden on researchers, nonprofit funders, and trial participants. Some of the data sharing approaches that have been developed by the participant and advocacy community may help relieve investigators of administrative burden by streamlining data storage, curation, sharing, and archiving processes. In addition, data sharing platforms have the potential to improve aspects of clinical trial research that go beyond data sharing alone (eg, enhancing participant recruitment, engagement, retention, and encouraging collaboration).

Nonprofit funders, along with other key stakeholders, play an important role in ensuring the responsible sharing of clinical trial data. The goals in this paper offer a path forward for nonprofit funders to continue to take steps, even if incremental, toward a more robust data sharing ecosystem.

## Organizations Supporting These Goals

- Alzheimer's Association
- Center for Open Science
- Genetic Alliance
- Critical Path Institute
- Doris Duke Charitable Foundation
- Food Allergy Research & Education
- Geoffrey Beene Foundation Alzheimer's Initiative
- Global Healthy Living Foundation
- Michael J. Fox Foundation for Parkinson's Research
- Multiple Myeloma Research Foundation
- National Health Council
- National Multiple Sclerosis Society
- National Psoriasis Foundation
- New York Stem Cell Foundation
- Open Humans Foundation
- Pancreatic Cancer Action Network
- Parent Project Muscular Dystrophy
- Parkinson's Foundation
- Parkinson's UK
- Susan G. Komen
- The V Foundation for Cancer Research
- Vivli

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## Conflicts of Interest

Author BAN is the Executive Director of the non-profit Center for Open Science that operates the Open Science Framework (<http://osf.io/>) and has a mission to increase openness, integrity, and reproducibility of research; Author IS is the Co-Founder and consultant to Vivli. Author AFH has received research funding from American Regent, Astra Zeneca, Boehringer Ingelheim, Merck, Novartis, and Verily and is also a consultant to Amgen, Astra Zeneca, Boehringer Ingelheim, Boston Scientific, Bayer, Merck, and Novartis. All other authors have no conflicts to declare.

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## Abbreviations

- FAIR:** findable, accessible, interoperable, and reusable  
**IOM:** Institute of Medicine  
**IPD:** individual participant data

**NIH:** National Institutes of Health

**PEER:** Promise for Engaging Everyone Responsibly

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Original Paper

# Diabetes Prevention in Adolescents: Co-design Study Using Human-Centered Design Methodologies

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## Abstract

**Background:** The rise in pediatric obesity and its accompanying condition, type 2 diabetes (T2D), is a serious public health concern. T2D in adolescents is associated with poor health outcomes and decreased life expectancy. Effective diabetes prevention strategies for high-risk adolescents and their families are urgently needed.

**Objective:** The aim of this study was to co-design a diabetes prevention program for adolescents by using human-centered design methodologies.

**Methods:** We partnered with at-risk adolescents, parents, and professionals with expertise in diabetes prevention or those working with adolescents to conduct a series of human-centered design research sessions to co-design a diabetes prevention intervention for youth and their families. In order to do so, we needed to (1) better understand environmental factors that inhibit/promote recommended lifestyle changes to decrease T2D risk, (2) elucidate desired program characteristics, and (3) explore improved activation in diabetes prevention programs.

**Results:** Financial resources, limited access to healthy foods, safe places for physical activity, and competing priorities pose barriers to adopting lifestyle changes. Adolescents and their parents desire interactive, hands-on learning experiences that incorporate a sense of fun, play, and community in diabetes prevention programs.

**Conclusions:** The findings of this study highlight important insights of 3 specific stakeholder groups regarding diabetes prevention and lifestyle changes. The findings of this study demonstrate that, with appropriate methods and facilitation, adolescents, parents, and professionals can be empowered to co-design diabetes prevention programs.

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**KEYWORDS**

diabetes prevention; adolescents; human-centered design

## Introduction

Excess weight and obesity in youth continue to be a serious public health concern [1] and put youth at risk of developing

type 2 diabetes (T2D) [2]. T2D in youth increased by 4.8% per year from 2002 to 2012 [3] and is predicted to increase fourfold by 2050 [4]. Minority youths are disproportionately affected [5,6]. Non-Hispanic Black youth experienced the largest annual

increases (6.3%) in T2D compared to non-Hispanic White youth (0.6%) [3]. Furthermore, early onset of T2D and poor glycemic control increase the risk of diabetes-related complications and decrease life expectancy [7]. Findings from the Treatment Options for Type 2 Diabetes study and the Restoring Insulin Secretion Pediatric Medication Study illustrate the aggressive nature of T2D in youth and assert the urgent need for efficacious diabetes prevention strategies for at-risk youth [8,9].

Diabetes prevention strategies for adults have seen significant progress [10-17], but less is known about effective diabetes prevention strategies for adolescents. The Bright Bodies Healthy Lifestyle program and The Every Little Step Counts-Diabetes Prevention Program show promising outcomes for modifying risk factors for developing T2D in adolescents [18,19]. However, behavior modification of adolescents is complex as family dynamics at home play a pivotal role in facilitating change and shaping attitudes and beliefs about food choices and physical activity [20-26]. Low socioeconomic status, limited access to healthy food choices and physical activity, and individual motivators pose further barriers to lifestyle changes in high-risk adolescents [27-33]. These complexities make it especially important to solicit the expertise of adolescents and their families in shaping prevention strategies [34]. This can be accomplished by using human-centered design (HCD) techniques.

HCD is a qualitative problem-solving approach that engages stakeholders in the process of exploration, development, and implementation of solutions [35]. HCD is particularly effective in facilitating multidisciplinary collaboration, eliciting deep insights, and creating solutions compatible with end stakeholders' needs [36]. HCD may be a promising approach for diabetes prevention [37], but more studies on the application of HCD in health care are needed [38].

For these reasons, we engaged at-risk adolescents, their parents, and professionals in a series of HCD sessions to answer the following questions: (1) what environmental factors inhibit/promote lifestyle changes in adolescents and their families? (2) what are the ideal characteristics of a diabetes prevention program for this population? and (3) what are the effective strategies to engage adolescents and their families in a diabetes prevention program? This paper describes the first phase of a study to co-design a diabetes prevention program for adolescents and their parents by using HCD.

## Methods

### Study Design

This formative study consisted of 4 HCD sessions: 1 professional session, 2 adolescent and parent sessions, and 1 adolescent-only session. We collaborated with Research Jam, which is part of the Indiana Clinical and Translational Sciences Institute's Patient Engagement Core [39]. Research Jam is a multi-disciplinary team of bachelor's and master's level human-centered designers and health services researchers with experience in using HCD methods to engage stakeholders in exploring health challenges and cocreating solutions.

### Participant Recruitment

#### Professionals

We recruited a group of individuals with expertise in diabetes prevention or adolescents (referred to as professionals for brevity) to participate in 1 HCD session. Initially, the primary investigator reached out to colleagues who were involved in diabetes prevention or experts working with adolescents. Examples include physicians, diabetes educators, and community youth organizations. Additional professionals were recruited through a snowball sampling technique as initial participants invited colleagues who met the aforementioned criteria. Professionals were invited to participate in one 90-minute session and were compensated with US \$50 per hour for their time.

#### Adolescents and Parents

Adolescents and parents were recruited in 4 ways. First, the professional group members recruited adolescents and parents in connection with their organizations by distributing flyers and word of mouth. Second, adolescents and parents were recruited from a youth diabetes prevention clinic. Third, adolescents and parents were recruited from an existing local family-focused nutrition and physical activity program. Finally, a school-based adolescent group was recruited by a school nurse from a local high school.

#### Inclusion Criteria

The inclusion criteria for adolescents were (1) between the ages of 10 years and 17 years, (2) overweight (BMI  $\geq$ 85th percentile for age and gender, weight for height  $\geq$ 85th percentile, or weight  $\geq$ 120% of 50th percentile for height), (3) with 2 additional risk factors for T2D (diagnosis of prediabetes, family history of T2D in first-degree or second-degree relatives, belong to racial/ethnic minority group with high risk, have conditions associated with insulin resistance, have had gestational diabetes or exposure to gestational diabetes in utero), (4) English speaking, and (5) a parent willing to participate in the family session (with the exception of the high school group).

Two adolescent and parent research sessions were offered simultaneously in the same building but in separate rooms. The school-based adolescent group took part in 1 session at a high school. Participants were compensated with US \$20 per hour of their time. These sessions lasted 3 hours. The Indiana University Institutional Review Board approved this study and participants provided written informed consent prior to engaging in any research activities. In order to address ethical considerations, adolescents younger than 14 years underwent the assenting process, documents were written at a sixth-grade reading level, and compensation was set at a level that covers participants' time and effort without being coercive.

#### Data Collection

Research Jam facilitated the HCD sessions. All sessions were audio recorded with participant permission. Research Jam recorded field notes during activities and discussions. Each session consisted of activities that aligned with the study objectives to (1) better understand environmental factors that inhibit/promote lifestyle changes, (2) elucidate desired program

characteristics, and (3) explore improved activation in diabetes prevention programs (Table 1). The purpose of the activities was to understand diabetes prevention from the participants' perspective and elicit desired prevention strategies. Activities used a variety of methods to explore participant insights, including barrier mapping, envisioning and enacting, drawings, and discussions. For instance, Research Jam utilized a drawing activity as a method to elicit tacit knowledge. Small groups of participants were instructed to draw the "worst diabetes prevention program ever" and share their drawings with the larger group for discussion. Another activity involved drawing

the "best party ever," and then modifying the party to motivate healthy behaviors. The outcomes of the drawing activities acted as a catalyst for brainstorming among participants. To engage participants in a potentially sensitive topic, Research Jam used activities that were age appropriate and nonjudgmental. Adolescent and parent sessions began with a Forever/Never icebreaker. Participants shared something they wished to do all the time and something they wished to never do again. This allowed group members to get to know each other while providing information about the possible components to include in the program design (Multimedia Appendix 1).

**Table 1.** Objectives of the sessions and the activities performed.

Sessions, activities	Objective
<b>Adolescents and parents session 1</b>	
Perception of risk	Engagement strategies
Forever/Never icebreaker	Ideal characteristics
Barrier issue posters (Part 1)	Environmental factors
Barrier issue posters (Part 2)	Ideal characteristics
Worst/Best program ever drawing	Ideal characteristics and engagement strategies
Program pitch	Ideal characteristics and engagement strategies
<b>Adolescents and parents session 2</b>	
Barrier issue posters (response)	Environmental factors and ideal characteristics
Forever/Never icebreaker	Ideal characteristics
Motivator discussion	Engagement strategies
Worst/Best program ever drawing	Ideal characteristics and engagement strategies
<b>School-based adolescent session</b>	
Cartoon caption	Engagement strategies
Forever/Never icebreaker	Ideal characteristics
Diabetes prevention party drawing	Ideal characteristics and engagement strategies
<b>Professionals session</b>	
Barrier mapping	Ideal characteristics and environmental factors
Best program ever drawing	Ideal characteristics and engagement strategies
Bad idea parking lot	Ideal characteristics

**Analysis**

The Research Jam project lead conducted collaborative analysis meetings with 4 members of Research Jam who helped facilitate the sessions. The team physically separated individual pieces of explicit data onto slips of paper. Data that required interpretation such as drawings were analyzed by capturing components included in the drawings onto slips of paper. For example, a picture of people sitting still in chairs was coded as physically inactive. This work was reviewed by Research Jam team members to ensure all data were captured. The team then

used affinity mapping to physically organize the data pieces by similarity [40]. Team members continuously discussed data groupings and theme identification to iteratively refine and ensure consensus. This was particularly important as Research Jam staff members facilitated different sessions and no member was involved in every session. Next, Research Jam staff members mapped the themes related to the ideal diabetes program and engagement strategies by population to the Activity, Environment, Interaction, Object and User framework, which is based on ethnography traditions and data organization into activities (goal-directed sets of actions), environments (the

arena in which activities take place), interactions (interplays between people or objects), objects (key elements that make up the environment or with which people may interact), or users (people active in the environment) categories [41] (Multimedia Appendix 2). Research Jam did not use the user category as the participants did not discuss the ideal program users.

## Results

### Session Participation

#### *Professionals*

Fourteen individuals participated in the professional group session. This session took place at a community church that had space to accommodate this group size. The group consisted of physicians, researchers, diabetes educators, school personnel, Young Men's Christian Association staff members, a nurse manager at a community health center, a church pastor, a youth mentor, and a youth counselor.

#### *Adolescents and Parents*

The first adolescent and parent session consisted of 18 people with 5 parents and 13 adolescents and took place at a community church. The second adolescent and parent session consisted of 14 people with 6 parents and 8 adolescents and took place at a community center. The school-based adolescent group session consisted of 12 adolescents and took place at a high school.

#### *Session Findings*

The session findings are presented based upon the objectives of the session. No other evaluation of participation was conducted.

### Environmental Factors That Promote Adopting Lifestyle Changes

#### *Healthy Choices Are Acceptable*

Both adolescents and professionals stated that creating an environment where healthy choices are acceptable and appealing was important. One professional stated, "What they would actually want to do, not what they feel like they're supposed to do or have to do, but that the healthy choice is like the awesome choice."

#### *Affirming*

Both adolescents and professionals stated that it was important that a diabetes prevention program was affirming and not judgmental.

#### *Focus on Positive*

Parents and adolescents reported they wanted a program that avoided focusing on what not to do. This was best illustrated with cupcakes on the table with a sign reading "do not eat" (Multimedia Appendix 3).

