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A Web-Based Alcohol Risk Communication Tool: Development and Pretesting Study

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Abstract

Background: Alcohol use is a major public health concern associated with an increased risk of morbidity and mortality. Health professionals in primary care commonly see patients with a range of alcohol-related risks and problems, providing an ideal opportunity for screening and brief intervention (BI).

Objective: This study aimed to develop a prototype for a Web-based tool for use by primary care health professionals (eg, doctors and nurses) to communicate alcohol harm risk to their patients and to engage with them regarding ways this risk could be reduced.

Methods: Following conceptualization and development of prototype wireframes, formative work and pretesting were undertaken. For the formative work, focus groups and key informant interviews were conducted with potential end users of the risk communication tool, including health professionals and consumers. The focus groups and interviews explored perceptions of alcohol risk communication and obtained feedback on the initial prototype. For pretesting, participants (primary care doctors and nurses) completed a Web-based survey followed by a period of pretesting before completion of a follow-up survey. The study was designed to gain feedback on the tool's performance in real-world settings as well as its relevance, ease of use, and any suggested refinements.

Results: In the formative work stage, 11 key informants and 7 consumers participated in either focus groups or individual interviews. Participants were very positive about the prototype and believed that it would be useful and acceptable in practice. Key informants identified that the key point of difference with the tool was that it provided *all the pieces* in 1 place (ie, assessment, interpretation, and resources to support change). Participants provided feedback on how the tool could be improved, and these suggestions were incorporated into the prototype where possible. In the pretesting stage, 7 people (5 doctors and 2 primary care nurses) completed the pretesting. Participants reported that the tool provided a useful framework for an intervention, that it would be acceptable to patients, that it was easy to use, that they would be likely to use it in practice, and that there were no technical issues.

Conclusions: The alcohol risk communication tool was found to be acceptable and has the potential to increase the confidence of health professionals in assessing risk and providing BI.

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KEYWORDS

alcohol drinking; risk assessment; risk communication; harm minimization, primary care

Introduction

Background

Alcohol use is a major public health concern associated with an increased risk of morbidity and mortality [1]. Approximately 1 in 5 New Zealanders aged older than 15 years drinks in a way that is hazardous to their health [2]. Alcohol-related harm has an enormous impact on the lives and health of New Zealanders [3].

Alcohol screening tools are designed to help practitioners identify people not seeking treatment for alcohol problems but whose alcohol use may be harmful or people who may be at risk of an alcohol use disorder. Assessing alcohol consumption, drinking behaviors, and alcohol-related problems is relatively easy using validated clinical alcohol risk assessment tools such as the Alcohol Use Disorders Identification Test (AUDIT) [4]. However, many practitioners can find it difficult to explain to patients their risk of alcohol-related harm and how small changes can have positive benefits [5-7].

Alcohol brief interventions (BIs) are broadly defined as a single short session of structured advice and information for those identified via screening as hazardous or harmful drinkers. They can be conducted by health or social care professionals and delivered by face-to-face sessions, written self-help materials, telephone counseling, or digital programs [8,9]. Most types of alcohol screening and BI are underpinned to some degree by the *stages of change* theory [10] and motivational interviewing [11].

The efficacy and cost-effectiveness of alcohol BIs in primary care settings are well established [8,12-15]. However, primary care offers a different experience than the commonly studied emergency department or hospital setting. Primary care clinicians commonly examine patients with a range of alcohol-related risks and problems [16]. Despite this evidence, the implementation of alcohol screening and BI in primary care remains a challenge. Clinicians in primary care often lack confidence in their ability to do this and are reluctant to initiate discussions about alcohol. This reluctance is not only attributed to perceived lack of resources and training but is also compounded by heavy staff workloads and alcohol-related stigma, along with uncertainty on how to assist patients with more severe alcohol problems [6,17].

As more consumers turn to the internet for health-related information, the internet is increasingly being used by health organizations as a medium to deliver interventions, including alcohol BIs, resources, and services [18]. Web-based interventions have perceived advantages over the more traditional modes of health information delivery, in terms of acceptability and accessibility, privacy and anonymity, and the ability to reach a large audience in a cost-effective manner [19]. A number of recent systematic reviews and meta-analyses lend support to the notion that Web-based interventions offer promise as a strategy to reduce alcohol-related harm in a way that is appealing and nonintrusive to particular groups (eg, those who are unaware of their hazardous drinking behavior or those who are less likely to access traditional alcohol treatment services) [18-23]. Although results tend to show small but significant overall effects in favor of Web-based interventions, it is suggested that the public health impact of large-scale usage in a wide range of community settings could be substantial [23].

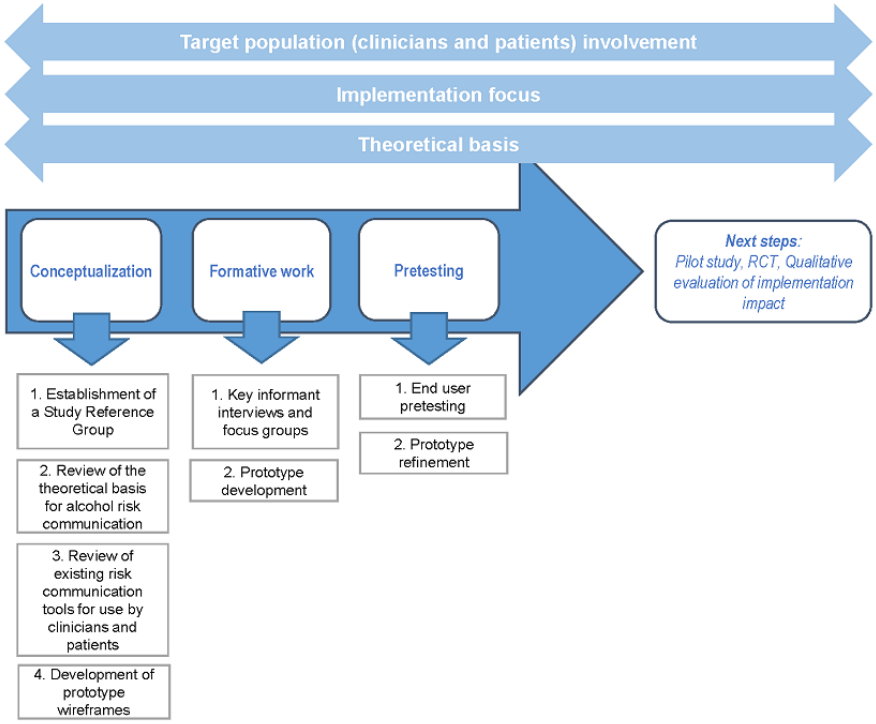
In addition, Web-based alcohol screening and assessment tools offer health care professionals the ability to rapidly assess their patient's alcohol use; detect those with potentially harmful patterns of use; and where appropriate, provide them with a BI [24], helping to remove the barrier for clinicians who are reluctant or who feel ill prepared to proactively discuss with patients their alcohol use [6,17,25]. A systematic review conducted in 2014 by Harris et al [26] exploring the efficacy and feasibility of technology-based alcohol screening and BI tools in medical settings found growing evidence of their benefits.

The aim of this study was to develop a novel prototype for a Web-based alcohol risk communication tool for use by primary care health professionals (eg, doctors and nurses) to communicate patients' risks of alcohol-related harm during routine appointments and to engage with them as to how they can reduce their risk.

Development

The development of the alcohol risk communication tool followed the mHealth Development and Evaluation framework [27]. This framework describes a process, using a series of 7 research steps, in which an intervention (or communication approach) is created based on theory and evidence; involvement of the target audience to ensure the intervention is engaging, useful, and culturally appropriate; and a focus on pragmatic implementation from the outset. This approach is robust and has been successfully utilized in a range of mobile health interventions [28-30]. This study has used the following first 3 stages of this framework: conceptualization, formative work, and pretesting (see Figure 1).

Figure 1. Adapted mHealth Development and Evaluation framework showing stages presented in this paper. RCT: randomized controlled trial.



Conceptualization

An alcohol risk communication tool development team was established to oversee and guide the development process. The team comprised experts in alcohol and injury epidemiology, biostatistics, public health, Māori health, Pacific health, health technology and Web development, health literacy, primary care, risk communication, and drug and alcohol counseling and a health consumer representative. The group provided guidance on all stages of the development and testing of the prototype. During the conceptualization stage, reviews of the relevant evidence and resources were undertaken and discussed with the alcohol risk communication tool development team. Alignment of this information with the stages of change model led to the development of the study's initial prototype wireframes for the Web-based alcohol risk communication tool.

The initial prototype wireframes were developed for the Web-based alcohol risk communication tool. The purpose of the tool was to provide a framework for use in primary care to communicate alcohol harm risk and the benefit of lifestyle changes. For the tool to communicate risk, it was necessary for the tool to incorporate risk screening. The AUDIT [4] was chosen for this purpose because of it being a commonly used tool in primary health care settings. The initial prototype wireframes include the following screens:

- Screen 1: welcome
- Screens 2 to 4: demographic questions
- Screens 5 to 14: risk screening—the AUDIT alcohol risk screening tool [4] incorporating visual representations of responses to items and pop-up boxes providing further details to assist with completing the screening tool
- Screen 15: current drinking behavior—the AUDIT risk score presented using a risk continuum incorporating traffic light colors to indicate level of risk, interpretation of this in relation to risk, and considerations
- Screen 16: changing drinking behavior—details on where changes can be made to lower risk
- Screen 17: others drinking—a question about concern for others drinking and a pop-up for what signs to look for
- Screen 18 to 19: resources—details of available resources and support and the ability of these to be emailed directly to the patient
- Screen 20: close and thank you

Example screens from the initial prototype are displayed in Figure 2.

Figure 2. Example screens of the initial prototype.

Formative Work

Formative work was undertaken to explore ideas about alcohol risk communication, including perceptions about what helps or hinders effective alcohol risk communication in the primary care setting, and to get feedback on the initial prototype. This information was discussed by members of the alcohol risk communication tool development team, and the findings informed changes to the initial prototype, resulting in a revised prototype for pretesting.

Pretesting

Pretesting of the prototype by primary care health professionals (eg, doctors and nurses) was undertaken to gain feedback on the tool's performance in real-world settings as well as its relevance, ease of use, and any suggested refinements.

This paper presents the results of the formative work and pretesting of this tool.

Methods

Formative Work

Study Design

A mix of focus groups and key informant interviews were conducted with potential end users of the risk communication tool, including primary care health professionals (eg, doctors and nurses) and consumers. We aimed to conduct up to 5 focus groups and 6 key informant interviews.

Participants

Participants were identified by the study investigators from existing networks and selected to ensure a range of perspectives representing different health care professionals, representatives of different ethnic groups, and both academic and clinical perspectives. Consumers were identified and invited to participate through the Waitemata District Health Board Community Engagement Team.

Procedures

Both interviews and focus groups were semistructured. The domains of inquiry were identified from a review of the relevant published literature and drawing on the expertise of the research team. The domains of interest included the following:

- Perspectives on risk communication
- How risk should be communicated and by who
- Barriers and enablers to risk communication
- Demonstration of the initial prototype using a hypothetical patient
- Look and feel
- Content (eg, language, complexity, and health literacy aspects)
- Functionality
- Acceptability
- Usefulness

All interviews and focus groups were recorded for the purpose of supplementing notes taken. Participants were offered a NZ $20 shopping voucher as an acknowledgment of their participation.

Analysis

Inductive content analysis [31] was used to analyze the data obtained from the interviews and focus groups. This approach systematically and objectively reduces the data to concepts that describe the research phenomenon [32]. The results are presented by main category. All data were combined, but where differing views were reported, these were categorized by type: health professional or consumer.

Pretesting

Study Design

Participants completed a Web-based survey followed by a period of pretesting before completion of a follow-up survey. The questions in the Web-based survey were, where possible, drawn from previous relevant research. The questions were piloted with members of the alcohol risk communication tool development team (a number of whom are clinicians), and revisions were made accordingly.

Participants

Participants were primary care health professionals (doctors or nurses). Those eligible from the formative work were invited to take part in the pretesting study. Additional participants were identified via existing clinical networks.

Procedures

Eligible participants were invited to participate via email. Following consent, participants were emailed a link to a baseline Web-based survey. On completion of the survey, they received

access to the Web-based tool. Participants were able to test the tool over a 1-week period before completing a follow-up survey.

Measures

Web-based surveys were developed based on a review of surveys used in previous studies of a similar nature. The surveys were built in REDCap software (v8.5.0) and covered the following:

- Baseline survey
- Sample characteristics including demographics and practice characteristics
- Current alcohol screening behavior and barriers to screening
- Perceptions of confidence to identify and manage at-risk drinkers
- Follow-up survey
- Usability and acceptability of the tool
- Suggestions for improvement of the tool
- Perceptions of confidence to identify and manage at-risk drinkers

Analysis

Survey data were analyzed and summarized using descriptive quantitative analyses, including means, standard deviation, and proportions. Qualitative comments were analyzed using inductive content analysis. Where relevant, anonymized quotes from participants are used to illustrate key points.

Ethics Approval

Ethics approval was obtained from the University of Auckland Human Participants Ethics Committee (reference number 020502). Written informed consent was obtained from the focus group, key informant, and pretesting participants before their participation in the studies.

Results

Formative Work

A total of 11 key informants and 7 consumers participated in either the focus groups or interviews. There were 2 focus groups completed: the first with 5 health care professionals (4 doctors and 1 nurse) and the second with 7 consumers. A total of 6 individual interviews were completed involving clinicians from Community Alcohol and Drug Services, academics in addiction research, primary care nurses, health literacy experts, consumers, and primary care doctors. Health professionals working directly with Māori and Pacific people participated in focus groups and key informant interviews. The results are presented by the following domains: (1) general risk communication and (2) feedback on the initial prototype.

General Risk Communication

Consumers strongly felt that their family doctor was the best person to assess their alcohol risk because of the established relationship and the ability of a family doctor to put the drinking into context, that is, family history, current health, and medications. Similarly, most key informants felt that family doctors are appropriate health professionals to assess alcohol risk. Essential to successful risk communication was that it was personalized, that is, the need to focus on the health effects of drinking in a personalized way, and that it was positively framed and focused on improving outcomes.

The most common barrier to risk assessment and communication identified across all participants was time in the context of competing demands within a consultation. Other barriers identified included the invasive nature of risk assessment, confidence in conducting a risk assessment, personality of the family doctor, embarrassment and denial by patients, perceptions that alcohol risk prevalence is low, and perceptions that the risk and associated harms were not a priority for the patient.

Feedback on Initial Prototype

Overall, all key informants and consumers were very positive about the prototype. The participants liked it, felt it was clear and simple, and believed that it would be useful in practice. All participants felt that the tool would be highly acceptable to both clinicians and patients. Key informants identified that the main point of difference with the tool compared with what was already available was that it provided all the pieces in 1 place, that is, the tool included the assessment, its interpretation, ways to make positive changes, and resources, whereas other currently available tools only included 1 or some of these things.

Key informants liked the simplicity of the tool and the use of visual aids and felt that the look was appropriate for the health care setting. Consumers commented that they liked the use of traffic light colors as well as the overall layout and look of the tool. There was feedback from all participants about the length of the tool and the time taken to complete the tool; this related primarily to the AUDIT component of the tool, which was not being evaluated in this project. A potential solution identified by both key informants and consumers was the use of the AUDIT-C initially, with the full AUDIT-10 only being needed for those screened as greater than low risk.

Another common theme was that the tool assumed that the patient was ready to change their behavior and that behavior change had not already occurred. It was, therefore, felt that the tool needed to be refined to take into consideration that changes may already have been made or that the patient may not have prioritized behavior change. It was suggested that the tool could ask about changes in behavior that had already been made and assess motivation to change, which would allow for the identification of discrepancy between current behavior and where they want to be.

Although all participants felt the tool was culturally appropriate, key informants discussed the potential for cultural tailoring and translation of the tool into other languages. Feedback also suggested that tailoring could be expanded beyond culture to other demographic variables, for example, for teenage drinkers. Participants reported the health literacy level to be largely appropriate and that the use of visual aids, that is, risk continuum, helped this.

All key informants highlighted the importance of the tool being embedded and integrated within current patient management systems (ie, linked to the *dashboard* or pop-up within patient record). This was considered vital for getting doctors to use the tool, which, in turn, would be a key factor in the tool's success.

There were differing views on how the tool should best be administered. Some of the clinicians felt that the tool was appropriate for patient-led administration and that there was opportunity for it to be administered in waiting rooms on a tablet, through kiosks in pharmacies, or to be self-administered outside the clinical setting. Others, including all the consumers, felt that administration of the tool was best led by a clinician. They felt that part of the success of the tool would be because of its use being led by a trusted health care professional. They also expressed concern that not everyone that might benefit from using the tool would have access to the technology to use it. They also stressed that if the tool was used outside the clinical environment, then there needed to be appropriate avenues for follow-up if needed.

All key informants felt that the tool complemented other screening tools used in routine consultations, that is, initial visits and annual checkups. By combining the tool with other screening or processes, they felt it would easily become part of routine care. Key informants did not feel that there would be a need for clinician training to use the tool, but there may be a need for training on how it is delivered. It was recommended that simple supporting documents were made available, such as a small card with an overview of the process.

There were many suggestions for how the tool could be further improved within the interviews and focus groups. In addition to the changes described previously, other specific suggestions for improvement included the following: the addition of information on the specific health effects of alcohol consumption and population norms; the addition of an algorithm on the behavior change slide that shows the patient what they should be focusing on to reduce their risk, that is, if the greatest factor in their risk is the quantity they consume on an occasion, then this should be the one that they are encouraged to work on changing first; the ability to send a text message with the links to resources rather than email; and specify that the suggested resources including the phone and SMS helpline numbers were free to access.

Refinement of the Tool Based on the Formative Work

On the basis of findings from the formative work, the following changes were made to the prototype:

- The use of the AUDIT-C first to triage low-level drinkers. After completion of the AUDIT-C, if low risk, the patient is then sent directly to the risk summary page, whereas others continue with the full AUDIT-10 assessment
- The addition of a screen for recent or planned changes in drinking behavior
- Clarifying that the resources and services recommended were free for patients to access
- The removal of the email functionality
- The addition of a slider on the behavior change slide, which indicates where the patient is currently in relation to how often they drink, how much they drink, and how often they drink a lot. The patient can move the slider up and down to show how their behavior change in that area will impact on their risk.

Pretesting

Sample Characteristics

A total of 7 people completed the pretesting study, of which 5 were primary care doctors and 2 were nurses. Of the 7 participants, 3 had been in their current role for 5 to 9 years and 4 had been in their current role for 10 years or more. When asked to describe the ethnic makeup of their practice population, 2 participants were predominately European, 1 predominantly Pacific, 1 predominantly Māori, and the remaining 2 were mixed ethnicity. More than half (4/7) of the patient populations were urban low- to mid-socioeconomic status.

Current Screening Behavior

At baseline, more than half (4/7) of the participants reported that they *always* screen their patients for alcohol use, with the remainder reporting only screening *sometimes*. When asked about barriers to screening for alcohol use, the most common themes were time constraints (n=5) and the nature of the topic (eg, it being difficult to discuss or offensive, privacy, or patients not being honest; n=5). Other common themes included a lack of access to appropriate skills, resources, or referral options if an issue was identified (n=4) or it not being a priority in the consultation (n=3). Only 1 participant reported a lack of training being a barrier to screening.

Perceptions of Confidence to Identify and Manage At-Risk Drinkers

There was a modest increase in confidence to identify and manage at-risk drinkers from baseline to post pretesting (Table 1).

Table 1. Participants' rankings of confidence to identify and manage at-risk drinkers from 1 (not very confident) to 10 (extremely confident), N=7.

Confidence to identify and manage "at risk" drinkers	Baseline, mean (SD)	Follow-up, mean (SD)
Confidence in the ability to differentiate between patients who are "at-risk" drinkers versus those with alcohol use disorders	6.43 (1.99)	7.29 (1.60)
Confidence in knowledge regarding what advice to give at various drinking risk levels	6.57 (2.30)	7.57 (1.72)

Usability and Acceptability of the Tool

All 7 participants reported that the tool provided a useful framework for intervention and that if the tool were to become freely available, they would be likely to use it in their practice. There were no reports of technical issues while pretesting the tool.

When asked how acceptable they thought the tool was or would be for their patients, the majority (5/7) reported it would be very acceptable, 2 participants were ambivalent, and none felt it was unacceptable. Participants rated the tools' ease of use, on average, 8.43 (SD 1.13) on a scale from 1 (extremely difficult) to 10 (extremely easy). Participants were asked whether they thought the tool might be more acceptable by some groups than

others; 3 participants reported that it might be more acceptable to younger and more technologically savvy patients, and 1 participant each felt that it would be more acceptable to patients with English as the first language, risky drinkers (over those with established drinking problems), and specific ethnic groups:

> *Easier for those with English as a first language. Younger or more IT savvy will be more familiar with the format. I think overall it will be pretty acceptable to all.* [Participant 02]

> *Older people who are not computer literate may need guidance.* [Participant 03]

When asked whether they felt the tool had the potential to increase their own confidence in assessing alcohol risks and providing advice to patients, most (5/7) agreed and the remainder stated that it was not applicable as they already had high confidence. Reasons provided for why it increased confidence included it being a simple and straightforward tool (n=2), feeling that it increased the credibility of the clinician (n=1), that it reinforces harm minimization (n=1), and that the use of a visual tool was more engaging for patients (n=1):

> *I think it will increase the credibility of the clinician. Patients believe this sort of tool - they see the tool telling them something not the person [who might be biased].* [Participant 02]

> *To have a visual tool to use with a patient can be more engaging than just hearing advice.* [Participant 06]

Participants were also asked about whether there were any potential barriers to using the tool in general practice. The most common responses included if it was not integrated into the patient management system or dashboard (n=3), patient literacy skills or English language ability (n=2), limited consultation time (n=2), and that they were already using something else for this purpose (n=1).

Suggestions for Improvement of the Tool

The most common reported suggestion for improvement made by participants was to change or remove the pop-up instructions for the questions regarding the quantity of alcohol consumed on a typical drinking occasion (slide 6), which they felt was annoying and unnecessary (n=5). Other suggestions included minor changes to the terminology used on slides, the addition of a tab providing the health care professional with more information about what classifies a patient as low or high risk and associated interventions, and the ability for the data from the tool to be both written into clinical notes and printed in a summary form for the patient to take away.