#### *Try New Things*

Adolescents and parents felt that trying new foods and activities was an important part of adopting healthy behaviors that fit their lifestyle. Adolescents were interested in trying activities that were out of the ordinary or taking ordinary things and

experiencing them in novel ways. For instance, adolescents created a drinkable swimming pool as a component of the diabetes prevention party (Multimedia Appendix 4). This idea represents a new spin on the recommendation to drink water instead of sugary drinks.

### Barriers to Adopting Lifestyle Changes

#### *Environmental Barriers*

Adolescents, parents, and professionals reported barriers such as lack of access to reliable transportation, access to healthy foods, and safe places for physical activity.

#### *Limited by Availability*

Adolescents reported that food choices are often limited by the options offered by parents, schools, and vending machines. As one adolescent described, "If you go to the vending machine, everything has some sort of sugar or fat in it. There aren't really options for healthy stuff."

#### *Cost of Healthy Foods*

All groups discussed the costs of healthy versus processed foods as a significant barrier. In addition, participants viewed wasted food as wasted money and viewed free food as free money such as buffets and free refills.

#### *Lack of Time*

Parents felt that the time required to cook healthy meals and engage in exercise was a luxury not afforded to them. As one parent explained, "When they don't get home and mom doesn't get home until late, then it's like, okay throw a pizza in."

#### *Competing Priorities*

All participant groups identified competing priorities as a barrier. The demands of work, school, financial strain, and unsafe neighborhoods made healthy lifestyle change a lower priority than imminent needs. Adolescents felt that a long sedentary school day coupled with required evening homework time impeded efforts to increase physical activity. Parents' comments regarding the workday and challenges incorporating physical activity mirrored the adolescents' sentiments on this topic. Additionally, parents verbalized safety concerns around independent outdoor play for youth. One parent described how different her childhood was from that of her children, "Even though I tried, my kids' life is so much different from the way I was raised. Some of it was because I was afraid to send them out to play—but I was out and my mom didn't know where I was most of the day...I would ride my bike 2 or 3 miles from home. That's just not my kids' existence. They've never had that."

#### *Food is Addictive*

Adolescents and parents described foods and beverages high in sugar or salt as having an addictive quality. As one parent stated, "I'm trying desperately to find things that taste good and are healthy." They also felt that situations where others continued to eat those foods in their presence hindered their efforts. Adolescents specifically called out celebrations, which so often center around unhealthy foods, as problematic for maintaining healthy eating habits.

## **Ideal Characteristics of a Diabetes Prevention Program for Adolescents and Their Families**

### ***Fun***

All groups reported that having fun should be the primary focus of a diabetes prevention program.

### ***Importance of Play***

Adolescents, parents, and professionals identified “play” as an important factor in an ideal program. Adolescents expressed play as participation in sports and free movement activities (eg, basketball, swimming, volleyball, dancing). Parents identified play as hands-on learning activities such as cooking classes, recipe sharing, and exercises not available at home.

### ***No Lectures***

All participant groups were averse to didactic lecture-style sessions. For instance, the worst program ever drawings included an instructor in front of a class saying “blah, blah, blah” and a participant saying, “May I speak now?” ([Multimedia Appendix 3](#)). Additionally, an adolescent stated, “A lecture is when someone talks at you instead of talking with you.” Participants wanted hands-on, collaborative, and motivating learning experiences such as cooking and socializing. All participants wanted to avoid homework and handouts. As one parent stated, “I want to know how to cook the way my mother cooked but substitute things that are healthier, so I can still get the foods that I like.”

### ***Facilitator Characteristics***

Adolescents wanted a facilitator who incorporates fun. Parents desired a facilitator that adolescents can look up to. All participants wanted program staff who were fun, engaging, and respectful.

### ***Rewarding Success***

Adolescents, parents, and professionals saw value in rewarding success. Adolescents verbalized money or access to an experience as motivating rewards. For instance, in one of the diabetes prevention party drawings, adolescents envisioned a reward where trying healthy behaviors gained them access to “the real party” ([Multimedia Appendix 4](#)). Parents verbalized rewards such as gym memberships while professionals thought that free or discounted food or cooking equipment were good incentives.

### ***Try New Foods***

A central focus for all participants was the inclusion of delicious healthy foods to try.

### ***Build Relationships***

Adolescents, parents, and professionals saw value in friendships and personal relationships as part of the program. All participants identified personal relationships as vital to the success of their program or party drawings. One adolescent explained, “I think you get to know the people that you’re going to be doing the class with and it’s a lot easier. So, if you do some sort of like fun game or activity at the beginning and people get to know each other pretty well, it’s much easier to

have a good time.” The ability to collaborate was also important in their drawings.

## **Effective Strategies to Engage Adolescents and Their Families**

### ***Use the Right Messaging***

All participants agreed that messaging can be vital to getting adolescents to the program. Parents suggested using an acronym that sounded fun and social, such as “FIT: Fight it Together.” Adolescents suggested using messaging that sounded better than the actual program in order to get adolescents to the door. One adolescent answered the question about how to get adolescents to attend a diabetes prevention program by saying, “Probably make it sound better than it is because once they are there, they probably won’t leave.”

### ***Reward Healthy Behaviors***

All groups thought it was important to use rewards that promote healthy behaviors and celebrate success.

### ***Use Inviting Language***

Adolescents felt that “diabetes prevention” and “health” were not motivating messages to lead with because they were associated with uninteresting didactic learning experiences such as health class. Components of the program that adolescents and parents found most important (eg, play, making friends, trying new things, being active) should be highlighted in visual and written messaging and marketing of the program.

## **Discussion**

There is a need for efficacious diabetes prevention interventions for adolescents and their parents. We used HCD methods to better understand barriers, improve diabetes prevention program design, and optimize participant engagement. We found that lack of financial resources, limited access to healthy foods and safe places for physical activity, and competing priorities were significant barriers to adopting lifestyle changes. This is consistent with the findings that adolescents of low socioeconomic status have lower quality diets and lower levels of physical activity than their counterparts of high socioeconomic status [30].

We found that participants want interactive, novel, hands-on learning sessions that incorporate a sense of fun and play. Adolescents and their parents desire opportunities to try new behaviors in a supportive group environment and to work toward healthy incentives and rewards. It is important to make healthy choices intrinsically motivating because they are fun, they align with important values, or they are part of someone’s identity. If healthy choices are seen as obligatory, boring/uncool, or unenjoyable, they are less likely to be adopted. Stakeholders are averse to “one-size-fits-all” lecture-style sessions that focus on “what not to do,” recommending that the focus be kept on their interests.

Other types of formative research have been used in diabetes prevention program design. Vangeepuram and colleagues [42] conducted in-depth interviews with youth workers and focus groups with adolescents to learn about program preferences.

They found that offering choices, interactive workshops, personal stories, and games were the preferred methods for program delivery [42]. Community-based participatory research, another collaborative approach to research design, has been shown to be feasible and effective with adolescents in the design of health interventions [43-47]. MacDonald et al [47] used arts-based methods to engage adolescents in the process of designing a sexual health curriculum and concluded that partnering with adolescents improved the relevance of a prevention resource for them. Unfortunately, the inclusion of adolescents and parents in the design of prevention messaging and curriculum is often neglected [34]. Traditional pediatric weight management approaches often used to decrease T2D risk focus on evidenced-based lifestyle changes to promote healthy weight [48]. While evidenced-based messaging is key, program design is not typically informed by adolescents, their parents, or the professionals in their community. This may contribute to poor outcomes and attrition [49-51]. In this study, we engaged not only adolescents but also parents and professionals in the design of a diabetes prevention program that they would want to use. Thus, this study addresses this gap

in the literature by describing HCD methods and findings to better understand barriers, design diabetes prevention programs, and activate at-risk adolescents and their families.

This study has the following limitations. Recruitment strategies may have attracted participants who were more keen on making lifestyle changes. Participant perspectives may not be representative of the general population as the sample was small and from 1 urban community. Demographics of the research participants were not collected. The HCD sessions focused on desired program content rather than the delivery platform. We plan to further translate these findings into a curriculum and test its effectiveness in a larger sample size. Future research should investigate participant engagement by using different delivery modalities.

The findings of this study highlight important insights regarding diabetes prevention and lifestyle change from 3 specific stakeholder groups and demonstrate that, with appropriate methods and facilitation, adolescents, parents, and professionals can be empowered to co-design diabetes prevention programs.

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## Conflicts of Interest

None declared.

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### Multimedia Appendix 1

Human-centered design activities.

[DOCX File, 17 KB - [jopm\\_v13i1e18245\\_app1.docx](#) ]

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### Multimedia Appendix 2

Activity venn diagram.

[PNG File, 87 KB - [jopm\\_v13i1e18245\\_app2.png](#) ]

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### Multimedia Appendix 3

Drawing of the "worst program ever".

[PNG File, 457 KB - [jopm\\_v13i1e18245\\_app3.png](#) ]

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### Multimedia Appendix 4

Diabetes prevention party.

[PNG File, 885 KB - [jopm\\_v13i1e18245\\_app4.png](#) ]

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## Abbreviations

**HCD:** human-centered design

**T2D:** type 2 diabetes

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Original Paper

# Feasibility and Preliminary Effectiveness of a Peer-Developed and Virtually Delivered Community Mental Health Training Program (Emotional CPR): Pre-Post Study

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## Abstract

**Background:** The COVID-19 pandemic has led to a global mental health crisis, highlighting the need for a focus on community-wide mental health. Emotional CPR (eCPR) is a program and practice developed by persons with a lived experience of recovery from trauma or mental health challenges to train community members from diverse backgrounds to support others through mental health crises. eCPR trainers have found that eCPR may promote feelings of belonging by increasing supportive behaviors toward individuals with mental health problems. Thus, clinical outcomes related to positive and negative affect would improve along with feelings of loneliness.

**Objective:** This study examined the feasibility and preliminary effectiveness of eCPR.

**Methods:** We employed a pre-post design with 151 individuals, including peer support specialists, service users, clinicians, family members, and nonprofit leaders, who participated in virtual eCPR trainings between April 20, 2020, and July 31, 2020. Instruments were administered before and after training and included the Herth Hope Scale; Empowerment Scale; Flourishing Scale (perceived capacity to support individuals); Mindful Attention Awareness Scale; Active-Empathic Listening Scale (supportive behaviors toward individuals with mental health challenges); Social Connectedness Scale (feelings of belonging and connection with others); Positive and Negative Affect Schedule; and University of California, Los Angeles 3-item Loneliness Scale (symptoms and emotions). The eCPR fidelity scale was used to determine the feasibility of delivering eCPR with fidelity. We conducted 2-tailed paired *t* tests to examine posttraining improvements related to each scale. Additionally, data were stratified to identify pre-post differences by role.

**Results:** Findings indicate that it is feasible for people with a lived experience of a mental health condition to develop a program and train people to deliver eCPR with fidelity. Statistically significant pre-post changes were found related to one's ability to identify emotions, support others in distress, communicate nonverbally, share emotions, and take care of oneself, as well as to one's feelings of social connectedness, self-perceived flourishing, and positive affect ( $P \leq .05$ ). Findings indicated promising evidence of pre-post improvements (not statistically significant) related to loneliness, empowerment, active-empathetic listening, mindfulness awareness, and hope. Nonprofit leaders and workers demonstrated the greatest improvements related to loneliness, social connectedness, empathic listening, and flourishing. Peer support specialists demonstrated the greatest improvements related to positive affect, and clinicians demonstrated the greatest improvements related to mindfulness awareness.

**Conclusions:** Promising evidence indicates that eCPR, a peer-developed and peer-delivered program, may increase feelings of belonging while increasing supportive behaviors toward individuals with mental health problems and improving clinical outcomes related to positive and negative affect and feelings of loneliness.

**KEYWORDS**

Emotional CPR (eCPR); peer support; peer-delivered training; mental health; community mental health

## *Introduction*

To date, the United States has had over 22.8 million confirmed COVID-19 cases and over 500,000 associated deaths [1]. During the COVID-19 pandemic, rates of individuals experiencing psychological distress increased, which has happened during prior outbreaks of infectious diseases [2]. Over 1 in 3 adults in the United States reported symptoms of anxiety or depressive disorders since the onset of the COVID-19 pandemic [3]. Further, social isolation, loneliness, and fear, as well as significant life events during the pandemic (eg, the loss of a job or loved one), are all risk factors for suicidality [4]. The United Nations has called for widespread mental health psychoeducation to identify, understand, and support people outside of clinical environments [5].

Community mental health psychoeducation training programs have been disseminated internationally and have been shown to increase participants' knowledge regarding mental health, decrease negative attitudes about mental health care, and increase supportive behaviors toward individuals with mental health problems among a diverse group of trainees (eg, adults, youth and teens, public safety officials, first responders, veterans, rural community members, students in higher education, and older adults) [6]. Service users, advocates, provider organizations, policy makers, and researchers concur that widespread psychoeducation is essential for communities to identify, understand, and respond to signs of mental health conditions.

Substantial progress has been made in widespread psychoeducation among community members by making people aware of different mental health conditions, and it has shown effectiveness related to increased knowledge, social attitudes, and helping behaviors toward individuals with mental health challenges [7]. However, it is not known if it is effective in assisting a person through an emotional crisis in the moment. Emotional CPR (eCPR) has the potential to provide people with the skills needed to assist persons through emotional crises.

Community mental health psychoeducation trainings may offer a therapeutic component to facilitate the development of supportive behaviors toward individuals with mental health challenges in addition to clinical outcomes. People who have a lived experience of a mental health condition could be an important asset in these situations by sharing their lived experiences and recovery journeys and assisting in the development of trainings, yet the impact of such an approach is not known. eCPR is designed to educate individuals on mental health challenges and teaches the public how to support others through feelings of mental health distress, address stigmatizing attitudes toward oneself and others, and offer social support.

eCPR is a community mental health psychoeducation virtual training program that was developed to increase supportive practices in community settings and developed to be used by

both clinical and nonclinical community members. Specifically, eCPR, a peer-developed and peer-delivered manualized program, aims to teach the public how to (1) address mental health challenges, (2) support others as they work through feelings of mental health distress, (3) address stigmatizing attitudes toward oneself and others, and (4) offer social support. The purpose of this study was to examine the feasibility and preliminary effectiveness of eCPR by exploring pre-post changes in self-perceived levels of hope, empowerment, flourishing, mindful awareness, empathic listening skills, social connectedness, positive and negative affect, and feelings of loneliness among eCPR trainees. This is the first study conducted to examine both the feasibility and preliminary effectiveness of the eCPR training program on participants and the feasibility and effectiveness of delivering the eCPR training over a virtual platform.

## *Methods*

### **Peer-Academic Partnership**

This study employed the Peer-Academic Partnership [8] to explore the preliminary effectiveness of eCPR. The Peer-Academic Partnership is a community-engaged research approach based on 9 principles of community engagement set by the Centers for Disease Control [9]: (1) develop a clear understanding of the purpose, goal, and population involved in community change; (2) become knowledgeable about all aspects of the community; (3) interact and establish relationships with the community; (4) encourage community self-determination; (5) partner with the community; (6) respect community diversity and culture; (7) activate community assets and develop capacity; (8) maintain flexibility; and (9) commit to long-term collaboration. The partnership engages peer support specialists (ie, people with mental health challenges, trained and accredited by their respective state to offer Medicaid-reimbursable support services), people with lived experiences of mental health challenges, and peer and nonpeer scientific researchers in the development and implementation of research studies important to the mental health community.

### **Description of eCPR**

eCPR is a training developed by persons with a lived experience of a mental health condition and delivered by peer support specialists using a manualized workbook. This training has been offered internationally since its development over 10 years ago, yet this is the first empirical study of eCPR. The term "eCPR" is based on the original use of the term "CPR." Where traditional CPR revitalizes a person's physical heart, eCPR is intended to revitalize one's emotional heart. eCPR focuses on connecting, empowering, and revitalizing individuals in community settings. eCPR is based on the recovery model of mental health and guided by principles of recovery. Principles of recovery include hope, person-driven treatment, relationships, culture, multiple pathways, addressing of trauma, a holistic approach,

development of strengths and responsibilities, peer support, and respect [10]. Scientifically, recovery has been found to be associated with increased empowerment, hope, and quality of life and decreased incidence of psychiatric symptoms and loneliness [11].

eCPR was developed using an iterative design process based on the experiences of an expert panel of peer support specialists, nonprofit leaders, and people with mental health challenges through the National Empowerment Center, a peer-run nonprofit organization. Although eCPR has been offered for the past 10 years in person by a worldwide network of trainers, the COVID-19 pandemic prompted conversion to an online delivery of the training. Since April 2020, eCPR trainings have been delivered virtually using Health Insurance Portability and

Accountability Act (HIPAA)-compliant videoconference software over 3 days of 4 hours of training (12 hours total) by 2 trainers who identify as individuals with a lived experience of a mental health condition. Trainers completed 60 hours of training on eCPR, which included education and simulation-based training and a performance test. Between sessions, trainers assign eCPR trainees homework, which includes assigned readings from the online or mailed versions of the eCPR manual and practice exercises of newly learned skills with friends and among themselves. eCPR includes the following evidence-based principles to support recovery in the community: peer support, coping skills training, and psychoeducation. A total of 7 training modules are completed through group experiential learning, didactic learning, role-play, and dialogical formats (Textbox 1).

**Textbox 1.** Training modules in Emotional CPR (eCPR).

**Training modules**

1. Connecting with others: Participants are taught how to connect through feelings first, engaging all their senses and opening their heart while respecting each other as equally human. They learn the value of engaging in emotional dialogue through expressing and responding to each other's feelings.
2. Using nonverbal communication: Participants learn to connect without asking questions or pursuing a story through emphasis on nonverbal dimensions of communication, such as facial expression, gestures, tone of voice, and description of bodily sensations.
3. Cultural empathy across worldviews: Participants learn to validate another person's worldview by entering their frame of reference and sensing the inner meaning. This includes not only awareness of cultural differences but interconnected social categorizations, such as race, class, gender, and whatever way a person defines themselves.
4. Learning a trauma-informed approach: Participants learn about possible causes and types of trauma as well as ways to heal trauma, understanding that trauma causes alienation, disempowerment, and emotional numbing, while eCPR creates emotional connection, empowerment, and revitalization.
5. Addressing feelings of mental distress and thoughts of suicide: Participants discuss crisis situations, including suicidal thoughts and behaviors, acute stress reactions, and extreme or altered states of consciousness, as well as ways to help.
6. Empowerment: Participants learn that they can facilitate empowerment by being with a person in distress in such a manner that they respect that the person has a healer within and refrain from judging, fixing, or planning for the person.
7. Revitalization: Participants learn that mutual revitalization occurs through deep emotional connection, which is experienced by all participants as increased energy, life, creativity, and hope.

Group trainings include individuals from a variety of backgrounds and experiences to promote diversity of perspectives and experiential learning through interacting with one another outside of a clinical environment. For example, one eCPR training could potentially include caregivers, emergency workers (eg, firefighters, hospital staff), peer support specialists, family of individuals with mental health challenges, and clinicians.

A total of 56 eCPR trainings occurred virtually via a HIPAA-compliant videoconferencing platform between April 20, 2020, and July 31, 2020, and included an average of 10 participants. Using a pre-post, single-arm design, individuals were asked to complete online surveys to examine the impact of the eCPR training on themselves. No incentive was provided. The Dartmouth College Institutional Review Board approved this study.

**Instruments**

Online surveys were administered both prior to the eCPR training and upon its conclusion. Trainers sent the pretraining survey link via email both 1 week prior to the start of the training and the day before the training. At the conclusion of each training, trainers sent the posttraining survey link to participants

via email. Reminders to complete the surveys were emailed to participants in the days following each training. Items included in the surveys were selected to reflect key goals described in the research literature on peer support, including engendering hope, facilitating empowerment, and providing social support. The surveys also included eCPR-specific items designed using the Peer-Academic Partnership through a series of meetings with the principal investigator (KLF). These items were designed based on what the National Empowerment Center views as the most crucial elements and aims of eCPR (including trauma-informed support, the act of being with another person in crisis, communication, and self-care) and aimed to explore participants' agreement with statements related to emotional support. Sample questions include "I feel comfortable being with another person and listening to them," "I can sit with another person and let them express strong emotions," "Trauma plays a significant role in people's emotional states," "I recognize nonverbal ways others communicate," and "I know how to take care of myself before and after being with someone in distress." Response options include "strongly agree," "agree," "disagree," "neither agree or disagree," and "strongly disagree."

## Perceived Capacity to Support Individuals

To measure perceived capacity to support individuals, we incorporated 3 scales. To measure empowerment, we used the Empowerment Scale [12,13], which was developed with service users with serious mental illness and is a widely used, valid, reliable 28-item scale that measures empowerment [13]. Sample questions include “I can pretty much determine what will happen in my life” and “People are only limited by what they think is possible.” Response options include “strongly agree,” “agree,” “disagree,” and “strongly disagree.” Scores were totaled and averaged, with a potential score of 1 through 4, in which lower scores indicated higher levels of empowerment.

The Herth Hope scale was used to measure (1) inner sense of temporality and future, (2) inner positive readiness and expectancy, and (3) interconnectedness with self and others [14]. This scale was established as reliable and valid for both elderly and ill populations [14]. Sample questions include “I have a positive outlook toward life,” “I have short- and/or long-range goals,” and “I feel scared about my future.” Response options include “strongly agree,” “agree,” “disagree,” and “strongly disagree.” Two items, “I feel scared about my future” and “I feel all alone,” were reverse scored. Scores were totaled and averaged, with a potential score of 1 through 4, in which lower scores indicated higher levels of hope.

The Flourishing Scale [15] was used to measure self-perceived success in important areas such as (1) relationships, (2) self-esteem, (3) purpose, and (4) optimism. The scale has good psychometric properties and is strongly associated with other psychological well-being scales [16]. The Flourishing Scale has been deemed both reliable and valid for measuring psychosocial functioning in adults, including those with mental and physical health challenges [16]. Sample questions include “I lead a purposeful and meaningful life,” “I am engaged and interested in my daily activities,” and “I am competent and capable in the activities that are important to me.” Response options include “strongly disagree,” “disagree,” “slightly disagree,” “neither agree nor disagree,” “slightly agree,” “agree,” and “strongly agree.” Scores were totaled, with a potential score of 8 through 56, in which a high score indicated a person with many psychological resources and strengths.

## Supportive Behaviors Toward Individuals With Mental Health Problems

To measure supportive behaviors toward individuals with mental health problems, we incorporated 2 scales. The Mindful Attention Awareness Scale is a 15-item scale designed to measure core characteristics of dispositional mindfulness [17]. The scale was established as a valid measure of receptive attention to and awareness of present experience [17]. Sample questions include “I could be experiencing some emotion and not be conscious of it until some time later” and “I tend not to notice feelings of physical tension or discomfort until they really grab my attention.” Response options include “almost always,” “very frequently,” “somewhat frequently,” “somewhat infrequently,” “very infrequently,” and “almost never.” Scores were totaled and averaged, with a potential score of 1 through 6, in which higher scores reflected higher levels of dispositional mindfulness.

The Active-Empathic Listening Scale measures active-empathic listening. Active-empathic listening is the active and emotional involvement of a listener during a given interaction [18]. The multidimensional scale was established as a valid measure of interpersonal communication [18]. Sample questions include “I am sensitive to what others are not saying,” “I am aware of what others imply but do not say,” “I listen for more than just the spoken words,” “I understand how others feel,” and “I show others that I am listening by my body language.” Response options include “always or almost always true,” “usually true,” “often true,” “occasionally true,” “sometimes true,” “usually not true,” and “never or almost never true.” Scores were totaled and averaged, with a potential score of 1 through 7, in which lower scores indicated higher levels of active-empathic listening.

## Feelings of Belonging and Connection With Others

To measure feelings of belonging and connection with others, we used the revised Social Connectedness Scale [19]. This 20-item scale was derived from the shorter Social Connectedness Scale. This scale was deemed valid, though it has been said to have psychometric limitations and possibilities of response bias [19]. Sample questions include “I feel distant from people,” “I am able to relate to my peers,” and “I find myself actively involved in people’s lives.” Response options include “strongly disagree,” “disagree,” “mildly disagree,” “mildly agree,” “agree,” and “strongly agree.” The negatively worded items were reverse scored and summed together with the positively worded items, with a potential score of 20 to 120. Higher scores indicated a stronger sense of social connectedness.

## Symptoms and Emotions

To measure symptoms and emotions, we incorporated 2 scales. The Positive and Negative Affect Schedule (PANAS) [20] is a mood scale that was used to measure positive and negative affect. PANAS was established as a reliable and valid measure of the positive and negative affects of mood. The scale lists mood descriptors, including “interested,” “distressed,” “ashamed,” and “active.” Participants were asked to “indicate the extent you have felt this way over the past week,” with response options including “very slightly or not at all,” “a little,” “moderately,” “quite a bit,” and “very much.” The negatively worded items were reverse scored and summed together with the positively worded items, with a potential score of 20 to 100. Higher scores indicated higher levels of positive affect and lower scores indicated higher levels of negative affect.

To measure loneliness, we used the University of California, Los Angeles (UCLA) 3-item Loneliness Scale [21]. This widely used and valid 3-item scale was derived from the longer 20-item UCLA Loneliness Scale that was deemed not suitable for telephone interviews [21]. Questions include “How often do you feel that you lack companionship?” “How often do you feel left out?” and “How often do you feel isolated from others?” Response options include “hardly ever,” “some of the time,” and “often.” Scores were totaled and averaged, with a potential score of 1 through 3, in which lower scores indicated lower levels of loneliness.

## Fidelity Assessment

The principal investigator monitored intervention fidelity through (1) biweekly discussions between the principal investigator and lead trainers' supervisors, (2) the trainer's self-report fidelity tool, and (3) confirmation that participants received an accompanying eCPR training manual (either online or through the mail).

## Procedures

### Recruitment

At a time that in-person peer support organizations were seeking new ways to bridge the new and sudden social distancing guidelines, trainers reached out to individuals and organizations they had been working with for years to let them know about this opportunity. In addition to reaching out to networks, an invitation was posted on the eCPR website for people to express their interest in participating in the eCPR trainings.

### Informed Consent

Prior to engaging in the presurvey, participants were given a consent statement on Qualtrics (Qualtrics International). Interested individuals were given the opportunity to meet with the principal investigator to ask questions and review the informed consent form and to contact the principal investigator at any time to withdraw their participation.

## Statistical Analyses

Descriptive statistics were conducted to describe demographic characteristics of the study sample. We conducted 2-tailed paired sample *t* tests to assess the difference between prescores and postscores for statistical significance. All incomplete survey responses were excluded from analyses. Descriptive statistics and analyses were computed using IBM SPSS software (IBM Corp) [22].

## Results

The study included 151 adults aged 18 years and older who identified as peers and service users with a lived experience of any mental health condition, as well as hospital staff, family members, clinicians, nonprofit leaders, and nonprofit workers (Table 1). Inclusion criteria were all members of the community who (1) were 18 years or older; (2) self-reported experiencing any mental health condition or were hospital staff, family members of individuals with mental or physical health conditions, clinicians, nonprofit leaders, nonprofit workers, and

all other members of the community; and (3) were able to provide informed consent. Exclusion criteria were as follows: (1) individuals younger than 18 years; (2) individuals deemed cognitively impaired and who were unable to provide consent, identified as not being able to log in to the training; and (3) potential participants who were cognitively impaired and had designated legal guardians.