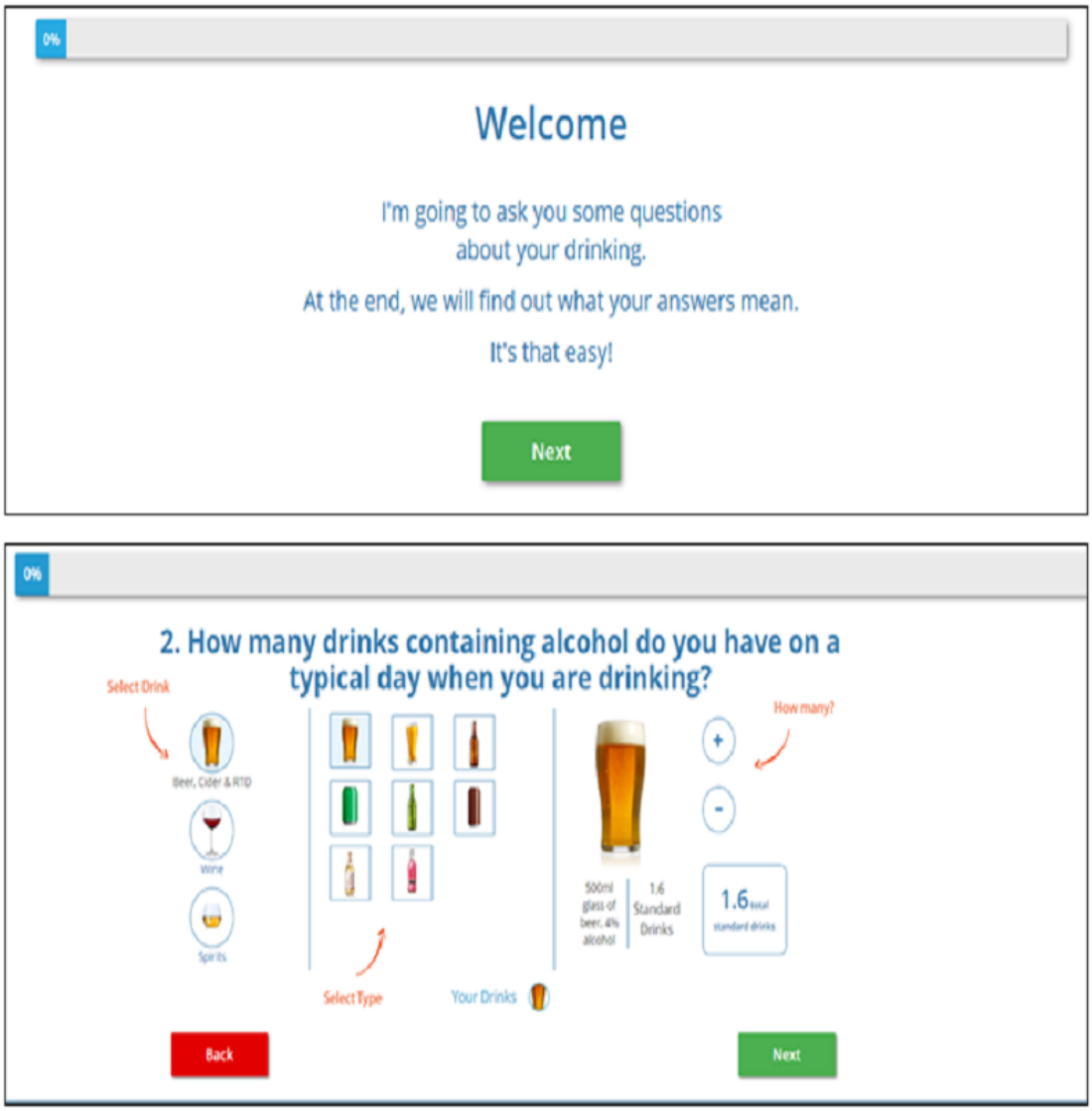
Refinement of the Tool Based on the Pretesting

On the basis of the findings and recommendations from the pretesting study, the following changes were prioritized for the final prototype of the tool:

- Removal of the pop-up on slide 6 and placement of simpler instructions on the actual tool rather than via pop-up
- Changes to the terminology on the age screen
- A print summary option that provides a brief summary that the patient can take away, including their risk score, and potential behavior changes, including a free text area to include any personalized actions discussed and available resources
- Minor layout and appearance changes.

Example screens from the final prototype are displayed in Figure 3. See Multimedia Appendix 1 for the full tool.

Figure 3. Example screens from the final prototype.



Discussion

Principal Findings

This study presents the development of a Web-based *alcohol risk communication tool* for use by health professionals in primary health care to communicate alcohol harm risk and the benefit of lifestyle changes to their patients during the course of routine appointments. The conceptualization, formative work, and pretesting of the tool are discussed. The tool was found to be acceptable by primary care health professionals during pretesting, with support for the tool to be made available in practice.

The alcohol screening and BI developed in this study provide a simple but evidence-based tool to screen, present risk, and provide BI to address this risk in a simple, accessible, and user-friendly way. This work builds on the previous evidence supporting the use of alcohol screening and BIs [8,12,13] and Web-based tools for providing more accessible and cost-effective intervention [19].

In line with other published research, our study found that barriers of time, access to resources, and the nature of the topic still exist in primary care [5-7]. There is potential for this tool to overcome some of the previously identified barriers to the implementation of alcohol screening and BI [6,17]. This tool provides a simple framework for communicating risk and providing BI, is quick and easy to use, and includes all steps in 1 place—screening, BI, and suggested resources and support. Findings from the pretesting showed that the tool has the potential to increase the confidence of health professionals in assessing alcohol risks and providing advice to patients because of it being simple and straightforward, because it increased the credibility of the clinician, and because it was engaging for patients. If the tool was to be integrated into patient management systems, it would have the potential to increase the reach of alcohol BI.

Limitations

The main limitation of this work was the low number of participants (health providers and consumers) representing key priority populations. This limits the generalizability of the

findings, and questions remain about the tool's acceptability to priority populations. It is recommended that further pretesting is conducted with priority populations before the tool is disseminated. Feedback from participants in the formative work indicated that although they felt the tool would be relevant to a diverse population, there was potential for cultural tailoring. The use of further imagery and Te Reo Māori language was suggested. Furthermore, key informants felt that there was potential for the tool to be used with young people; therefore, further work is needed to assess the acceptability in this group.

Although the tool is designed to overcome barriers associated with alcohol screening in primary care, there were some barriers identified in the formative work, which it is not possible to overcome within the scope of this project. Future work is needed to look at how other barriers such as time can be addressed to ensure the widespread adoption of alcohol screening tools.

Implications for Policy, Practice, and Future Research

Further research is required to assess the feasibility and acceptability of the revised tool in a range of settings. The use of the tool in young people, priority populations such as Māori and Pacific, and rural populations needs to be explored. In addition, although the tool was found to be acceptable and perceived to be useful for providing alcohol screening and BI, further research needs to be conducted to evaluate the effectiveness of the tool for reducing the harmful consumption of alcohol.

The findings of this study have confirmed the benefits of engaging with primary care health professionals in the development of technology-based tools for use in that setting. Designing and developing tools for this setting alongside health care professionals ensures greater acceptability and potential use of the tool but is an aspect of technology development that is often overlooked. Health care professionals in this study (both in the development team and as participants) demonstrated a willingness to be involved in the development process because they want tools that can support improved patient care in the primary care context of time-limited consultations, diverse patient needs, and their patient management systems.

Feedback from this study has highlighted the importance of the tool being integrated into the patient management systems of primary health care. Further work needs to be conducted to explore the best way for this to be done across the range of existing patient management systems used in New Zealand primary health care. It is envisaged that including alcohol screening and BI as part of service-level measures will be the most effective way to support and embed screening and BI into primary care.

Although upstream activities such as policy-level changes are most effective at addressing alcohol harm (eg, pricing, regulation, and limiting access), there remains a need for alcohol screening and BI to support individuals to make positive behavior change in reducing their risk of alcohol-related harm.

Conclusions

This study describes the development and pretesting of an alcohol risk communication tool, which has the potential to provide an evidence-based and cost-effective tool for addressing harmful drinking in primary care settings. Next steps will explore the integration into primary care patient management systems, the acceptability in priority populations, and its effectiveness.

Acknowledgments

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Authors' Contributions

All authors contributed to intervention development. BK, SA, SS, RW, and RD contributed to study design and procedures. BK and RD collected, analyzed, and interpreted the data. RD and BR wrote the manuscript. SA, SS, RW, and GH provided critical feedback on the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Screenshots of the final prototype.
[DOCX File , 859 KB - formative_v4i1e13224_app1.docx]

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Abbreviations

AUDIT: Alcohol Use Disorders Identification Test
BI: brief intervention

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Original Paper

An Integrated mHealth App for Dengue Reporting and Mapping, Health Communication, and Behavior Modification: Development and Assessment of Mozzify

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Abstract

Background: For the last 10 years, mobile phones have provided the global health community with innovative and cost-effective strategies to address the challenges in the prevention and management of dengue fever.

Objective: The aim is to introduce and describe the design and development process of Mozzify, an integrated mobile health (mHealth) app that features real-time dengue fever case reporting and mapping system, health communication (real-time worldwide news and chat forum/timeline, within-app educational videos, links to local and international health agency websites, interactive signs and symptoms checker, and a hospital directions system), and behavior modification (reminders alert program on the preventive practices against dengue fever). We also aim to assess Mozzify in terms of engagement and information-sharing abilities, functionality, aesthetics, subjective quality, and perceived impact.

Methods: The main goals of the Mozzify app were to increase awareness, improve knowledge, and change attitudes about dengue fever, health care-seeking behavior, and intention-to-change behavior on preventive practices for dengue fever among users. It was assessed using the Mobile Application Rating Scale (MARS) among 50 purposively sampled individuals: public health experts (n=5), environment and health-related researchers (n=23), and nonclinical (end users) participants (n=22).

Results: High acceptability and excellent satisfaction ratings (mean scores ≥4.0 out of 5) based on the MARS subscales indicate that the app has excellent user design, functionality, usability, engagement, and information among public health experts, environment and health-related researchers, and end users. The app's subjective quality (recommending the app to other people and the app's overall star rating), and specific quality (increase awareness, improve knowledge, and change attitudes about dengue fever; health care-seeking behavior; and intention-to-change behavior on preventive practices for dengue fever) also obtained excellent satisfaction ratings from the participants. Some issues and suggestions were raised during the focus group and individual discussions regarding the availability of the app for Android devices, language options limitations, provision of predictive surveillance, and inclusion of other mosquito-borne diseases.

Conclusions: Mozzify may be a promising integrated strategic health intervention system for dengue fever case reporting and mapping; increase awareness, improve knowledge, and change attitude about dengue fever; and disseminating and sharing information on dengue fever among the general population and health experts. It also can be an effective aid in the successful translation of knowledge on preventive measures against dengue fever to practice.

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KEYWORDS

dengue fever; mHealth; real-time surveillance; health communication; behavior modification

Introduction

For the last 10 years, mobile phones have provided the global health community with innovative and cost-effective strategies to address the challenges in the prevention and management of dengue fever [1]. Dengue fever, which is considered an international public health concern, especially in tropical and subtropical countries, puts an estimated 2 to 3.97 billion people at risk of hospitalization and even death [2,3].

Mobile health (mHealth) is a concept that uses mobile communication devices, such as mobile phones, to deliver services through mobile apps [1]. Apps are specialized software programs that are often equipped with the capability to link to internet sources and services, including health care providers [1]. App-enabled mHealth is emerging as the driver for next-generation telemedicine and telehealth [1]. However, there is a lack of apps that address the prevention and control of dengue fever with relevant studies.

To our knowledge, only one app has been developed with relevant studies, Mo-Buzz. It is a mobile pandemic surveillance system for dengue fever with three main components: predictive surveillance, civic engagement, and health communication [4,5]. These components address the three main limitations in the control and management of dengue fever: (1) use of traditional epidemiological methods (eg, failure to identify the "turning point" of the outbreak leads to vector control measures such as carpet-combing ["search-and-destroy" mosquito breeding sites] near or at the peak of transmission be less impactful [6]), which leads to reactive or poor disease monitoring and surveillance; (2) lack of participation from the public; and (3) lack of effective and interactive health education for the public, which prevents successful translation of awareness or knowledge into actions [4].