In total, 560 individuals participated in any portion of the 56 virtual eCPR trainings offered between April 20, 2020, and July 31, 2020. An online website posting reached 64 of the 560 (11.4%) individuals who participated in the trainings. The remainder of the participants were invited through their organizations or through direct emails.

Of the participants who attended the training, we obtained pre-and postsurveys from individuals who completed the full 12 hours of training and completed both the presurvey and postsurvey. Out of the 560 training participants, we received a total of 452 presurvey responses and 318 postsurvey responses. Individuals who did not complete both the pre- and postsurveys in full were excluded from analyses. Of the 560 training participants, the total sample of individuals who completed both a presurvey and postsurvey was 151 participants. Of the final sample of participants (N=151), 81 (53.6%) identified as peer support specialists, 44 (29.1%) were individuals with a lived experience of a mental health challenge, 10 (6.6%) were family members of individuals with mental health challenges, 8 (5.3%) were nonprofit leaders or worked for a nonprofit, and 8 (5.3%) were clinicians. No differences were noted in participants who completed both a presurvey and postsurvey compared with individuals who only completed 1 survey (presurvey or postsurvey). The majority of participants were women (116/151, 77.3%). The majority of the participants were within the age range of 27 to 49 years (71/151, 47.1%), followed by 50 to 64 years (55/151, 36.4%). Of the 151 participants, 115 (77.7%) identified as White, 13 (8.8%) as Black, 4 (2.7%) as American Indian or Alaska Native, 4 (2.7%) as Asian, and 12 (8.1%) as more than one race (Table 2).

Before attending the eCPR training, 151 participants reported their eCPR abilities on a scale of 1 to 5 (1 being the highest ["strongly agree"] and 5 being the lowest ["strongly disagree"]). The average pretraining score was 2.17. After participating in the training sessions, the same group of participants reported an increase in their eCPR abilities and reported an average posttraining score of 2.02 ( $P<.001$ ).



**Table 1.** eCPR participant demographics.

Characteristics	Participants, n (%) (N=151)
<b>Gender</b>	
Male	32 (21.3)
Female	116 (77.3)
Other	2 (1.3)
<b>Age (years)</b>	
19-26	16 (9.9)
27-49	71 (47.1)
50-64	55 (36.4)
65+	10 (6.6)
<b>Race</b>	
White	115 (77.7)
Black/African American	13 (8.8)
American Indian/Alaska Native	4 (2.7)
Asian	4 (2.7)
Native Hawaiian/Pacific Islander	0 (0.0)
More than one race	12 (8.1)
<b>Ethnicity</b>	
Hispanic/Latino	14 (9.5)
Non-Hispanic/Latino	134 (90.5)
<b>Employment status</b>	
Full-time	77 (51.3)
Part-time	42 (34.2)
Volunteer	11 (7.9)
Unemployed	15 (3.9)
Retired	6 (4.0)
<b>Role</b>	
Service user	44 (29.1)
Peer support specialist	81 (53.6)
Family member	10 (6.6)
Clinician	8 (5.3)
Nonprofit leader or worker	8 (5.3)

**Table 2.** eCPR pre- and postsurvey responses by item.

eCPR <sup>a</sup> item	Presurvey, mean (SD) (N=151)	Postsurvey, mean (SD) (N=151)	<i>P</i> value	Cohen <i>d</i> <sup>b</sup>
1. When I see someone in emotional distress, I usually have a good sense about what's wrong, what they need, and how to help them.	2.72 (0.897)	2.58 (1.029)	.11	0.13
2. Support is helping a person solve their problems.	3.41 (1.043)	3.81 (1.137)	<.001*	-0.34
3. Support is about trying to be with another person.	2.13 (0.946)	1.47 (0.757)	<.001*	0.62
4. Trauma plays a significant role in people's emotional states.	1.36 (0.582)	1.28 (0.582)	.17	0.11
5. When I see someone in emotional distress, I want to help them, but don't know how.	3.05 (0.925)	3.74 (0.833)	<.001*	-0.60
6. I can identify my emotions.	1.93 (0.713)	1.73 (0.688)	.002*	0.26
7. I can sit with another person and let them express strong emotions.	1.58 (0.719)	1.39 (0.541)	.003*	0.24
8. I am willing to share my emotions with another person who may be in distress.	1.95 (0.703)	1.60 (0.624)	<.001*	0.42
9. When I'm with someone in distress, I try to figure out solutions for them.	3.15 (1.022)	3.69 (0.967)	<.001*	-0.44
10. I know what it means to "be with" another person.	2.08 (0.728)	1.36 (0.509)	<.001*	0.91
11. I recognize nonverbal ways I have of communicating.	1.91 (0.683)	1.54 (0.651)	<.001*	0.49
12. I feel comfortable being with another person and listening to them.	1.59 (0.667)	1.36 (0.495)	<.001*	0.38
13. I know how to take care of myself before and after being with someone in distress.	2.31 (0.926)	1.80 (0.760)	<.001*	0.61
14. I am open to new ideas and ways of doing them.	1.44 (0.511)	1.34 (0.555)	.06	0.16
15. I recognize nonverbal ways others communicate.	1.92 (0.661)	1.54 (0.551)	<.001*	0.53

<sup>a</sup>eCPR: Emotional CPR.

<sup>b</sup>Cohen *d* measures effect size (0.20=small effect, 0.5=medium effect, 0.8=large effect).

\*Statistically significant ( $P \geq .05$ ).

Before attending this training, 151 participants reported their perceived capacities to support individuals by responding to the Herth Hope Scale, Empowerment Scale, and Flourishing Scale. There was no significant difference in levels of hope reported before and after the training sessions. However, we did observe an improvement between pretraining and posttraining scores. The average pretraining score was 20.38. The same group of participants reported an average posttraining score of 19.97, resulting in an improvement of 0.41 ( $P=.11$ ). Similarly, there was no significant difference between the average levels of empowerment reported before and after the training sessions. The average pretraining score was 2.15, and after participating in the eCPR training, the same participants reported an average posttraining score of 2.13, resulting in an improvement of 0.02 ( $P=.10$ ). Statistically significant differences were observed in questions related to self-perceived flourishing. Participants demonstrated an average pretraining score related to flourishing of 16.53. After participating in the training sessions, the same group of participants reported an increase in their self-perceived success and reported an average posttraining score of 15.58 ( $P=.008$ ) (Table 3).

Regarding supportive behaviors toward individuals with mental health challenges, 151 participants reported their mindfulness abilities and active-empathic listening skills. There were no statistically significant differences in mindfulness abilities or active-empathic listening skills observed between the pre- and posttraining surveys, but posttraining improvements were observed related to both mindfulness and listening skills. Participants demonstrated an average mindfulness awareness pretraining score of 3.99. After the eCPR training sessions, the same group of participants reported an average posttraining score of 3.87, resulting in an improvement of 0.12 ( $P=.09$ ). In regard to active-empathic listening, participants reported an average pretraining score of 2.41. After the eCPR training sessions, participants reported an average improvement of 0.09 and an average posttraining score of 2.32 ( $P=.11$ ).

Regarding feelings of belonging and connection with others, 151 participants reported their feelings of social connectedness. The average pretraining score was 51.28. After participating in the training sessions, the same group of participants reported an increase in social connectedness and reported an average posttraining score of 48.59 ( $P=.002$ ).

**Table 3.** eCPR training pre-post changes by measure.

Measure	Presurvey, mean (SD) (N=151)	Postsurvey, mean (SD) (N=151)	P value	Cohen <i>d</i> <sup>a</sup>
Herth Hope Scale	20.38 (2.96)	19.97 (3.29)	.11	0.13
Empowerment Scale	2.15 (0.19)	2.13 (0.21)	.10	0.13
Flourishing Scale	16.53 (5.92)	15.58 (6.08)	.008*	0.22
Mindful Attention Awareness Scale	3.99 (1.03)	3.87 (1.13)	.09	0.14
Active-Empathic Listening Scale	2.41 (0.77)	2.32 (0.78)	.11	0.13
Social Connectedness Scale	51.28 (14.77)	48.59 (14.69)	.002*	0.25
PANAS <sup>b</sup>	72.18 (11.94)	76.42 (12.32)	<.001*	-0.48
UCLA <sup>c</sup> Loneliness Scale	1.75 (0.57)	1.69 (0.57)	.12	0.13

<sup>a</sup>Cohen *d* measures effect size (0.20=small effect, 0.5=medium effect, 0.8=large effect).

<sup>b</sup>PANAS: Positive and Negative Affect Schedule.

<sup>c</sup>UCLA: University of California, Los Angeles.

\*Statistically significant ( $P \geq .05$ ).

Regarding symptoms and emotions, participants (N=151) reported positive and negative affect and levels of loneliness. The average pretraining score related to affect was 72.18. After participating in the training sessions, the same group of participants reported an increase in their positive affect and reported an average posttraining score of 76.42 ( $P < .001$ ). Although there was no significant difference between the average level of loneliness reported before and after the training session, we observed an improvement in scores. The average pretraining score was 1.75. After participating in the eCPR training sessions, the same group of participants reported a decrease in their loneliness and reported an average posttraining score of 1.69 ( $P = .12$ ).

When compared to the pre-post changes observed in other roles, nonprofit leaders and workers reported the greatest improvements in self-perceived flourishing (2.12-point improvement), active-empathic listening abilities (0.5-point improvement), social connectedness (6.5-point improvement), and loneliness (0.37-point improvement). Clinicians reported the greatest improvements in self-reported mindfulness abilities (0.56-point improvement). Additionally, peer support specialists reported the greatest improvements in positive affect (5.10-point improvement).

## Discussion

### Summary of Findings

To the authors' knowledge, this is the first study to date that aimed to explore the feasibility and preliminary effectiveness of online eCPR. Our findings suggest that eCPR is feasible, as it can be delivered through an online platform with fidelity by peer support specialists. Promising evidence indicates that eCPR, a peer-delivered program, may promote social connectedness by increasing supportive behaviors toward individuals with mental health challenges and improving potential clinical outcomes related to positive and negative affect and feelings of loneliness. Of note, the impact of eCPR may be greater in person and reach a different audience than online eCPR. Exploring

these differences in future studies after the COVID-19 lockdown measures and social distancing is an important next step.

The feasibility of eCPR delivery was determined by peer support specialists' high fidelity scores. Of note, the eCPR training and related manual may have supported peer support specialists' proficiency in integrating standardized evidence-based intervention components. This study highlights promising findings that a peer-developed and peer-delivered program may support fidelity-adherent mental health psychoeducation and potentially support individuals outside of clinical environments or between clinical encounters. As eCPR training was offered virtually, it is possible this delivery method may reach audiences that would not have otherwise been able to attend an in-person training (ie, individuals with physical limitations, transportation issues, etc).

eCPR may increase feelings of belonging and connection with others. eCPR offers another perspective than the traditional medical model of treatment, as it has a human-centered and trauma-informed approach that focuses on individuals sharing lived experiences with people from varying backgrounds. The practice of eCPR focuses on encouraging individuals to express their feelings and share their lived experiences and perspectives to learn from one another, which may impact perceived and real stigma. Exploring the impact of eCPR on stigma may be an important future study.

eCPR may increase supportive behaviors toward individuals with mental health problems, particularly among clinicians in terms of mindfulness awareness. eCPR demonstrates the value of being with one another, or mindful awareness, and actively listening to the individual who is experiencing mental health problems or a mental health crisis. This trauma-informed approach creates a safe environment for people to experience mental health challenges without fear of involuntary hospital commitment. This type of support is not focused on being solution-driven, which is a common goal of clinicians; rather, eCPR focuses on creating a supportive environment to experience and share feelings and emotions. In this approach,

eCPR trainees are coached to trust that the solutions lie within the person being helped.

eCPR is related to the development of new skills to support individuals, and it impacts a person's emotions. Interestingly, eCPR demonstrated potential effectiveness related to positive and negative affect and a reduction of feelings of loneliness across groups. eCPR's approach promotes the integration of diverse groups in regard to race, age, roles, and lived experiences. Diversity among group members provides an opportunity to learn from one another's experiences and perspectives. eCPR's ability to help individuals provide support to one another is not dependent on whether the individuals are trained mental health clinicians; rather, people from varying educational backgrounds can provide services to one another in a group environment, which may help them relate or grasp new situations related to work with others with mental health challenges.

### Limitations

This study is not without limitations and the results should be interpreted with caution. First, the study design limits the findings and does not allow us to determine the causality of eCPR on outcomes. However, this design was consistent with the purpose of the study, which was to explore feasibility and preliminary effectiveness. As feasibility and preliminary effectiveness have been established, future studies can consider increasing the methodological quality of the study designs. Second, all the trainings studied were online; thus, generalizability is limited to online environments. A scientifically rigorous study exploring barriers and facilitators to eCPR implementation in digital environments may increase understanding of the ease of its implementation. The sample size is too small for subgroup analysis (ie, analysis by role, diagnosis, age, race, etc) but is large enough for the purposes of this study. We do not have further data on why the remaining surveys were incomplete or not completed at all, since the

surveys were completely voluntary and participation in the surveys for research purposes did not impact one's ability to participate in the trainings. Additionally, we have not tracked data on who completed the full 12 hours.