Although Mo-Buzz was found to play a significant role in the management and control of dengue fever, we have developed a different mobile app, Mozzify, which offers an integrated mHealth system to address the challenges in dengue fever prevention and management. It has three components: real-time surveillance, health communication, and behavior modification. The main component is the real-time surveillance feature for reporting and mapping dengue fever cases (both laboratory-confirmed hospital and probable dengue fever cases) and mosquito bites. Compared with Mo-Buzz, Mozzify reports and maps dengue fever cases and mosquito bites in real time (versus predictive surveillance) through an online Web map system. There is a lack of spatiotemporal data for dengue fever cases; the data from the real-time surveillance will serve as springboard data for combined predictive and real-time reporting and mapping features of the app in the future. These will be helpful to identify dengue fever hotspots (locations with high incidences of dengue fever cases), so health officials can deliver prompt and early warning communication as well as awareness to the public who are at risk of contracting the disease. Another difference is that Mozzify not only allows reports of probable cases of dengue fever and mosquito bites but also allows reporting of laboratory-confirmed dengue fever cases. Kao et al [7] recommended the introduction of a holistic surveillance system (eg, clinical, serological, and virological) to prevent large-scale epidemics and severe dengue fever cases. The study also recommended the use of a geographical information system for spatial analysis and epidemic prediction models [7].

Another difference of Mozzify from Mo-Buzz is the inclusion of some features in the health communication component. We have developed a system that reports real-time worldwide news about dengue fever and other mosquito-borne diseases; within-app educational videos on the diagnosis, treatment, and management of dengue fever and control of vector mosquitoes; links to websites of local and international health agencies; and a real-time timeline chat forum for sharing information among users. These features aim to increase the public's awareness of the signs and symptoms, treatment, and management of dengue fever as well as the prevention and control of vector mosquitoes.

In addition to these features that center on real-time data, two other unique features of Mozzify that differentiate it from Mo-Buzz are the signs and symptoms checker and the interactive hospital directions. We designed a system that lets users check their signs and symptoms of dengue fever and identify the hospitals that have dengue fever express lanes and cater to Dengvaxia-vaccinated individuals. The aim is to not only inform users about the signs and symptoms of dengue fever but also motivate their health care-seeking behavior, which is based on the health belief model.

The health belief model is a widely used social cognition model to predict health behaviors. This model suggests that a change in behavior or action can be expected if a person perceives themselves to be at risk or susceptible to the disease (perceived susceptibility), that the disease will have serious consequences (perceived severity), a course of action will minimize consequences (perceived benefits), and the benefits of action will outweigh the cost of barriers (perceived barriers) and self-efficacy [8]. However, barriers to sustained self-prevention against dengue fever are caused by a lack of self-efficacy, lack of perceived benefit, and low perceived or unsure susceptibility [9]. People who perceive themselves at risk of dengue fever visit a health care provider promptly compared with those who perceive the opposite [10]. Health care-seeking behavior is also greatly influenced by the inadequacy of primary health care facilities in giving adequate services to dengue fever patients [11].

More importantly, what makes Mozzify different from Mo-Buzz is the inclusion of behavior modification as an important component to address the poor translation of awareness or knowledge of the different preventive practices against dengue fever into actions. To address this, we added a feature that allows users to choose and add items on the list of preventive practices against dengue fever and directly transmit it to the built-in iPhone iOS Reminders app to set-up dates and locations of alerts. It has been reported that epidemiology is strongly

associated with human habits and activities [12]. Kumaran et al [13] and Shuaib et al [14] reported that knowledge of the causes, signs, symptoms, mode of transmission, and preventive practices against dengue fever is not correlated with the practice of preventive measures against dengue fever. Thus, health programs should be designed to focus on translating knowledge into better and effective practices against dengue fever through behavior change. Many programs continue to focus only on changing people's knowledge or raising awareness rather than physical activity programs, which are more successful at producing behavior change [15]. We have used the concept behind Communication for Behavioral Impact (COMBI), a comprehensive strategy that uses communication for knowledge to have a significant effect on behavioral change (making people aware, informed, convinced, and decide to act, then repeating and maintaining that action) to increase the practice of preventive measures against dengue fever [13,16].

This paper aims to describe the design and development process of the Mozzify app. We will also assess it in terms of engagement and information-sharing abilities, functionality, aesthetics, subjective quality, and perceived impact among public health experts, environment and health-related researchers, and nonclinical or general public participants (end users). We hypothesize that the participation and acceptance rates (user's intention to use the app) among the participants will be high due to the app's relevance to the dengue fever control and health communication program. We also hypothesize that the majority of participants will perceive that users will have increased awareness, improved knowledge, and changed attitudes about dengue fever, which will increase health care-seeking behavior and behavior change (on preventive practices against dengue fever) through the use of the app.

Methods

Mozzify App Design and Development

Mozzify is an integrated mHealth app for dengue fever cases reporting and mapping, health communication, and behavior modification. It was developed for the iOS mobile phone platform using Xcode (versions 10.1 to 11.0) software in Swift (versions 4.2 to 5) programming language. The name, Mozzify, is based on the word *mosquito* because its primary purpose is to collect and disseminate information about dengue fever, which is a viral infection transmitted by mosquitoes.

Mozzify has three components: (1) real-time dengue fever cases reporting and mapping, (2) health communication, and (3) behavior modification. These components were matched to three main goals: (1) increase awareness, improve knowledge, and change attitude about dengue fever; (2) increase health care-seeking behavior; and (3) increase intention-to-change behavior on preventive practices against dengue fever. Figure 1 shows the app's three components and goals with its corresponding features. Screenshots of some of the features are shown in Figure 2.

Figure 1. Mozzify's three components with their corresponding features and goals. DF: dengue fever; DOH: Department of Health; WHO: World Health Organization.

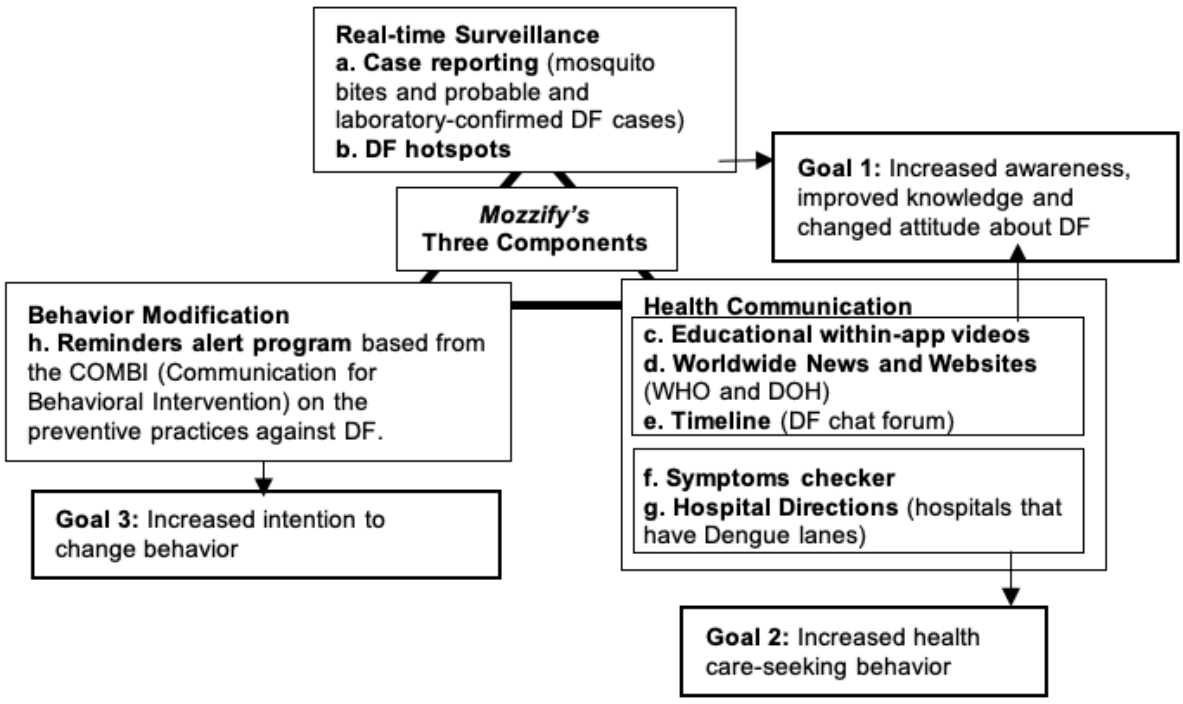
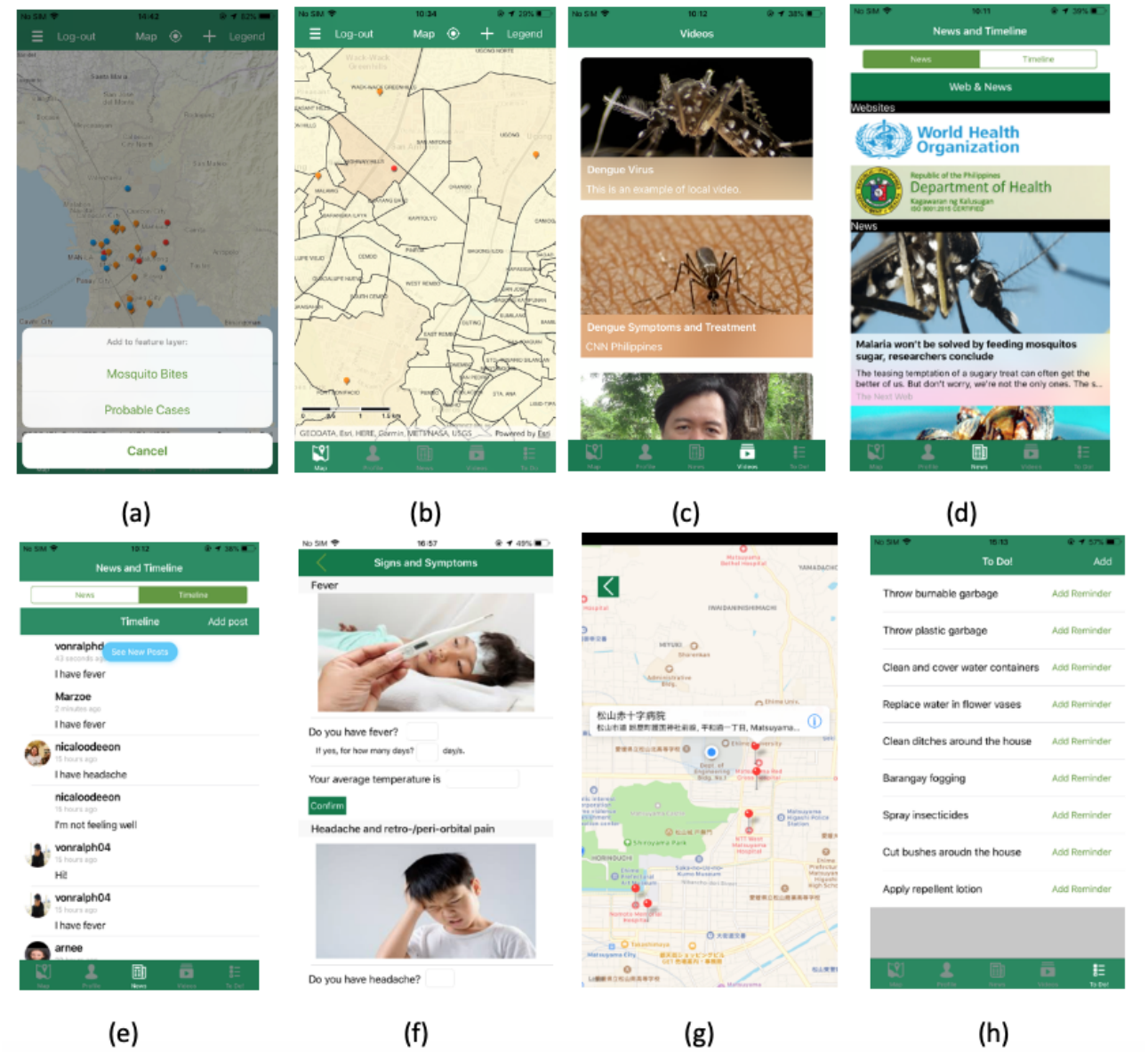


Figure 2. Screenshots of the Mozzify app. (a) Real-time dengue fever cases and mosquito bite reporting and mapping, (b) dengue fever hotspots, (c) within-app educational videos, (d) worldwide news and health agencies websites, (e) chat forum (timeline), (f) symptoms checker, (g) hospital directions, and (h) reminders alert program.



Sign-Up

Sign-up required users to provide information (eg, username and photo [optional], email, and password) to access the app's features. The app collects, stores, and uses personally identifiable information through Firebase, a third-party service provider that serves as our database. The app will collect, store, and use some identifiable information from users to provide its services; therefore, we generated our own privacy policy and terms and conditions (see the Mozzify app user guide Multimedia Appendix 1). Agreement to these was necessary to proceed with sign-up.

Component 1: Real-Time Dengue Fever Cases Reporting and Mapping System

The main feature of this app is the real-time reporting and mapping of dengue fever cases and mosquito bites through ArcGIS Online. ArcGIS Online is an online, cloud-based, collaborative and configurable Web geographical and information system that allows developers to use, create, analyze, and share maps in mobile apps [17]. To use the ArcGIS Online features in our app, we configured the source code provided by Data Collection.NET, which required the installation of ArcGIS Runtime SDK (version 100.5) [18]. Configuration involved registration of our own ArcGIS Portal app, modifying the project in reference to our app, and licensing it for deployment [19]. The map shows real-time probable and laboratory-confirmed dengue fever cases and mosquito bite reports in pins. Probable cases are in blue pins, confirmed dengue fever cases are in red pins, and mosquito bite reports are in orange pins. Users will be able to report a probable case or a mosquito bite incidence, which they can pin at their current location (or any other location). In reporting, users can disclose their personal information (eg, name, home address, and age) and attach images. The map also shows the location (*barangay* or village) with high dengue fever incidences by color using the ArcGIS analysis feature. This feature assigns a darker color

to a location with high dengue fever incidences by counting the number of pins (confirmed and probable dengue fever cases) within its boundary. This analysis is done on a daily basis.

Component 2: Health Communication

The unique parts of the health communication component are the dengue fever warning signs and symptoms checker and the hospital directions feature. Users can answer 26 simple questions (three questions per symptom) in each symptom (eg, Do you have fever? If yes, for how many days? What is your average temperature?), and the app alerts the user if the symptoms need prompt clinical attention by a physician. We formulated the questions and set an algorithm based on the clinical diagnosis, treatment, and management guidelines of dengue fever to allow the app to analyze whether the user needs to go to the nearest hospital to receive prompt clinical assessment by a health professional based on their answers (eg, a fever above 41°C for four days requires immediate clinical assessment by a physician) [2]. If the user's symptoms require prompt medical assessment by a physician, the app sends an alert that the user needs to go to the hospital. Then the app will present a map that shows the user's current location and the nearest hospitals. We collected the coordinates (latitude and longitude) of each hospital and pinned them as an annotation in the map using Google Maps. Once the user clicks a pin of a hospital, the app then shows the directions from their current location to the chosen hospital. In this trial, we selected random nearby hospitals to show the app's feature. The app is intended to be trialed in the Philippines; therefore, we used the list of the hospitals from the Department of Health that has dengue express lanes (including for Dengvaxia-vaccinated individuals who might need immediate medical assistance and free hospital services) [20]. This feature aims to increase health care-seeking behavior among users by encouraging them to go to the hospital to seek medical help from health care professionals and not to self-diagnose or, more importantly, cause a panic.

The app contains different online-sourced, evidence-based, local and international guidelines on the control, prevention, diagnosis, and treatment of dengue fever in PDF (portable document format) files [2,21-24]. Users can also watch predownloaded videos in English and Filipino (Tagalog) on the dengue fever virus, symptoms, diagnosis, and treatment available. We also used news Application Programming Interface (API), a free, open-source, and noncommercial API that collects news from our set request parameters (eg, keywords: mosquito, dengue fever) and shows users the latest international and local news from almost 30,000 news sources and blogs on dengue fever and other mosquito-borne diseases, such as malaria, zika, chikungunya, and Japanese encephalitis. The app also shows the websites of international and local health agencies, such as the World Health Organization and Department of Health, which give the users information on key facts, prevalence, treatment, immunization, prevention, and control guidelines and programs on dengue fever [25,26]. The app's health communication feature was also designed to let users exchange and share posts on events, concerns, and questions on dengue fever through a chat forum (timeline) by using the Firebase online database. Altogether, these aim to increase awareness, improve knowledge, and change attitudes about dengue fever.

Component 3: Behavior Modification (Preventive Practices Against Dengue Fever)

Another component of the app is the behavior modification feature, which includes the Reminder alerts program based on COMBI. This is expected to develop or improve users' behavior on practicing preventive measures against dengue fever. COMBI is a comprehensive strategy that uses communication for knowledge to have a significant effect on behavioral change (making people aware, informed, convinced, and then deciding to act, and repeating and maintaining that action) or increase practices against dengue fever [13,16]. The app has a list of practices against dengue fever based on international and local guidelines on prevention, management, and vector control programs [2,21-24]. The user has the option to select and add practices according to their needs or preference. After selection, the app adds all the items to the built-in iOS Reminders app on their mobile phones. In that app, users can set the priority and edit when (eg, time, day, and frequency [daily, weekly, or monthly]) and where (radial location settings) they want alerts.

Testing and Assessment

This study was written and conducted in accordance with international guidelines: the Declaration of Helsinki [27] and the International Council for Harmonization Good Clinical Practice guidelines [28]. The protocol was approved by the Ethics and Review Committee of Ehime University, Japan (ethics review approval number: K19-001). The app was tested in July 2019 after the completion of its development.

This study involved 50 purposively sampled participants grouped into three subgroups who tested the app: (1) public health experts (n=5), (2) environment and health-related researchers (n=23), and (3) nonclinical users (n=22). The participants were selected, recruited, and grouped according to the set inclusion criteria. Public health experts were academic and clinical research experts working directly on prevention, control (including an ArcGIS mapping expert), and clinical management of dengue fever. Environment and health-related researchers were university-based researchers working on vector-borne diseases and water ecology. Both the public health experts and environment and health-related researchers were from countries where dengue fever is prevalent (eg, the Philippines and Indonesia). The third subgroup, nonclinical, were considered as end users and had no comprehensive knowledge of or experience with dengue fever. A few information technology and computer science researchers were also included in the environment and health-related researchers and nonclinical groups.

All participants were aged 18 years and older, with sound psychological conditions, who were able to read and understand the informed consent contents, and used an iPhone mobile phone of any model with iOS of 11.0 and above. Initially, when found eligible, participants were asked to sign an informed consent sheet. Of the 50 participants, 36 (72%) were invited for either a focus group or an individual discussion session to provide more comprehensive qualitative feedback, whereas others, who

were mostly in the nonclinical group, were invited by email (n=14). All participants were asked to install the app on their mobile phones after a Web-based invitation by downloading Test Flight, the beta testing feature of the Apple Inc developer program. After installation, all participants were asked to use the app by following the instructions in the user's guide (see Multimedia Appendix 1), which was available in print and on a website.

Participants were asked to complete the Mobile Application Rating Scale (MARS). Their responses were automatically stored in the password-protected database, and each participant was given a unique code to protect their identity. MARS is a 23-item test that uses a 5-point scale (1=inadequate, 2=poor, 3=acceptable, 4=good, 5=excellent), which assesses the app quality on three subscales: objective quality, subjective quality, and app-specific quality [29]. The objective quality subscale has 19 items that are clustered into four parts: engagement (fun, interesting, customizability, interactivity, and well-targeted to audience), functionality (functioning, easy-to-learn, navigation, flow logic, and gestural design), aesthetics (graphic design, overall visual appeal, color scheme, and stylistic consistency), and information quality (containing high-quality information from a credible source) [29]. The subjective quality subscale has four items that measure the user's desire to recommend the app to others, use the app for short or long term, and overall star rating of the app [29]. The app-specific subscale was modified based on the perceived impact of the app on the user's awareness and knowledge (dengue fever symptoms, hospitals that cater to dengue fever patients, dengue fever hotspots, dengue fever prevention and treatment), attitudes (perceived risk or susceptibility, perceived severity, benefits and barriers, and self-efficacy), help-seeking behavior (health care-seeking behavior), intentions, and actual change of behavior in practicing preventive measures against dengue fever. Scoring was done by calculating the mean score of each subscale, adding them together, and dividing by four (four subscales) to get the app quality mean score, four (four items) to get the app subjective quality mean score, or six (six items) to get the app-specific mean score [29]. Irrelevant items were one item in the information subscale (if the app underwent evidence-based trial/test) and one item in the subjective quality subscale (Would you pay for this app?) and these were not included in the analysis (app has not been trialed/tested and will not be sold). MARS has an excellent total score internal consistency level Cronbach alpha (α=.90) and excellent level of interrater reliability (two-way mixed interclass correlation coefficient [ICC]=0.79, 95% confidence interval [CI] 0.75-0.83). Its subscales also had very high internal consistencies that ranged from alphas of .80 to .89, and fair to excellent interrater reliabilities (ICC 0.50-0.80, median 0.65) [29]. The MARS form is available in Multimedia Appendix 2.

Data Analysis

Statistical analysis was conducted using SPSS version 25 (IBM Corp, Armonk, NY, USA). We calculated the mean scores of each subscale in the app objective quality scale and each item in the app subjective scale. The app subjective quality scale was reported as individual items and by mean score. Comments and suggestions in the focus group and individual discussions were analyzed, and similar or overlapping topics were grouped into different themes.

Results

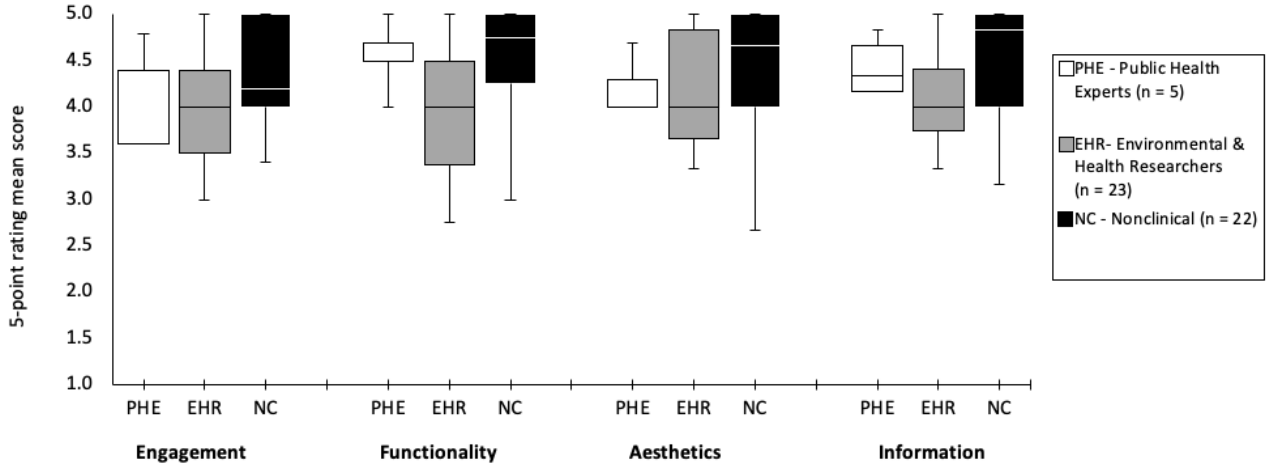
Participants

A total of 50 individuals, aged from 19 to 45 years and mostly males (60%, 30/50), participated in the app testing. All participants we approached and recruited agreed to test the app and answer the scale; the majority (78%, 39/50) attended the focus group and individual discussions. This indicates excellent acceptability and nonwithdrawal rates among experts, health researchers, and the general public or end users. In all, 68% (34/50) were able to install the app on their mobile phones, whereas the rest used our available prototypes.