It is unknown whether the improvement in eCPR training participants' scores is indicative of a change in real-life practice and behavior. Future studies should examine the impact of the training on whether participants exhibit these changes in social connectedness, eCPR skills, mindfulness awareness, and active-empathic listening in everyday practice with others in their community, clinical practice, and social circles. Additionally, further research can be done to examine the impacts of increased hope, positive affect, flourishing, and decreased loneliness on the daily life of eCPR training participants.

Unfortunately, we were unable to determine clinical significance, as comparing effect sizes with equipoise between different studies is not possible due to the heterogeneity of the sample in the current study (ie, nonprofit leaders and workers, clinicians, and peer support specialists). Adequately powered future eCPR studies should explore the clinical significance of the findings to determine real-world outcomes.

### Conclusions

To the authors' knowledge, this is the first study to examine the feasibility and preliminary effectiveness of a peer-developed and peer-delivered community mental health psychoeducation training. Promising evidence indicates that eCPR, a peer-delivered training, may increase feelings of belonging and closeness with the social world while increasing supportive behaviors toward individuals with mental health problems and improving clinical outcomes related to positive and negative affect and feelings of loneliness. eCPR has shown promising evidence that support services are not limited to a clinician's office; rather, we can help to heal our community using the skills that are taught throughout the sessions.

### Conflicts of Interest

KLF owns Social Wellness, LLC and is contracted by Trusst Health Inc and Inquisithealth Inc. The remaining authors declare no conflicts of interest.

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## Abbreviations

**eCPR:** Emotional CPR

**HIPAA:** Health Insurance Portability and Accountability Act

**PANAS:** Positive and Negative Affect Schedule

**UCLA:** University of California, Los Angeles

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Original Paper

# Patient Experience and Predictors of Improvement in a Group Behavioral and Educational Intervention for Individuals With Diabetes and Serious Mental Illness: Mixed Methods Case Study

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## Abstract

**Background:** In a previous study, participation in a 16-week reverse integrated care and group behavioral and educational intervention for individuals with diabetes and serious mental illness was associated with improved glycemic control (hemoglobin A<sub>1c</sub>) and BMI. To inform future implementation efforts, more information about the effective components of the intervention is needed.

**Objective:** The goal of this study is to identify the aspects of the intervention participants reported to be helpful and to evaluate the predictors of outcomes.

**Methods:** This study involved qualitative evaluation and post hoc quantitative analysis of a previous intervention. Qualitative data were collected using semistructured interviews with 69% (24/35) of the individuals who attended 1 or more group sessions and 35% (9/26) of the individuals who consented but attended no sessions. Quantitative mixed effects modeling was performed to test whether improved diabetes knowledge, diet, and exercise or higher group attendance predicted improved hemoglobin A<sub>1c</sub> and BMI. These interview and modeling outcomes were combined using a mixed methods case study framework and integrated thematically.

**Results:** In qualitative interviews, participants identified the application of health-related knowledge gained to real-world situations, accountability for goals, positive reinforcement and group support, and increased confidence in prioritizing health goals as factors contributing to the success of the behavioral intervention. Improved knowledge of diabetes was associated with reduced BMI ( $\beta=-1.27$ , SD 0.40;  $P=.003$ ). No quantitative variables examined were significantly associated with improved hemoglobin A<sub>1c</sub> levels.

**Conclusions:** In this mixed methods analysis of predictors of success in a behavioral diabetes management program, group participants highlighted the value of positive reinforcement and group support, accountability for goals set, and real-world application of health-related knowledge gained. Improved diabetes knowledge was associated with weight loss.

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**KEYWORDS**

mental disorders, severe; diabetes mellitus; delivery of health care, integrated; behavior and behavior mechanisms; patient education as topic

## Introduction

### Background

The lifetime rate of diabetes among people with schizophrenia is at least twice than that seen in the general population [1,2]. A study of Medicaid patients with serious mental illness found an 11.8% prevalence of diabetes [3]. Suboptimal diabetes management in people with serious mental illness is common [4-8] and estimated to cost approximately US \$8 billion in the United States annually [8]. High rates of tobacco dependence and poor understanding of diabetes self-management, including diet and physical activity goals, are modifiable factors contributing to the morbidity and mortality associated with diabetes in people with serious mental illness [9-11]. Serious mental illness is used to refer to schizophrenia-spectrum illness, bipolar disorder, or severe major depressive disorder.

Despite high diabetes prevalence and high rates of associated morbidity and mortality, it has been reported that fewer than one-third of adults with serious mental illness are screened for diabetes [8,12]. Moreover, among those diagnosed with diabetes, individuals with mental illness receive less frequent monitoring of glycemic control and cardiovascular risk factors such as hypercholesterolemia than those in the general population, despite recommendations of more frequent monitoring for individuals taking antipsychotic medications [2]. Although providers may assume that people with serious mental illness will be poorly adherent to treatment, adults with serious mental illness have demonstrated good adherence to glucose-lowering medications, disease self-management, and weight loss programs when these treatments have been made available to them [13-16]. At least one large study reported superior adherence to antihyperglycemic medications among people with schizophrenia compared with people without schizophrenia [17].

### Objectives

Our open trial of a group intervention for individuals with serious mental illness and diabetes demonstrated significant improvement in hemoglobin A<sub>1c</sub> (HbA<sub>1c</sub>) and BMI for participants with serious mental illness and diabetes [18]. Although previous studies of diabetes self-management interventions in this population have reported improvements in BMI, diabetes knowledge, and psychiatric symptoms, to date, no published randomized controlled trials have demonstrated improvements in HbA<sub>1c</sub> [19,20]. Before designing a larger, more methodologically rigorous controlled trial, we sought to identify unique features of our intervention, successful strategies, key messages retained, and potential predictors of positive outcomes. The purpose of this study is to expand our understanding of successful intervention components through an assessment of patient experience, motivations, and perception of key aspects of the intervention, in addition to quantitative predictors that emerged through repeated surveys during the intervention. As 43% (26/61) of the individuals who consented to this study did not attend any groups, we additionally sought to ascertain barriers to the participation of these individuals to better engage and encourage retention in future iterations of this intervention.

## Methods

### Parent Study Design

The authors designed and tested in an open trial, a behavioral and educational group intervention, modeled on the Diabetes Prevention Program [21], for individuals with comorbid diabetes and serious mental illness that sought to help participants to reduce their HbA<sub>1c</sub> and BMI by providing health education and support for implementing practical strategies to address the social, economic, and behavioral determinants of health faced by the participants. In the parent study, 61 participants consented to participate and 35 participants attended at least one session of the 16-week intervention over a 2-year period. Details of this trial are given in the study by Schnitzer et al [18].

In this intervention, the modules covered basic diabetes education, diet, exercise, stress reduction, and positive psychology, taught in a simple format with frequent repetition and frequent use of concrete, real-world examples that participants described in the groups. The intervention actively addressed barriers identified by participants to important health-related behaviors and choices. These included barriers to purchasing and preparing healthy food, such as lack of safe or private food storage options, tendency to obtain food from convenience stores and fast-food restaurants, and barriers to exercise (such as discomfort exercising outside because of paranoia or unsafe neighborhoods). Problem solving using the Specific, Measurable, Achievable, Realistic, Timely Framework for individualized behavior goals [22] was tailored to patients' community environment, for example, how to make healthier choices at the nearby convenience stores and fast-food restaurants. Barriers were addressed in concrete ways with the support of the group to decrease the initial activation demands associated with trying a new behavior on their own. For example, nonsugar-containing beverages were sampled in the group meeting, trips to the Department of Mental Health gym were taken in a group with coleaders exercising alongside the participants, labels were read together in food stores to model how this information might be used to guide the purchase of healthier food options, and a field trip was taken to the nearby affordable hospital cafeteria to demonstrate and practice the identification and purchase of a healthy lunch from available options.

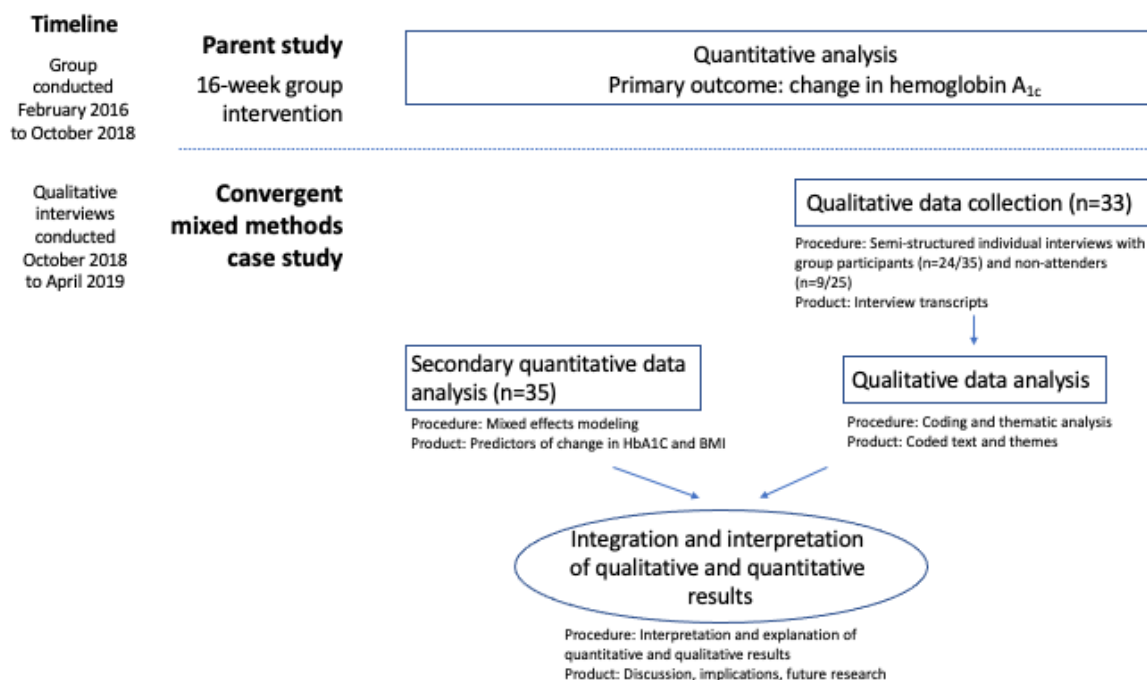
### Current Study—Secondary Analysis Using a Convergent Mixed Methods Design

Following the completion of the parent study, the authors conducted semistructured interviews with participants, with the goal of identifying aspects of the intervention that the participants found most helpful. Using an interactive convergent mixed methods study design [23,24], the authors mapped themes that emerged in the qualitative data to quantitative data domains and evaluated these as predictors of improved HbA<sub>1c</sub> and BMI. The authors also interviewed participants who consented but did not participate to identify barriers to participation and inform implementation of similar interventions in future work (Figure 1). All study procedures were approved by the institutional review board (IRB) of the Massachusetts General Hospital. The



parent study IRB was amended to allow the recontacting of previous study participants.

**Figure 1.** Procedural diagram.



## Qualitative Methods

### Participants

After completion of the parent study, the authors requested a follow-up interview with all individuals who consented to participate in the study (n=61) about their study experience or barriers to participation. Criteria for eligibility for the initial study included the diagnosis of serious mental illness and HbA<sub>1c</sub> ≥6.5, HbA<sub>1c</sub> ≥6 and metformin, or the known diagnosis of diabetes. A total of 33 participants (24 who attended at least one group and 9 who attended no groups) agreed to be interviewed, and the remaining 28 declined to participate or could not be contacted.

### Exit Interviews

Semistructured individual interviews were designed with open-ended questions querying participants’ overall experience with the behavioral and educational intervention, with questions tailored to reflect their experience as either participating or declining to participate in the group (Multimedia Appendix 1). Interviews were conducted by 3 individuals trained in qualitative interviewing techniques who were not involved in the original study (VZ, RP, and KL). Questions were posed in a neutral and open-ended manner to minimize bias. The interview guide was piloted with 5 participants to assess the clarity of the questions; no subsequent modifications were made. Interviews were conducted in English between October 2018 and April 2019 at the community mental health clinic where the intervention took place and were audio recorded. Individuals received US \$10 for their participation.

## Qualitative Analysis

Interviews were transcribed using TranscribeMe Inc to secure transcription services. Analyses were conducted using a grounded theory approach, with the goal of identifying patterns and arranging these in relationships [25,26]. During open coding, a team of 6 researchers met and read 3 transcripts to gain an awareness of the initial thematic content that arose from the interviews. This was followed by analytical coding with grouping of content in consideration of broader meaning and overarching themes. Two codebooks, one for individuals who completed the group and one for individuals who consented to participate but attended no groups, were developed to reflect patterns of response for each of the 2 study paths. These 2 codebooks were revised over the course of 3 meetings.

The finalized codebooks were used in conjunction with NVivo qualitative software version 12.0 (QSR International Pty Ltd) for data organization. Qualitative coding was completed by 2 individuals (KS, VZ) with training in qualitative data analysis. KS and VZ coded all transcripts and held weekly recalibration meetings to ensure reliability of coding, reduce coding drift, and resolve discrepancies in coding. Following the completion of coding, the final stage of analysis involved the query of coding reports and a further round of data immersion first individually and then discussed in team meetings to identify content patterns and themes to allow for final interpretation of data. Selected participant quotations were chosen to illustrate the prominent themes expressed by the study sample.