App Objective Quality

Mozzify was assessed using the MARS app objective quality, which has four subscales: engagement, functionality, aesthetics, and information. Figure 3 shows the mean score ratings of the public health experts, environment and health-related researchers, and nonclinical or general public participants. Mozzify received high (≥4 out of 5; 74%, 37/50) satisfaction mean ratings in all four subscales among the participants, with the highest mean score ratings (mean 4.3, SD 0.2) for items relating to the app's functioning, easiness to learn, navigation, flow, logic, and gestural design, graphic design, overall visual appeal, color scheme, and stylistic consistency, and for containing high-quality information from a credible source. A mean rating of 4.2 (SD 0.2) was obtained for items relating to the app being fun, interesting, customizable, interactive, and well-targeted to the audience.

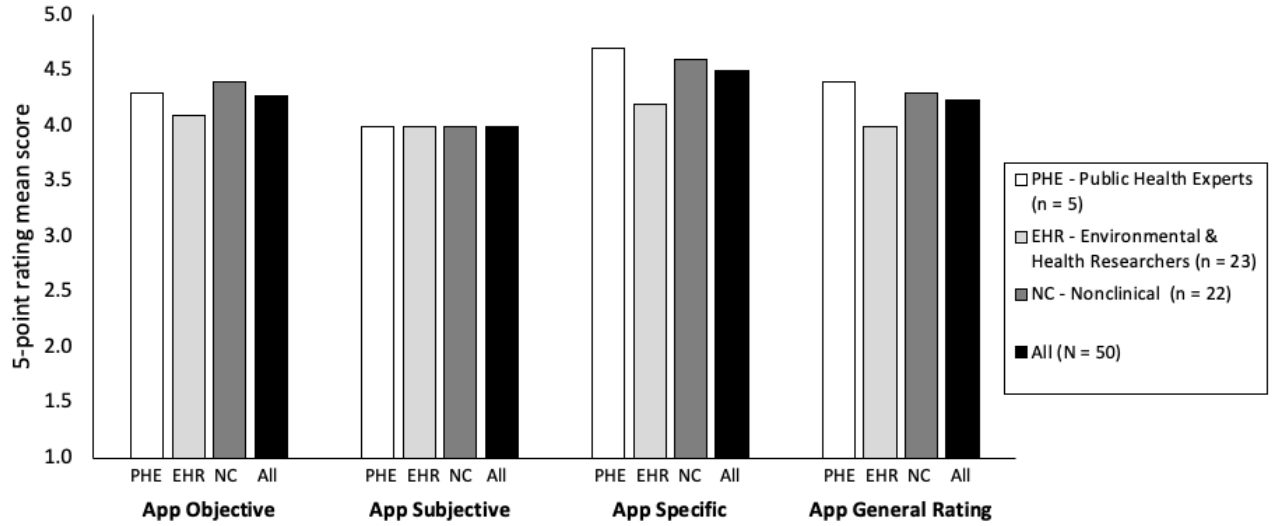
Figure 3. Mean scores of app objective subscales based on the Mobile Application Rating Scale (MARS) from public health experts, environment and health-related researchers, and nonclinical participants.



App Subjective Quality

Public health experts, environment and health-related researchers, and nonclinical participants had similar satisfaction mean ratings (mean 4.0, SD 0.4) in the app subjective quality subscale, as shown in Figure 4. Specifically, items about recommending the app to other people and the app's overall star rating had relatively high satisfaction mean ratings of 4.2 (SD 0.2), whereas the item on using the app in the next 12 months obtained the lowest satisfaction mean rating of 3.4 (SD 0.3) among the participants. All participants reported that they would recommend the app to people who might benefit from it. All public health experts and a majority of the environment and health-related researchers (86.9%, 20/23) and nonclinical participants (77.3%, 17/22) perceived that the app was relevant to them and they would use it 3 to more than 50 times in the next 12 months. Public health experts gave the app the highest overall star rating of 4.4 (SD 0.5), whereas both environment and health-related researchers and nonclinical participants gave it 4.1 (SD 0.7 and 0.8, respectively).

Figure 4. Mean scores of app objective, subjective, specific, and general rating based on the Mobile Application Rating Scale (MARS) from public health experts, environment and health-related researchers, and nonclinical participants.



App-Specific Quality

The MARS app-specific quality subscale items were modified based on the components and goals of the app, which were to increase awareness, improve knowledge, change attitudes about dengue fever, and increase intention to change and help-seeking behavior among users. The item on increasing users' knowledge or understanding of dengue fever symptoms, hospitals that cater to dengue fever patients, dengue fever hotspots, and dengue fever prevention and treatment obtained an excellent satisfaction average mean rating of 4.7 (SD 0.3) (Figure 4). Items on increasing user awareness of the importance of addressing dengue fever symptoms, hospitals that cater to dengue fever patients, dengue fever hotspots, dengue fever prevention and treatment, and encouraging users to seek clinical assessment when they have dengue fever symptoms (if required) obtained an average satisfaction mean rating of 4.5 (SD 0.3 and 0.1, respectively) from all participants. Moreover, items on changing users' attitudes toward improving practices against dengue fever and increasing users' intentions or motivation to address behavior change (practicing preventive measures against dengue

fever) obtained overall mean ratings of 4.4 (SD 0.3) and 4.3 (SD 0.3), respectively, among the participants. In general, the app obtained a high satisfactory mean rating of 4.5 (SD 0.1) in the app-specific quality subscale among the participants.

Focus Group and Individual Discussions

Approximately 78% (39/50) of participants were able to attend the focus group and individual discussions. Five public health experts were able to participate in the focus group discussion. All found the app useful and were positive about its concept, components, and goals. However, three issues were raised during the session. The first issue was the availability of the app for iOS (iPhone) mobile phones only. Participants mentioned that it would be better if the app was also available for Android so that everyone with a mobile phone could use it. The second issue was the app was only available in English, and it should also be available in other languages. This would allow the app to be distributed in many countries where dengue fever is highly prevalent. Lastly, one expert mentioned about the ability of the app to do predictive surveillance and identify dengue fever hotspots based on past annual dengue fever incidence reports and not only based on the number of pins in a location (barangay or village).

Environment and health-related researchers also had positive feedback about the app. They found the app concise and relevant, interesting, and convenient. Some perceived that the app was effective in reducing the number of dengue fever patients, and it would help increase user's awareness of dengue fever, especially those who live in tropical and subtropical countries with high numbers of dengue fever cases. Although the majority of the environment and health-related researchers mentioned that the app was easy to use, some suggested that it should include a within-app user's guide (eg, pop-ups or labels). Two other suggestions were raised about increasing the engagement ability of the app: (1) the app should include games so people will use it daily and (2) it should include other mosquito-borne diseases (eg, zika, chikungunya, Japanese encephalitis, and malaria) in the real-time reporting and mapping feature of the app. Similar to the public health experts, they also suggested that the inclusion of many languages other than English is highly desirable.

The nonclinical group, who were considered the end users, found the app excellent, useful, exciting, interesting, and helpful for countries that suffer from dengue fever outbreaks. They perceived the app was able to improve their knowledge, attitudes, and awareness by seeing the pictures of symptoms, videos, dengue fever hotspots, and nearby hospitals that cater to dengue fever patients. Specific suggestions were mentioned about the technical and functional details of the app that needed polishing and revisions (eg, buttons and gestures).

Discussion

We have introduced and described the design and development process and the testing of the functions and features of Mozzify. Results show that it obtained excellent acceptability and satisfaction ratings based on the MARS app quality subscales among the participants. This indicates that it has good user design, functionality, usability, engagement, and contains a relevant information system. The app subjective ratings also indicate that the experts and users are more likely to recommend the app to others and more likely to use it frequently in the future. Moreover, based on the specific quality subscale ratings of the participants, the app achieved what it intended to achieve. It could be a highly effective tool in increasing user's knowledge and awareness of dengue fever symptoms, hospitals that cater to dengue fever patients, dengue fever hotspots, and dengue fever prevention and treatment; changing user's attitudes about dengue fever and its symptoms; and encouraging users to seek clinical assessment when they have dengue fever symptoms (if required). It also indicates the app can improve users' practice of measures against dengue fever, and increase users' intentions or motivation to address behavior change by practicing preventive measures against dengue fever.

Based on the focus group and individual discussions, participants found the app concise, relevant, interesting, convenient, excellent, useful, and exciting. Some perceived that the app is effective in reducing the number of dengue fever patients, and it will help increase user's awareness of dengue fever, especially those who live in countries with high incidences of dengue fever cases. They also perceived that the app was able to improve their knowledge, attitudes, and awareness of dengue fever. Although participants were positive toward the app, some issues were also raised: the availability of the app on iOS (iPhone) mobile phones only, language option limitations, the need for a within-app user's guide (eg, pop-ups or labels), and polishing of the app's technical and functional details (eg, buttons and gestures). Some suggestions were also given by the participants: the use of predictive surveillance, inclusion of other mosquito-borne diseases in the real-time reporting and mapping feature, and use of games to increase usability and engagement among users.

We have only managed to do minimal revisions (simpler log-in and sign-up pages and pin legend in the map screen) in the design of the app for an immediate trial and assessment in the Philippines.

We have developed and designed a mobile app, Mozzify, which obtained excellent acceptability and ratings (mean scores ≥4.0 out of 5) based on the MARS subscales among health experts and researchers and the general public, which indicate that it is ready for another trial among a larger population in the Philippines. It may be a promising integrated strategic health intervention system for reporting and mapping dengue fever cases; increasing awareness, improving knowledge, and changing attitudes about dengue fever; and disseminating and sharing information on dengue fever among the general population and health experts and for the knowledge on how to prevent dengue fever to be successfully translated to practice.

We have started to collect data on the longitudinal spatial analysis of dengue fever hotspots in the Philippines as a provision for a predictive surveillance feature, and the inclusion of other mosquito-borne diseases in the reporting and mapping system in the future. Thus, we also plan to design an alert system on the map that would warn users when they enter or when they are near a barangay/village or area with a high incidence of

dengue fever cases and mosquito abundance. We are also working on developing an Android version of the app, more language options, and the possible inclusion of games to increase usability and engagement among users in the future. Our aim is that Mozzify will address the lack of available apps for the control and prevention of dengue fever not only in the Philippines but also in other countries with dengue fever and other mosquito-borne diseases worldwide.

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The authors would like to thank Yoshihiro Yagi, Yoshiya Furukawa, and all the health experts, environment and health-related researchers, and end users from Ehime University, Japan, who participated in this study. This study was supported by the Japan Society for the Promotion of Science (JSPS) Grant-in-Aid for Scientific Research (17H01624, 19H01144), JSPS Core-to-Core Program B Asia-Africa Science Platforms, and Endowed Chair Program of the Sumitomo Electric Industries Group Corporate Social Responsibility Foundation, which had no role in the design, data collection, statistical analysis, and writing of this manuscript.