## Quantitative Analysis

The primary outcome for the parent study was change in HbA<sub>1c</sub> at week 16 [18]. For this secondary analysis, a linear regression with a random intercept for subjects was used to identify

potential predictors of 2 physiologic outcomes that were significantly improved from pretreatment to posttreatment, HbA<sub>1c</sub>, and BMI. The authors ran a multivariate analysis within a penalized regression framework, which shrinks estimates slightly toward zero to minimize the risk of false positives and manage any dependencies between predictors. The variables examined included the number of sessions attended, improvement in diabetes knowledge assessed through the Short Diabetes Knowledge Instrument (SDKI) [27], and improvement in diabetes self-care assessed through the Summary of Diabetes Self-Care Activities (SDSCAs) subscales [28]. The SDKI is a 13-item questionnaire developed and validated in a multiethnic sample of individuals >60 years of age to assess an individual's understanding of diabetes illness and management. The SDSCA measures an individual's attendance to various aspects of diabetes self-management (general diet, specific diet, and exercise) through assessment of days per week a particular activity is performed.

### Integration of Results and Development of Joint Display

Following qualitative and quantitative data analyses, data were integrated to identify congruencies and discrepancies, allow for meta-inferences, and facilitate richness of data [29-32]. The results were illustrated with a joint display of quantitative predictors mapped to relevant qualitative themes and the resulting mixed method research inference.

## Results

### Sample Characteristics

Full demographic characteristics of the parent study participants are given in the study by Schnitzer et al [18]. Among the sample of individuals who attended at least one group (n=35), the mean age was 53 years, 77% (27/35) were male, 46% (16/35) were white, 34% (12/35) were black, and 20% (7/35) were from *other* race. Among individuals who did not attend any group (n=25), the mean age was 57 years, 60% (15/25) were male, 64% (16/25) were white, 20% (5/25) were black, and 12% (3/25) were from *other* race. Among those who attended at least one group and agreed to participate in the qualitative interview (n=24), the mean age was 52 years, 79% (19/24) were male, 63% (15/24) were white, 33% (8/24) were black, and 4% (1/24) were from *other* race. Among those who did not attend any groups and agreed to participate in the qualitative interview (n=9), the mean age was 50 years, 78% (7/9) were male, 67% (6/9) white, 22% (2/9) black, and 11% (1/9) were from *other* race. Interview participants did not differ in age or racial composition from the parent sample.

### Qualitative Results

The mean duration of interviews was 13 min (SD 6) for those who participated in the groups and 4 min (SD 1) for those who did not participate. Interviews of group participants and nonparticipants are reported separately. Quotes provided include minor editing for flow and clarity.

### Group Participants

Among those who attended at least one group, 5 major themes developed around the key aspects of the intervention: (1) health-related knowledge gains and application to real-world situations, (2) positive reinforcement from the group, (3) accountability for setting and achieving goals, (4) group support, and (5) increased confidence in the ability to prioritize health goals.

### Health-Related Knowledge Gains and Application to Real-World Situations

Participants reported learning new information from the group that helped them improve their diabetes self-management. They noted increased confidence in their ability to make changes and said that learning more about how to manage diabetes helped them feel more in control of their health-related decisions. In addition to being able to implement new, healthy behaviors, they also reported being better able to reduce behaviors they learned were unhealthy:

*I've learned that many of the foods that I like and have considered relatively innocuous are, in the quantities that I eat them, not conducive to maintaining a good A<sub>1c</sub>. The starches, the breads that I grew up with as someone in an Italian home, pasta and ravioli. [M, 48yo]*

*If I'm going to eat cake, chocolate cake, my sugar level's going to go up, who knows up to how much. I may get dizzy, but if I eat the right things, the ones the group taught me, I can't go wrong. [M, 54yo]*

*Actually, what I did start drinking after I started going to the group was sparkling water or seltzer water. Yeah. I like that. I always get the lime or lemon flavor. [gender fluid, 48yo]*

*And when the clubhouse has their functions, they have all kinds of sweet foods and stuff. You know those little fruit cups? Well, if I go over there for lunch and they're having a fruit cup, I'll say to one of the staff, "I can't have this because it has sugar in it. So, can I have a piece of fruit?" [F, 53yo]*

*When you buy the food, you have to think of how much you need per serving. One time I went in and bought a slab of meat. It was nine servings. They say nine servings on the package. And I had nine servings of meat... I broke it up into nine servings. [F, 70yo]*

### Positive Reinforcement From the Group

The importance of positive reinforcement, which the authors define as encouragement from both group leaders and peers, was consistently mentioned by participants as a factor that encouraged their attendance and helped them develop momentum by continuing to build on positive changes:

*You build up morale, and you're encouraged to acknowledge people's success. If somebody had, let's say, four days over 10,000 steps, everyone basically applauded. And this is positive reinforcement... I can't stress enough the importance of the positive reinforcement. It almost never felt like a chore to*

come to the group. I mean, there were days when, owing to my physical limitations by the apnea and the weather, where it was like, "Okay. I got to go in." But, often enough, that was rewarded with some good thing. [M, 48yo]

They were also good in that no one threw the book at you. If you said, "well, I went to the bar and I drank six liters of beer and I had 19 plates of pasta," they would say, "but one of your days your step count was above 8000." They would do that... They would say, "More of that and less of the other stuff." ... They would say, "Here is a good sign." They'd point out what was going right, and you would get it without having to be beaten over the head with it. [M, 48yo]

I got an award for it. Yeah, they gave me a little diabetic award for finishing the course. [M, 42yo]

### Accountability for Setting and Achieving Goals

Many participants commented on the importance of being held accountable to previously set goals, something they did not feel had been a part of efforts to help manage their diabetes before participating in the groups:

You realize, what'd you do well this week? What didn't you do well? We talked about that at the end of the group, and that really helps. That really helps. [M, 68yo]

The people, they helped us out a lot. They weighed us. Made sure we were able to keep our weight under control, because they said that was important. [M, 62yo]

The very existence of the group certainly helps. The weekly, or every other weekly, depending on when I get in here, accountability to [group leaders] and the other members of the group. [M, 48yo]

### Group Support

Participants reported that being a part of a group entity comprising peers with shared experience caused them to feel less alone and isolated in their efforts to manage their diabetes and improve their overall health:

I mean, here I love people, how they're doing, how their struggles are, and how they're combating it, and how they're dealing with it. It reinforces you, and it's like we're all human. We all fall. [M, 68yo]

People like that are family, because you know everybody's in the same category. And it was a nice feeling, you know, you were working at keeping your

lifestyle better, living longer, staying healthy. [M, 62yo]

Everyone does bring something to the group who shows up and talks candidly. And say, "Oh, yeah. You've discovered that too," or, "I've done that, too," or, "Oh, this was a hard week, weather-wise." [M, 48yo]

### Increased Confidence in the Ability to Prioritize Health Goals

Individuals found reward in and support for making their health a priority and described feeling empowered to continue to make positive changes:

Especially on the food tip. Oh, man. I don't eat as heavy as I used to. I miss it, but my health is more important. [M, 52yo]

Yeah. I mean, it just makes you feel like you've got a chance (against diabetes); if you can't beat it, you can control it to where it's not that much of a problem. [M, 68yo]

With respect to motivation for group attendance, 58% (14/24) of group participants stated that receiving US \$3 was an incentive for group attendance and 63% (15/24) of group participants reported that receiving a free, healthy meal was an incentive for attendance.

### Group Nonparticipants

Analysis of responses from those who did not attend any groups did not lend itself to a grounded theory approach because of limited and categorical replies. The authors examined categories of responses and summarized the impressions as follows.

Among the 9 individuals interviewed who consented to participate but attended no groups, only 1 reported declining participation because of feeling uncomfortable in a group setting. Two declined because of transportation issues, although both stated that they would have attended if transportation had been provided. Three individuals cited distance as a barrier—of these, 1 stated that he or she would have come if he or she had known about the available US \$3 remuneration and 1 stated he or she would have come if remuneration had been US \$5. Four individuals cited a time conflict as a barrier, and all the 4 stated that they would have attended if the group intervention were held at a different time.

### Quantitative Results

In regression models, improvement in the diabetes knowledge questionnaire was the only significant predictor of improvement in BMI ( $\beta=-1.27$ , SD 0.40;  $P=.003$ ). There were no identified predictors of improvement in HbA<sub>1c</sub> (Table 1).

**Table 1.** Predictors of improvement in hemoglobin A<sub>1c</sub> and BMI.

Variable	Estimate (β)	SD	P value
<b>HbA<sub>1c</sub><sup>a</sup></b>			
Sessions attended	0.18	0.15	.23
SDKI <sup>b</sup>	-0.17	0.16	.28
General diet <sup>c</sup>	0.02	0.16	.89
Specific diet <sup>c</sup>	0.14	0.15	.34
Exercise <sup>c</sup>	-0.12	0.16	.43
BMI	0.26	0.17	.13
<b>BMI</b>			
Sessions attended	0.43	0.38	.25
SDKI <sup>b</sup>	-1.27	0.40	.003
General diet <sup>c</sup>	-0.75	0.40	.06
Specific diet <sup>c</sup>	-0.63	0.39	.11
Exercise <sup>c</sup>	-0.03	0.40	.93
HbA <sub>1c</sub>	0.76	0.49	.11

<sup>a</sup>HbA<sub>1c</sub>: hemoglobin A<sub>1c</sub>.

<sup>b</sup>SDKI: Short Diabetes Knowledge Instrument; score range 0-13, with higher scores indicating greater knowledge.

<sup>c</sup>Subscale of summary of diabetes self-care activities measure: multidimensional assessment of diabetes self-management, number corresponding to days per week activity is performed, range 0-7.

### Data Integration

Improvements in diabetes knowledge emerged as the only predictor of outcome supported by both qualitative and quantitative data, insofar as participants self-reported improvement in diabetes knowledge as important on interview and SDKI score predicted improvement in BMI over the course

of the 16-week intervention (Table 2). Although participants identified accountability, group support, positive reinforcement, and self-management (health prioritization and improved self-confidence) as helpful, neither session attendance rate nor score improvements on a measure of diet and exercise self-care predicted improvement in HbA<sub>1c</sub> or BMI.

**Table 2.** Joint display of quantitative predictors mapped to relevant qualitative themes and resulting mixed methods research inference for group attenders.

Quantitative measures	Predictive of Improvement in A <sub>1c</sub> or BMI	Emergent qualitative themes	MMR <sup>a</sup> inference
Improvements in diabetes knowledge	Yes	Health-related knowledge gains and application to real-world situations	Convergence
Session attendance	No	<ul style="list-style-type: none"> <li>Accountability in goal setting</li> <li>Group support</li> <li>Positive reinforcement</li> </ul>	Divergence <ul style="list-style-type: none"> <li>Importance of factor expanded through qualitative data</li> </ul>
Diet and exercise self-care	No	Health prioritization and improved self-confidence	Divergence <ul style="list-style-type: none"> <li>Importance of factor expanded through qualitative data</li> </ul>

<sup>a</sup>MMR: Mixed Methods Research.

## Discussion

### Principal Findings

Although the open trial demonstrated significant improvement in HbA<sub>1c</sub> with a diabetes self-management intervention, none of the variables the authors investigated (attendance, change in

diabetes knowledge, and change in diabetes self-care) emerged as a significant predictor of this improvement. Of the predictors investigated, only improvement in diabetes knowledge predicted improved BMI. Qualitative interviews shed light on additional thematic and structural group components that participants viewed as key to their group engagement and success.

Knowledge gains related to diabetes, as measured by SDKI, and knowledge gains related to health-promoting behaviors identified through qualitative interviews appear to be an important piece of facilitating behavior change commensurate with improved diabetes self-management. SDKI improvements did not, however, significantly predict changes in HbA<sub>1c</sub>, the primary outcome of the study. This suggests that although objective knowledge gains may be important, these are not the only factors driving improved diabetes self-management, and others may be learned through capture of emergent qualitative themes.

Although session attendance was not predictive of outcomes, participants identified accountability, group support, and positive reinforcement attained through group attendance as crucial to their success. This suggests that the absolute number of sessions attended may be less important than a patient's ability to engage meaningfully with the intervention, such as the individual's capacity to give and receive positive reinforcement and interact in a group setting. Our results align with work supporting the value of peer support in promoting self-management of mental health [33-35], which underscore the importance of peer support, encouragement, hope, and empowerment. Novel interventions show promise in the management of physical health for individuals with serious mental illness, which incorporate peer supporters as change agents [36], and one future direction is to consider employing peers to help deliver diabetes self-management interventions.

Of note, measures of psychiatric symptom severity were not collected during this study but could be important proxies for an individual's ability to benefit from such an intervention, with negative symptoms and cognitive limitations likely presenting barriers to meaningful engagement. Similarly, although scores on diet and exercise self-care scales were not significantly predictive of group performance, improved self-confidence and empowerment to prioritize health were frequently coded themes in the interviews. This has important implications for how the authors may operationalize success from such interventions, including the potential importance of measuring additional outcomes and process variables such as hope, self-efficacy, and empowerment [37].

Payment for group attendance was noted as a moderate incentive for individual attendance for approximately half of the interviewed participants who reported that they used it primarily for transportation or for purchase of food. Similarly, receiving lunch as part of the group appeared to be a moderate incentive for over half of the interviewed participants. Although these 2 contingencies were helpful with retention, most participants cited aspects of the group itself (camaraderie and support) and the positive health behavior changes they were making as their primary incentive for continued participation.

The most cited reason for not attending any group was time conflict, followed by distance and transportation difficulties. Importantly, only one individual stated that he or she declined to participate because of the group format itself, suggesting that, if such programs are made more available, this population is largely willing to participate in a group setting.

This intervention was delivered in a community mental health center where the majority of patients received treatment. Reverse integrated care interventions, defined as medical care delivered in behavioral health care settings, have the potential for high impact on medical management in this population, as individuals with serious mental illness visit psychiatric providers more frequently than their primary care providers and often feel more comfortable in their behavioral health care settings [38]. Moreover, familiarity and knowledge of strengths and self-efficacy of individuals with serious mental illness whom they treat may enable psychiatric care providers to be particularly effective in supporting health behavior change [39,40]. In addition, increasing implementation of behavioral health homes and electronic medical records has increased the ease of communication between psychiatric and medical providers, which may enhance the feasibility and impact of reverse integrated care models for improving management of chronic medical illnesses in people with serious mental illness.

Future studies of diabetes and health management in this population would do well in considering the increasing role and, at times, the necessity of incorporating virtual care models into interventions such as the group intervention presented here, when traditional in-person models may not be possible. Studies have demonstrated the potential role of text messaging and mobile apps in increasing engagement and symptom tracking for individuals with psychosis [41,42] and a growing role for virtual components for enhancing diabetes self-management and support [43,44]; however, to our knowledge, no studies have examined a virtual group intervention for diabetes or a mobile intervention for diabetes tailored for individuals with serious mental illness.

### Limitations

To minimize potential threats to validity, the same sample was used for quantitative and qualitative analyses, a joint display was developed to depict congruency and discrepancy, and both quantitative and qualitative results were reported. The authors maximized variation by approaching all individuals who completed the study for interviews, in addition to individuals who did not attend any groups. As our sample contained individuals who were stable but with serious psychiatric illness and multiple medical comorbidities, this study may be applicable to populations with heavy medical and psychiatric burden served in the broader community, although we noted that in this study, only a small sample of individuals, at 1 community mental health center in Boston, were sampled. Several interviews were notably very brief, particularly among those who did not attend groups, although they were included as they provided information on rationale for group nonattendance and hold the potential to inform future implementation efforts. Researcher bias is possible in this open-label study, as one of the study clinicians who delivered the intervention also participated in coding the qualitative data. Bias was reduced by having a researcher not involved in the intervention conduct the qualitative interviews.

### Conclusions

This study highlighted the group model using a combined educational and behavioral approach as a potentially valuable

mechanism for health-related behavior change among individuals with serious mental illness who are affected by disproportionate morbidity and premature mortality from illnesses with large modifiable health behavior contributors. Participants highlighted the value of the group model and positive reinforcement, accountability, and real-world application of knowledge gained for improving health-related knowledge, behavior, and outcomes. This intervention, in which both psychiatric and medical professionals were on a team with

group members to guide and support, provides an example of participatory medicine in practice in the group setting. Larger scale reverse integrated care controlled trials for individuals with diabetes and serious mental illnesses are needed and would do well to incorporate the aspects of positive reinforcement, patient accountability for individual goals set in the program, and real-world application of the educational concepts highlighted here.

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## Conflicts of Interest

AE receives National Institute on Drug Abuse Grant subcontracts from Brain Solutions, Limited Liability Company, and Charles River Analytics; is on the Data Safety Monitoring Board for Karuna Pharmaceuticals; and has performed Advisory Board work for Alkermes. CC receives a National Institute on Drug Abuse grant subcontract from Charles River Analytics.

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## Multimedia Appendix 1

Semistructured interview guide.

[[DOCX File, 239 KB - jopm\\_v13i1e21934\\_app1.docx](#)]

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## Abbreviations

**HbA<sub>1c</sub>**: hemoglobin A<sub>1c</sub>

**IRB**: Institutional Review Board

**SDKI**: Short Diabetes Knowledge Instrument

**SDSCA**: Summary of Diabetes Self-Care Activity

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Original Paper

# Best Practices for Virtual Engagement of Patient-Centered Outcomes Research Teams During and After the COVID-19 Pandemic: Qualitative Study

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## Abstract

**Background:** Patient-centered outcomes research (PCOR) engages patients as partners in research and focuses on questions and outcomes that are important to patients. The COVID-19 pandemic has forced PCOR teams to engage through web-based platforms rather than in person. Similarly, virtual engagement is the only safe alternative for members of the cystic fibrosis (CF) community, who spend their lives following strict infection control guidelines and are already restricted from in-person interactions. In the absence of universal best practices, the CF community has developed its own guidelines to help PCOR teams engage through web-based platforms.

**Objective:** This study aimed to identify the important attributes, facilitators, and barriers to teams when selecting web-based platforms.

**Methods:** We conducted semistructured interviews with CF community members, nonprofit stakeholders, and researchers to obtain information regarding their experience with using web-based platforms, including the effectiveness and efficiency of these platforms and their satisfaction with and confidence while using each platform. Interviews conducted via Zoom were audio recorded and transcribed. We identified key themes through content analysis with an iterative, inductive, and deductive coding process.

**Results:** In total, 15 participants reported using web-based platforms for meetings, project management, document sharing, scheduling, and communication. When selecting web-based platforms, participants valued their accessibility, ease of use, and integration with other platforms. Participants speculated that successful web-based collaboration involved platforms that emulate in-person interactions, recognized the digital literacy levels of the team members, intentionally aligned platforms with collaboration goals, and achieved team member buy-in to adopt new platforms.

**Conclusions:** Successful web-based engagement in PCOR requires the use of multiple platforms in order to fully meet the asynchronous or synchronous goals of the project. This study identified the key attributes for the successful practice of PCOR on web-based platforms and the common challenges and solutions associated with their use. Our findings provide the best practices for selecting platforms and the lessons learned through web-based PCOR collaborations.

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**KEYWORDS**

attributes; best practices; COVID-19; cystic fibrosis; engagement; outcome; patient; patient-centered outcomes research; qualitative; research; stakeholder engagement; user guide; virtual care; virtual teams; web-based collaboration

## Introduction

Patient-centered outcomes research (PCOR) entails patients and stakeholders partnering with researchers to define research questions, design studies, interpret findings, and generate schema to disseminate information among patients and communities [1]. Authentic collaboration among researchers, providers, and community members requires open lines of communication and trust [2]. During the COVID-19 pandemic, PCOR teams must consider not only the management of team dynamics but also the technology they would use to facilitate successful collaboration. PCOR teams have acknowledged the need to rapidly adapt to web-based team interactions; hence, the demand for web-based operating guidelines has increased [3-6]. While PCOR is traditionally conducted in person, social distancing is now recommended in most cities and states during the COVID-19 pandemic, forcing PCOR teams to collaborate on web-based platforms for continued engagement.

Studies examining virtual team science emphasize the need for web-based technology for meetings, scheduling, day-to-day correspondence, task management, and document sharing, among other purposes [2,7]. The shift from in-person interactions to web-based interactions appears simple; however, evidence indicates that web-based collaboration requires more attention to team dynamics, as conflict and problems in coordination may arise [8]. Additionally, building strong interpersonal connections and trust among team members can be more challenging in a remote working environment [8]. When some team members are colocated and others are geographically dispersed, certain in-groups and out-groups might be unintentionally formed, which can lead to tension and feelings of exclusion among some group members [9].

Our PCOR team, composed of adults with cystic fibrosis (CF), academic researchers, and staff, has only interacted remotely since its establishment in 2016. CF is a rare, multisystem progressive genetic disease. One of its hallmarks is the high risk of persistent lung infections, which causes permanent damage. These infections render individuals with CF at a high risk of cross-infection [10,11]. In 2003, the Cystic Fibrosis Foundation established infection control guidelines to reduce the risk of cross-infection among individuals with CF [12]. Updated in 2013, the guidelines now suggest that individuals with CF should always practice social distancing, staying 6 feet apart from other individuals with CF [12]. Therefore, to support interpersonal connections, the CF community has developed an extensive web-based community, including support groups and medical or scientific conferences [13,14]. The CF community has thus provided a wealth of guidelines for web-based engagement, particularly during the COVID-19 pandemic.

Our study seeks to guide PCOR teams transitioning to web-based community engagement in selecting the best

web-based platforms to sustain authentic interactions among all team members.

## Methods

### Study Design

We conducted qualitative semistructured interviews within an interpretivist paradigm, in which researchers and research participants develop interpretive frameworks to design questions and corresponding responses [15].

Because of its long-standing experience with web-based engagement, the CF community constitutes a primary stakeholder. We interviewed individuals with CF, caregivers of individuals with CF, and employees of a CF advocacy organization. We also interviewed researchers, research staff, and several employees at a training institution. The University of Washington Institutional Review Board approved this study (IRB 6146). Three patient partners (GB, LM, and MP) participated as team members and were engaged throughout the study.

### Participant Recruitment

We used purposive and snowball sampling to target individuals for PCOR, who collaborated mostly or solely through web-based platforms [16]. We aimed to enroll enough participants to reach saturation [17]. Because few PCOR teams engaged only through web-based platforms during recruitment, we expanded our eligibility criteria to include any research team member who self-identified as collaborating either mostly or solely through web-based platforms. Within the CF community, we recruited participants through our partner organizations including the Cystic Fibrosis Reproductive and Sexual Health Collaborative; Cystic Fibrosis Foundation; Cystic Fibrosis Research, Inc; and their networks. Outside the CF community, we recruited participants through the North American Primary Care Research Group's Patient and Clinical Engagement Program, the American Academy of Family Physicians, the National Patient-Centered Clinical Research Network, and the University of Washington's International Training and Education Center for Health. Participants were categorized by stakeholder groups defined by the PCOR Institute [18]. Under these definitions, "patients" include both patients with CF, their caregivers, and advocates; "researchers" include researchers and research staff; and "training institutions" include those that deliver education on health professions or represent the organizations that provide such programs.

### Data Collection

We developed our semistructured interview guide on the basis of 3 components of usability: effectiveness, efficiency, and satisfaction [19,20]. Brooke [20] defined *effectiveness* as the ability of users to complete tasks and achieve goals, *efficiency* as the extent to which users expended resources to achieve their goals, and *satisfaction* as the level of comfort users experience while achieving their goals. We asked participants what

web-based platforms their teams or collaborators use, their experience with these platforms, and their perceptions of the effectiveness, efficiency, and satisfaction with each platform. [Multimedia Appendix 1](#) displays our interview guide.

The interviewer (EKT) was experienced with qualitative research methods. She is a White, cisgender graduate student at the University of Washington and was blinded to the identities of the participants prior to the interviews. On providing informed consent, the study participants were interviewed remotely through Zoom videoconferencing, and the audio in the meetings was recorded. Participants were offered a gift card for up to 45 minutes of their time. At least one other team member transcribed and reviewed each interview for accuracy.

### Data Analysis

We performed content analysis as described by Elo and Kyngäs [21]. We developed a codebook based on 3 robust interviews with inductive and deductive coding approaches [22,23] using the a priori domains “ease of use,” “efficiency,” and “satisfaction.” On developing the codebook, we used team-based coding [22]. Two independent research team members (EKT and MP) coded all interviews using Dedoose qualitative analysis software [24]. When discrepancies occurred, excerpts were read again to clarify the meaning of the code and the selected text.

**Table 1.** Participant characteristics (N=15).

Stakeholder group	Stakeholders, n (%)
Patients	4 (26.7)
Researchers	6 (40.0)
Training institutions	5 (33.3)

### Technological Considerations

Respondents noted that every team member needs to have the proper technology to be equal contributors to research discussions. This is especially important for adhering to the PCOR principles of transparency, partnership, and colearning. We included the following 5 considerations.

#### Variability in Internet Connections

To ensure team cohesion and good communication, participants with either low-bandwidth internet connections or no internet access need accommodations or alternatives to connect and engage with others. Respondents reported that certain videoconferencing platforms were better equipped to handle low-bandwidth internet connections than others. Teams should avoid platforms that deliver inconsistent services, which can lead to poor video quality and cause computers to crash.

*We were having more audio issues with [video conferencing platform] within our country offices. But they were greatly reduced once we started using [a different video conferencing platform].* [Participant #6; training institution]

#### Availability of the Necessary Technology

Respondents noted that every team member needs to have access to a camera and speaker system, which is doable with platforms

EKT led the group to review codes, resolve discrepancies to obtain consensus, and develop the themes through an iterative process [22].

Furthermore, we used PCOR Institute’s 6 principles of engagement (reciprocal relationships, colearning, partnerships, transparency, honesty, and trust) [1] to guide the reconstruction of the themes. We redeveloped and reorganized themes to make our findings practical and usable as guidelines, and this process helped us identify key considerations and challenges for PCOR teams collaborating through web-based platforms.

## Results

We interviewed 15 participants belonging to three separate stakeholder groups—patients, researchers, and teaching institutions (Table 1)—between January and February 2019. Each interview was conducted on a one-on-one basis, although one interview included two interviewees. In total, 10 participants had team members based solely in the United States, and 5 had members outside the United States. Furthermore, we reviewed the participant considerations in the selection of web-based platforms and the common challenges participants faced while collaborating through web-based platforms, along with proposed solutions for these challenges.

that operate on different devices, such as computers, cellphones, or tablets. Respondents cited equipment disparities as a barrier to successful web-based collaboration.

*It would be very important for people who are regularly using online meeting[s] to get the webcam and speaker system just because it... streamlines everything so much. And also, I think the face-to-face is really nice, but most people seem to not have webcams.* [Participant #8; researcher]

#### Institutional Firewalls

Every PCOR team member should be able to easily log into the platforms to effectively engage with others. Participants cited onerous logins and restricted access or institutional firewalls as a barrier to communication and collaboration among teams with community members or patients.

*One thing I don’t like about [document sharing platform] is that it is not possible for me to give access to someone outside [the university]. So, if I’m working on a project where I’m collaborating with someone at another institution or in a community setting, it’s really hard to get them access to a file that’s related to a project. So that is one disadvantage of having [institutional access].* [Participant #15; researcher]

Even certain platforms that do not require an institutional login have requirements that hinder easy access.