Authors' Contributions

Author VRDMH conceptualized, designed, and developed the Mozzify app, designed the study, wrote the protocol, conducted the data gathering, analyzed the data, and wrote this manuscript. Author TK helped design the framework and features of the mobile app. Author MEF provided guidance in using the ArcGIS mapping system, the user privacy policy, and the app's terms and conditions. Author KW supervised the data gathering and provided guidance and comments on the analysis and the initial drafts of this manuscript. All authors contributed to and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Mozzify's user guide.
[PDF File (Adobe PDF File), 150524 KB - formative_v4i1e16424_app1.pdf]

Multimedia Appendix 2
MARS form.
[PDF File (Adobe PDF File), 175 KB - formative_v4i1e16424_app2.pdf]

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Abbreviations

API: Application Programming Interface
COMBI: Communication for Behavioral Impact
MARS: Mobile Application Rating Scale

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Original Paper

Using Natural Language Processing to Examine the Uptake, Content, and Readability of Media Coverage of a Pan-Canadian Drug Safety Research Project: Cross-Sectional Observational Study

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Related Article:

This is a corrected version. See correction statement: http://formative.jmir.org/2020/6/e20211/

Abstract

Background: Isotretinoin, for treating cystic acne, increases the risk of miscarriage and fetal abnormalities when taken during pregnancy. The Health Canada–approved product monograph for isotretinoin includes pregnancy prevention guidelines. A recent study by the Canadian Network for Observational Drug Effect Studies (CNODES) on the occurrence of pregnancy and pregnancy outcomes during isotretinoin therapy estimated poor adherence to these guidelines. Media uptake of this study was unknown; awareness of this uptake could help improve drug safety communication.

Objective: The aim of this study was to understand how the media present pharmacoepidemiological research using the CNODES isotretinoin study as a case study.

Methods: Google News was searched (April 25-May 6, 2016), using a predefined set of terms, for mention of the CNODES study. In total, 26 articles and 3 CNODES publications (original article, press release, and podcast) were identified. The article texts were cleaned (eg, advertisements and links removed), and the podcast was transcribed. A dictionary of 1295 unique words was created using natural language processing (NLP) techniques (term frequency-inverse document frequency, Porter stemming, and stop-word filtering) to identify common words and phrases. Similarity between the articles and reference publications was calculated using Euclidian distance; articles were grouped using hierarchical agglomerative clustering. Nine readability scales were applied to measure text readability based on factors such as number of words, difficult words, syllables, sentence counts, and other textual metrics.

Results: The top 5 dictionary words were *pregnancy* (250 appearances), *isotretinoin* (220), *study* (209), *drug* (201), and *women* (185). Three distinct clusters were identified: Clusters 2 (5 articles) and 3 (4 articles) were from health-related websites and media, respectively; Cluster 1 (18 articles) contained largely media sources; 2 articles fell outside these clusters. Use of the term *isotretinoin* versus *Accutane* (a brand name of isotretinoin), discussion of pregnancy complications, and assignment of responsibility for guideline adherence varied between clusters. For example, the term *pregnanc* appeared most often in Clusters 1 (14.6 average times per article) and 2 (11.4) and relatively infrequently in Cluster 3 (1.8). Average readability for all articles was high (eg, Flesch-Kincaid, 13; Gunning Fog, 15; SMOG Index, 10; Coleman Liau Index, 15; Linsear Write Index, 13; and Text Standard,

13). Readability increased from Cluster 2 (Gunning Fog of 16.9) to 3 (12.2). It varied between clusters (average 13th-15th grade) but exceeded the recommended health information reading level (grade 6th to 8th), overall.

Conclusions: Media interpretation of the CNODES study varied, with differences in synonym usage and areas of focus. All articles were written above the recommended health information reading level. Analyzing media using NLP techniques can help determine drug safety communication effectiveness. This project is important for understanding how drug safety studies are taken up and redistributed in the media.

(JMIR Form Res 2020;4(1):e13296) doi:10.2196/13296

KEYWORDS

natural language processing; mass media; readability; pharmacoepidemiology; knowledge translation

Introduction

Web-Based Health Information and News Media

Easy access to health-related information has rapidly transformed the traditional health care delivery paradigm. Patients increasingly use the internet to seek health information and learn more about symptoms, diseases, treatments, self-management, risk mitigation strategies, and shared decision-making with their health care providers [1]. Up to 35% of all adults in the United States (and up to 45% of women and people with higher education) consulted the internet for health or medical information, either for themselves or someone else [2]. In the United Kingdom, 87% of adults read either electronic or traditional newspapers [3]. In 2012, 66.8% of Canadians aged 16 years and older searched the Web for medical or health-related information per Statistics Canada's *Canadian Internet Use Survey* [4].

News media can have a significant impact on people's perception and interpretation of scientific research. Journalists and science writers present the results from scientific publications in news articles for the public, health care providers, and policymakers, but also may influence attitudes and health behaviors [5]. Although some believe that the process of journalism is relatively linear with information received from researchers and transmitted by journalists to a poorly informed public, others discuss the cocreation of media with journalists and the public, voluntary health organizations, or professionals in health services delivery, government, and private sector health care companies [3]. News media have guidelines and ethical principles for reporting [6,7], as well as resources to help them interpret the technical material (eg, Evidencenetwork.ca and HealthNewsReviews.org) and review criteria for elements to include in health reporting [5,8]. In addition, organizations such as the Health and Medicine Division of the National Academies of Sciences, Engineering, and Medicine have provided information on communicating the risk, benefit, and uncertainty related to drug therapy [9]. Nevertheless, it has been reported that some media interpretation may be hard to comprehend, fail to provide context, or contain exaggeration, false impression, incorrect numbers, immature data, or not-yet approved methods from ongoing research [3,10-13]. It is, therefore, critical to study how the media cover medical research and investigate the quality of reporting and presentation of scientific findings [14,15].

The use of natural language processing (NLP) techniques and readability assessments can help us better understand how the media are reporting on the medical research we conduct. We used a study conducted by the Canadian Network for Observational Drug Effect Studies (CNODES) evaluating the effectiveness of one aspect of the isotretinoin Pregnancy Prevention Program in Canada [16] as a case study to explore how the media present pharmacoepidemiological research.

Canadian Network for Observational Drug Effect Studies

CNODES is a network of Canadian pharmacoepidemiologists—distributed across 7 provincial sites and supported by 4 collaborative teams working across all sites—funded by the Canadian Institutes of Health Research (CIHR) to study the risks and benefits of postmarketed drugs [17]. CNODES responds to queries on drug safety and effectiveness from decision makers and other stakeholders (eg, Health Canada and federal, provincial, and territorial pharmacare decision makers) by using meta-analytic methods to combine deidentified administrative health data from across Canada, the United Kingdom, and the United States [18]. The CNODES knowledge translation team leads the network's activities related to translating and mobilizing research results from specific studies for decision makers, stakeholders, and the public via the media. The results of the CNODES isotretinoin study, described below and published in the *Canadian Medical Association Journal* (CMAJ) in April 2016 [16], were shared via a press release, subsequent media interviews with lead investigators, and a podcast developed by CMAJ to accompany the publication.

Case Study: Isotretinoin and Pregnancy Prevention Program Adherence

Isotretinoin, a known and potent teratogen, is widely used to treat cystic acne. Fetal exposure may result in a range of severe congenital anomalies and may increase the risk of spontaneous and induced abortion [19,20]. Although the risks of pregnancy during isotretinoin therapy are well recognized, research continues to reveal poor adherence to pregnancy prevention guidelines and programs [21-24]. In Canada, a voluntary pregnancy prevention program was designed to prevent fetal exposure to isotretinoin. It requires informed written consent, 2 pregnancy tests with negative results before starting isotretinoin, and 2 reliable forms of contraception during treatment [25]. The objective of the CNODES study [16] was to evaluate specific aspects of the effectiveness of the Canadian pregnancy prevention program in 4 provinces: British Columbia, Saskatchewan, Manitoba, and Ontario.

In total, 59,271 female patients received 102,308 courses of isotretinoin therapy. Oral contraceptive use during treatment ranged from 24.3% to 32.9%. Overall, there were between 186 and 367 pregnancies during isotretinoin treatment (3.1-6.2 per 1000 isotretinoin users), depending on the method used to define pregnancy. When follow-up was extended to include the full gestational period (up to 42 weeks), there were 1473 pregnancies (24.9/1000 users) using the high specificity definition. Most of these (1331 pregnancies, or 90.4%) were lost spontaneously or terminated by medical intervention. A total of 118 live births were identified and 11 (9.3%) had a diagnosis of congenital malformation. Annual rates of pregnancy during isotretinoin therapy did not change between 1996 and 2011. The CNODES study concluded that adherence to the isotretinoin pregnancy prevention program was poor during the 15-year period [16].

Objectives of This Study

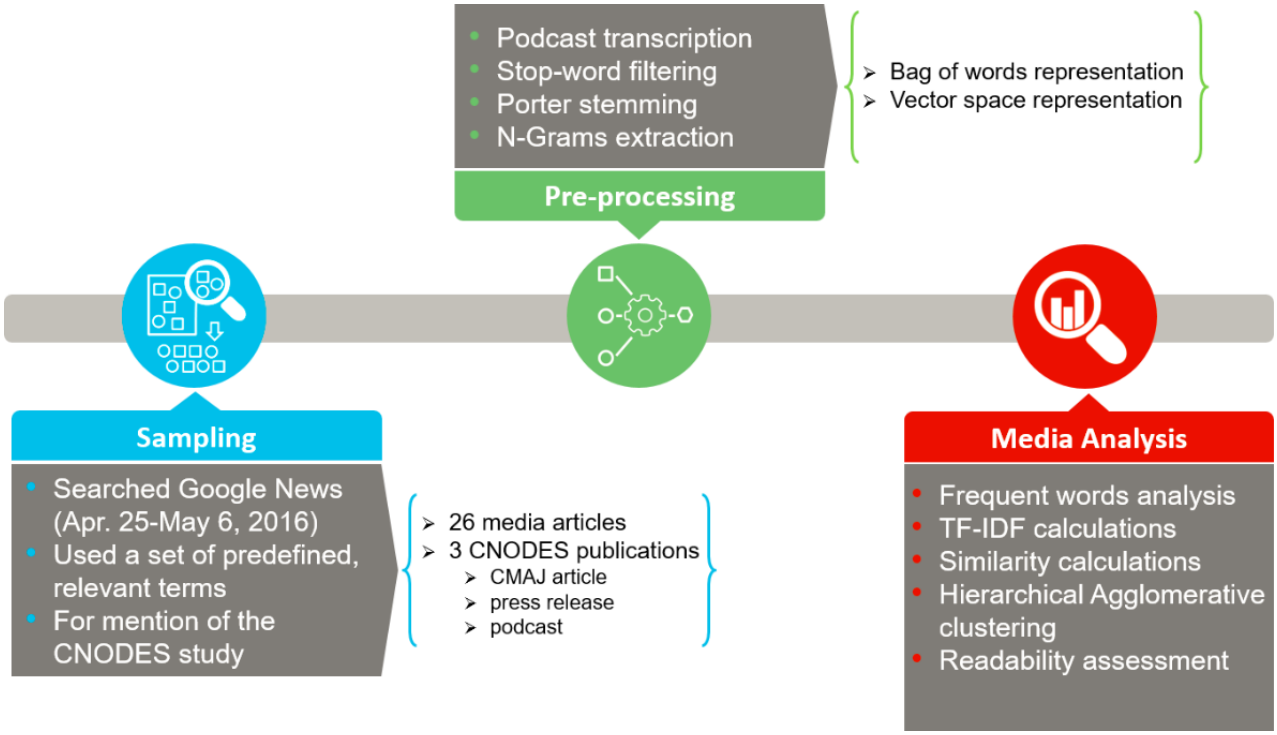
This study examined media representation and uptake of the CNODES study on the occurrence of pregnancy and pregnancy outcomes during isotretinoin therapy. The specific objectives of this study were to use NLP and other text-analytic methods to: (1) summarize and comprehend the content of the media coverage; (2) identify relationships between the media articles; and (3) analyze the reading levels of the media articles. By obtaining these preliminary objectives, we aimed to explore potential improvements in the way we present future research.