*[Document sharing platform] is good, except for the fact that you have to have a [specific email] address. So, we've worked with some people that need access to [a project] but they don't have a [specific] address... So, they had to create a separate email address and have a password to access it. [Participant #10; researcher]*

### **Accommodation for Multiple Languages**

For PCOR teams engaging members who are not fluent in English, participants highly rated platforms that offered translation services.

*I stumbled onto the translation function available in that version of [video conferencing platform], which was great, because one of our managers is in Mozambique. She speaks Portuguese and her English is proficient, but there are times that we struggle in our communication... It allowed us to type in our native language and then translate it into the recipient's language. [Participant #6; training institution]*

### **Cost**

Cost was an especially important consideration for teams with collaborators who have fewer financial resources. Most participants preferred platforms that were either sponsored at low or no cost by an institution or those with free public access.

*In terms of meetings, [video conferencing platform] has been really good, because everyone has access to it and it's mostly free. So that is good in terms of equity for us and our country partners or partners in other resource limited countries. [Participant #13; training institution]*

[Multimedia Appendix 2](#) summarizes the attributes of various tools in web-based platforms for engagement, which were noted by participants interviewed in this study. Considering the breadth of platforms available to teams, we have provided additional details regarding the attributes valued by participants, such as security and privacy, along with other noteworthy benefits and challenges.

### **Challenges and Solutions for Successful Engagement on Web-Based Platforms**

Participants voiced several challenges associated with successful engagement on web-based platforms. We grouped these challenges into 4 separate themes and indicated participants' solutions for each challenge.

#### **Aligning Platform Selection With Collaboration Goals**

##### **Challenge**

One challenge was the misalignment between the tools in web-based platforms and type of communication. For example, short, quick messages delivered through instant messaging (or texting) appeared to lack nuance and were often misinterpreted,

especially if the communication required refinement and explanation.

*When you're writing an email you elaborate, but when you're using [instant messaging], sometimes you have a few sentences or a few words and it might be perceived differently than the message you wanted to send. [Participant #13; training institution]*

##### **Potential Solutions**

Participants emphasized a need for groups to establish policies regarding the choice of platform and the intended purpose (eg, email vs instant messaging vs text messaging). For videoconferencing, respondents indicated that their teams followed certain rules when using the chat feature to reduce cross-talk, which still allow participants to comment (in written form) in real time or appoint a videoconference leader to facilitate the discussion and monitor the conversation for any cross-talk or feedback, muting team members whenever necessary.

*..As we've built out our community engagement efforts, we've actually created best practices for other teams who are collaborating with community members on how to host a virtual meeting in the best possible way. [Participant #3; patient]*

#### **Resembling In-Person Interactions**

##### **Challenge**

Participants reported that interactions on web-based platforms are not the same as those in person because of the loss of nuances that commonly occur during face-to-face interactions. Additionally, participants indicated that it was difficult to develop personal connections with other team members when collaborating on web-based platforms.

##### **Potential Solutions**

Videoconferencing and instant messaging platforms resemble in-person interactions by providing the following advantages: (1) facilitation of verbal and nonverbal communication, (2) focus and accountability, and (3) instant connectivity.

##### **Verbal and Nonverbal Communication**

Participants appreciated videoconferencing platforms because they allowed them to simultaneously see facial expressions and body language while other team members spoke, which facilitated deeper understanding and collaboration.

*It's neat to see, especially with the video, how connected I can feel to people who are working across the country. I see these faces every month, hear these voices, but [when] you can see their face, it feels more connected. [Participant #8; researcher]*

Another participant concurred with the importance of video for engagement.

*Having the ability to ...connect via video chat has changed the way we work with the community... If we were still having phone line conference calls, it would be a disservice to the engagement work that*

*we do. It's as close to face-to-face as we can do.*  
[Participant #3; patient]

Other participants believed that the use of videoconferencing platforms helped team members track the conversation and navigate awkward cross-talk because of the ability to see body language.

### **Focus and Accountability**

Participants indicated that video also helped ensure that others paid attention to the conversation. Several participants described how videoconferencing added a level of focus or accountability similar to that during in-person meetings.

*Because the camera is on, you're accountable. You have to pay full attention to meetings, so that's been great.* [Participant #13; training institution]

### **Instant Connectivity**

Participants favorably described the instant connectivity associated with instant or text messaging. Participants speculated that instant messaging fostered greater cohesion when completing tasks and minimized work delays that often arise with regular email.

*It's just that instant connectivity. As opposed to waiting until the next day particularly with delays when you're working globally. Now you are able to have that instantaneous communication, direct link, to one another.* [Participant #6; training institution]

Additionally, participants described instant messaging as resembling spontaneous, office-based “water cooler” conversations, which are potentially more social and personal in nature. This phenomenon was noted in a team with members based in Seattle (WA, United States) and Harare (Zimbabwe).

*[We have] a [Instant Messaging Platform] group where we send each other little messages about some office things and a lot of times social things: holiday greetings or somebody's baby was born.* [Participant #2; training institution]

## **Learning and Adopting the Technology**

### **Challenge**

Participants noted the challenges associated with the use of the technology among some participants because of a lack of digital literacy (ie, not being “tech savvy”) or needing extra time with new or frequent software updates.

*This is a newer version of [video conferencing and instant messaging platform] and I wasn't able to find the translation. I just spent a couple minutes going, 'I wonder where that is?'...and I realized 'oh, I'd have to spend more time to dive deeper to find where that functionality is.' I am aware that that functionality exists, but I don't know how to get to it.*  
[Participant #6; training institution]

Another challenge in this category, which participants cited, was achieving buy-in from team members to adopt a new web-based tool.

*When something new comes out, it creates like 'Well, why do I need to use a different program management tool, this program management tool is working just fine for me.* [Participant #6; training institution]

### **Potential Solutions**

Designating a team technology champion as the “go-to” person to help select appropriate communication platforms and spend extra time assisting members with relatively lower digital literacy were noted as solutions to ensure every team member can learn and adopt the technology. Other solutions included selecting tools that are simple, intuitive, familiar, and quick to learn among team members or setting aside time during a meeting for all team members to learn the new platform.

*When you aren't comfortable with [a platform] you have to put more effort into it. Depending on the complexity of specific tasks in [the platform], people might be less comfortable using it...You have to take some time to learn the software.* [Participant #13; training institution]

Some participants found it easier to adopt current, mainstream platforms rather than new, customized platforms.

*I think people's familiarity with [frequently used platform] and the fact that many people are within that Google environment, just makes it a viable option.* [Participant #6; training institution]

Another solution suggested by participants was to generate buy-in for platform adoption by persuading an adequate number of team members to post important, interesting, or new content on the platform to entice reluctant adopters to access it.

*You have to be constantly putting content out onto the [instant messaging] platform to keep people engaged or you run the risk of falling off and not checking it.* [Participant #1; patient]

Furthermore, participants suggested adhering to the platform long enough for it to become habitual for all team members, regardless of varying digital literacy levels.

*It has nothing to do with a computer skill level or an intelligence level or competency. It is just simply the more you do it, the faster and easier it becomes.*  
[Participant #14; patient]

## **Improving Team Efficiency on Web-Based Platforms**

### **Challenge**

Participants reported that some platforms are inefficient (eg, the use of email for document editing), leading to multiple versions of the same document and reducing the goal of team efficiency and productivity. Furthermore, signing into multiple web-based platforms was a barrier to team efficiency and productivity.

### **Potential Solutions**

Participants reported that videoconferencing chats, especially with another moderator's assistance, and screen sharing features increased productivity. Other participants suggested that using a web-based platform for multiple individuals to edit a single

document (eg, Google Drive and Egnyte) helped manage the versions of a document and minimized the need for additional discussions through email, videoconferencing, or instant messaging.

*We can all be working on the same file and not have to email it and have 50 different versions floating around. This way we can have one version on [document sharing platform]. We know that's the one we are working on, which is incredibly helpful.*

[Participant #11; researcher]

Additionally, participants encouraged teams to select platforms that integrate with one another to reduce the burden of checking or signing into multiple platforms. For example, Google Drive and Slack (an instant messaging platform) integrate such that Google documents can be previewed, opened, shared, or saved in Slack; this prevents the need to switch to another platform (eg, email) to exchange documents. Platforms that integrate with computer desktops help avoid repeated downloading and reuploading of documents, facilitating easy access to the document among all team members.

*[Document sharing platform] has office integration... So, we can basically work directly on the desktop and everything saves up to [the online platform], so nothing actually ever touches our local workstation.*

[Participant #11; researcher]

## Discussion

### Principal Findings

This study identified platforms that emulate in-person interactions, such as videoconferencing or instant messaging platforms, which have helped regain nuances and social connections that are lost owing to the lack of in-person interactions, particularly during the COVID-19 pandemic. When selecting the appropriate platform tools to use, PCOR team members should consider the infrastructural requirements of the team for access to and comfort with individual platforms. These considerations, in turn, would facilitate the selection of web-based platforms and engagement strategies. Although this study does not provide an exhaustive list of platforms available, our findings would help streamline the selection of such platforms for teams by highlighting certain attributes considered to be of high value by our study participants, and consider other platform benefits and challenges when engaging solely through web-based platforms.

Concurrent with our findings, the National Research Council Committee on the Science of Team Science reported that the use of both video and screen sharing during videoconferencing helps ensure accountability and focus by visualizing facial expressions, body language, and directing attention using a mouse or pointer [2]. Moreover, the National Research Council reported that these nuances can be interpreted differently in different cultures and their implications can be misconstrued, thus emphasizing the need to establish guidelines for the use of the platform on initiating new collaborations [2]. While instant messaging does not emulate in-person interactions, it allowed teams to rapidly discuss work-related queries and provided

space for social interaction. Similarly, other studies have reported that instant messaging is effective for brief work-related communications and discussions, and to maintain social interaction [25,26].

In addition to our findings regarding the importance of selecting platforms that are easy to use, accessible, compatible with other platforms, and of low or no cost, a previous study reported security and privacy, levels of control, and response speed as necessary considerations [27]. Further, we found that access to a reliable internet connection is an important consideration. One study reported that interruptions in video transmission resulting from technical difficulties can be highly disruptive to conversational flow and collaboration [28]. Reliability of an internet connection is potentially important during the COVID-19 pandemic because almost all team members work from home. Further, our study participants reported they stopped sharing video or switched to a telephone call or teleconference when the internet connection was inconsistent. Additionally, if team members speak different languages or require other accommodations, teams should consider platforms with a translation feature. Notably, none of our study participants required accommodation for disabilities; nonetheless, closed captioning and text-to-speech reader features are available on some platforms [29,30].

The National Research Council reported that if a platform is difficult to use, does not align with the team's activities, or does not integrate well with other platforms, it would probably deter collaboration and team efficiency and eventually be abandoned [2]. Our study participants offered additional strategies to establish guidelines to use specific platforms and to designate a technology champion who can spend additional time with members who are less technologically savvy. Similarly, Berente and Howison [31] suggest that web-based collaborations are successful when they establish and maintain guidelines on the use of platforms, particularly when team members rotate across projects or work on multiple projects across different teams and institutions, as is common in PCOR and among other research teams. Since many platforms are designed for full-time use by teams, PCOR teams should consider patient partners, and other external stakeholders may benefit from adhering to one platform so that it becomes familiar to all members.

The unique feature of our study is that it examined methods to collaborate with community members on a research team through a web-based platform. While other studies have reported accessibility as an important attribute to consider when selecting web-based platforms, our study found that specific subthemes under accessibility were particularly important when engaging patient partners and community members. Additionally, [Multimedia Appendix 2](#) provides an opportunity for teams to review attributes of common web-based platforms before implementing them onto the team.

### Limitations

Several limitations in our study warrant mention. We had intended to enroll only PCOR teams to make our findings more applicable to this population; however, we found that few PCOR teams were already engaging solely on web-based platforms when we conducted our interviews in 2019. The CF community

was our key patient and advocacy stakeholder group because individuals with CF have a lifelong requirement to maintain social distance from other individuals with CF and have extensive experience with web-based collaboration. Although we enrolled other research and not-for-profit teams in this study, our findings may not be generalizable to nonresearch teams. Additionally, considering the dynamic nature of web-based platforms and software programs, we recognize that some of the platforms indicated in this study may stop being available. Although we included a diverse group of participants, including individuals with CF, researchers, other nonprofit stakeholders, their perspectives may not be generalizable to all the members of their group. Nonetheless, we believe that many of the valued attributes highlighted by our study participants would still hold true, even as new programs and tools enter the global market.

## Conclusion

This study provides valuable perspectives of PCOR and other research teams that engage through web-based platforms to establish guidelines for teams that were either already collaborating through such platforms or were forced to transition to such platforms owing to the COVID-19 pandemic. Our findings provide a roadmap for PCOR collaborations with considerations for selecting web-based platforms on the basis of individual team requirements, and solutions to potentially common challenges faced by research teams collaborating through web-based platforms. A guide for engagement on web-based platforms generated on the basis of our findings is available on the internet [32].

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## Conflicts of Interest

None declared.

### Multimedia Appendix 1

Semi-structured interview questions.

[DOCX File, 14 KB - [jopm\\_v13i1e24966\\_app1.docx](#) ]

### Multimedia Appendix 2

Benefits and Challenges of Specific Online Platforms.

[DOCX File, 31 KB - [jopm\\_v13i1e24966\\_app2.docx](#) ]

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## Abbreviations

**CF:** cystic fibrosis

**PCOR:** Patient-Centered Outcomes Research



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