Methods

Search Strategy and Media Sources

Our overall study methodology is depicted in Figure 1. We conducted a search in Google News from April 25 to May 6, 2016, using a predefined set of relevant search terms, to identify the traditional media sources (eg, local, national, and international news sources) reporting the CNODES isotretinoin study [16], but excluding social media sources. We used the following search strategy: (isotrétinoïne OR Accutane OR Clarus OR Epuris OR isotretinoin OR CNODES OR "Canadian Network for Observational Drug Effect Studies"). We also tracked the media sources captured on the *News* tab on the Altmetric.com page for this article [26], although these sources were all also retrieved through our Google News search. All retrieved articles were screened for relevance and to identify duplicates. The screening process did not consider quality or scope of coverage but was only performed to ensure that the retrieved articles (1) were not already in the corpus of articles, and (2) covered the original CNODES study (ie, were not false positives). Only English language articles were considered. This resulted in a dataset of 26 media articles and 3 publications produced by CNODES (the original CMAJ article, a press release, and a podcast produced by CMAJ of an interview with the study authors [Multimedia Appendix 1]). The texts of the articles were extracted and all 29 articles (26 media articles and 3 reference CNODES sources) were stored on a cloud-based server. All text preprocessing and analysis, as described below, were completed in Eclipse (Standard Luna-R), Microsoft Visual Studio 2013, and Python 3.7 (NLTK 3.2.1 and TextStat 0.3.1 libraries).

Figure 1. Methodology schematic for our study. CMAJ: *Canadian Medical Association Journal*; CNODES: Canadian Network for Observational Drug Effect Studies; TF-IDF: term frequency-inverse document frequency.



Natural Language Processing

NLP is, generally, the ability of computers to analyze and manipulate natural language text or speech to provide an understanding of the text and answer questions about its contents. Different studies have demonstrated the application of NLP to information retrieval in a variety of areas such as question answering, social media text mining, and decision support systems [27-29]. Mendonça et al showed that encoding clinical data in patient documents using NLP techniques, along with clinical rules, can help identify health care–associated pneumonia in infants [30]. In a similar study, Dublin et al used only radiograph reports of previous cases with pneumonia to train their system to classify reports as consistent with pneumonia, inconsistent with pneumonia, or requiring manual review [31]. Knirsch et al utilized NLP methods to encode radiology reports which, along with other data in the patient repository, help detect patients who should be isolated but were not identified using the normal protocols [32].

In a different study, Wang et al combined text mining techniques with statistical analysis and patient electronic health records to detect adverse drug events. They applied NLP techniques to narrative discharge summaries to identify the safety of drugs throughout their entire lifecycle [33]. McTaggart et al adopted an NLP approach to analyze and transform large volumes of collected prescriptions (about 100 million per annum) into regular structured information on medication dose instructions [34].

These studies, and many more, show that NLP is an interdisciplinary area that includes a variety of computational techniques that, alone or in combination with other approaches, can perform a diverse set of tasks and applications. Along with the main purpose of this study, we leveraged various text mining techniques to analyze media articles (each technique explored in detail below):

1. Frequent words analysis to study the occurrence of words in each article and cluster, recognize the pattern of the most frequently used words, and investigate how the articles and clusters differ.
2. Term frequency-inverse document frequency (TF-IDF) weighting to calculate the closeness and/or separation between the articles through cosine similarity and Euclidean distance.
3. Hierarchical agglomerative clustering (HAC) to group (ie, cluster) similar articles together and to compare them with the original CNODES study.
4. Readability scales to calculate readability and analyze how easily the articles can be read and understood by an average reader.

Data Cleaning and Text Preprocessing

NLP consists of 3 general steps: (1) text collection; (2) preprocessing; and (3) text analysis. Preprocessing is a crucial yet often undervalued part of the process and is key to the performance and accuracy of any text analysis [35,36]. Links, advertisements, and all multimedia components (eg, images, figures, and videos) that are not informative or related to the content of the article were removed [37].

The next step in preprocessing was the removal of stop words. Stop words (eg, conjunctions, prepositions, and articles) are uninformative, frequently occurring words that do not carry much meaning and do not contribute to the differentiation between documents [38]. We used simple automated text-searching techniques to remove any words of a standard English stop word list [39] (including 627 words) from all the collected media articles.

The final preprocessing step was to perform stemming. Stemming is the process of connecting different words that are derivatives of the same root (eg, *student*, *studies*, and *studied* are various forms of their stem, *study*) [40]. A stemming algorithm conflates all words with the same root to a common form. Stemming, compared with full word representations, improves the indexing time (ie, the time to create the dictionary and calculate the Vector Space Model (VSM) representation) in an information retrieval system by reducing the size of the dictionary (ie, index file) by 20%-50%. In addition, a shorter list of index terms helps to improve the relevancy of the retrieved documents [41-44].

There are different algorithms for stemming. In this study, we used Porter stemming [45], which is the most widely used stemming algorithm for different languages, including English. The Porter stemming algorithm is independent from the context and has significantly reduced the complexity of the rules associated with suffix removal [46]. It is worth mentioning that, to avoid any duplication, Porter stemming transforms all the words to lowercase and then calculates the stems.

Frequent Words Analysis

The purpose of the frequent words analysis was to provide an overall summary of the content of the media articles and to compare the content of the different articles—and the clusters identified later in the analysis—to learn more about the texts and the areas of their focus. These findings will help to identify how and why the clusters are different and refine further analyses [47].

Although frequent words analysis can provide a valuable broad overview of the content of the documents, this approach does not provide much insight into the differences between documents, as common words tend to be common across all media outlets. To provide deeper insight into the relationships between media articles, we looked at how the articles might cluster together based on the content of their coverage.

Article Clustering

The objective of article clustering was to identify patterns in coverage of the CNODES study. Using a 3-step process of TF-IDF weighting, similarity calculation, and HAC, we identified 3 potential clusters of similar media coverage and used the frequent words analysis to provide insight into how these clusters might have differed in their language and coverage choices.

Term Frequency-Inverse Document Frequency Weighting

We used TF-IDF weighting in our analysis to gain insight into what makes individual articles unique. TF-IDF values represent

the frequency of the words in a specific document relative to the frequency of that word over the entire corpus of documents [48,49]. The following equation depicts how the TF-IDF values are calculated in which $w_{i,j}$ is the weight for term i in document j, N is the number of documents in the corpus, $tf_{i,j}$ is the frequency of appearance of term i in document j, and df_i is the frequency of term i in the corpus [50]:

TF-IDF values were calculated for all unique terms (1-grams) and the combinations of 2 sequential terms (2-grams) from the corpus using the above weighting equation and stored in an n x k matrix—where each row represents an article (n=29) and each column (k=6158) represents a 1 or 2-gram. This is a standard VSM representation that prepares the data to calculate similarity between the documents.

Like most information retrieval systems, we considered multiword phrases (ie, 2-grams) as some phrases can be more meaningful and informative than individual terms. For example, in our study, the phrase *pregnancy prevention* can distinguish articles and find a degree of similarity between the collected documents better than 2 single terms *pregnancy* or *prevention*. In the calculations, we merged the combination of any 2 words in sequence (ie, 2 words that appear together) as a new phrase (ie, 2-grams) and included it in the VSM.

Similarity Calculations

A similarity measure reflects the degree of closeness between 2 articles using a single numeric value [51]. We chose cosine similarity as it is easy to calculate and interpret and is commonly used in the NLP literature [52]. Cosine similarity returns a value between 0 and 1, where 2 documents with a similarity value of 1 are regarded as identical, and a value of 0 implies no similarity between the documents [51]. The result of the similarity calculations is a symmetric n x n similarity matrix (in our case, n=29).

Hierarchical Agglomerative Clustering

In this study, we chose HAC to group the similarity matrix into groups of similar documents because of the flexibility of hierarchical approaches in the desired number of clusters, its efficiency for small datasets, and the feasibility of graphical representation of the results through a tree-like structure called a dendrogram [53,54].

In agglomerative clustering, cutting branches of the dendrogram at a selected height (cut-off point) defines the resulting clusters. Selecting the best cut-off point depends on a variety of parameters such as the desired number of clusters, the granularity of the categories, or the acceptable distance between the entities within the clusters [55,56].

We used Euclidean distance in the construction of the HAC clusters as it is more appropriate in this environment than the cosine similarity, but all the similarity values presented in this study are cosine similarity.

Readability Analysis

The final objective of our analysis was to measure the readability [57] of the articles covering our initial study. Health literacy describes the extent to which one is able to acquire, interpret, and comprehend health information and services to make informed health decisions; the reading level of health information will either enable or impede its consumption [58,59]. Readability may be influenced by a variety of factors: the writing style, the clarity of words and sentences, and/or the degree to which a given text is compelling and comprehensible, based on a reader's reading skill, prior knowledge, and motivation [60-63]. Although the average American reads at an 8th grade level, the American Medical Association and National Institutes of Health recommend that patient and health information be written at or below a 6th grade level [64-66].

There are a variety of ways to measure the readability of a text. Friedman and Hoffman-Goetz [67] found high concurrent validity and correlation between the various readability formulas, but no specific formula is accepted as the gold standard for assessing readability or reading ease of health information [68].

We used 9 well-formalized readability formulas (Table 1) to study the readability of the media articles. Multimedia Appendix 2 further elaborates the readability formulas and the scores. Readability measures were developed using TextStat 0.3.1 library (Bansal and Aggarwal, MIT) in Python Package Index 3.4.4.

Table 1. Readability formulas. C: number of characters; D: number of complex words; E: number of easy (not-complex words); P: number of polysyllables; S: number of sentences; W: number of words; Y: number of syllables; AC: average number of characters per 100 words; AS: average number of sentences per 100 words.

Readability score	Score type	Key statistical features	Formula
Flesch Reading Ease (FRES)	Numeric score (0-100)	Word length and sentence length	FRES=206.83 - 1.015 x (W/S) - 84.6 x (Y/W)
Flesch-Kincaid Grade (FKRA)	US grade level	Word length and sentence length	FKRA=0.39 x (W/S) – 11.8 x (Y/W) – 15.59
Gunning Fog Index (FOG)	US grade level	Number of complex words	FOG=0.4 x [(W/S) + 100 x (D/W)]
Simple Measure of Gobbledygook Index	US grade level	Number of complex words	SMOG=1.0430 x √(P x 30/S) + 3.1291
Automated Readability Index (ARI)	US grade level	Number of characters	ARI=4.71 x (C/W) + 0.5 x (W/S) – 21.43
Coleman Liau Index (CLI)	US grade level[a]	Number of characters	CLI=0.0588 x AC + 0.296 x AS – 15.8
Linsear Write Index (LWI)	US grade level	Sentence length, number of polysyllables	(1) Find a 100-word sample from your writing; (2) Calculate Val=[E+(3×D)]/S; (3) If Val >20, then LWI=Val/2; (4) If Val ≤ 20, then LWI=(Val-2) / 2;
Dale-Chall Readability Score (DCRS)	Numeric score (0-9.9)	Number of difficult words	DCRS=0.1579 x (D/S) + 0.0496 x (W/S)
Text Standard	US grade level		A voting system among the other metrics: the reading level that is most prevalent (the mode) among the other metrics calculated.

[a]The terms in the table are stemmed versions of the actual terms (for example, us represents various forms of the verb use, and pregnanc stands for pregnancy).Grade level may also be understood as the number of years of formal education needed to understand a given text, particularly when the level exceeds the typical range of US grades (e.g. 1-12). For example, grades 13-16 suggest undergraduate training, 17-18 graduate training, and 19+ professional qualification.[63,67]

Results

Overview of Retrieved Articles

In total, 29 articles, including 26 media articles and 3 CNODES reference articles, comprised the corpus of documents for this study, and were represented in a VSM. The articles were of varying length: from 13 to 51 sentences, or 227 to 1011 words. The combined vocabulary of all articles contained 7745 unique terms (out of 11,263 total terms that appeared in the entire dataset). There was an average of 35 sentences, 740 words, and 1380 syllables per article, with an average of 30.9% (229/740) of the words being complex—words with 3 or more syllables that do not belong to a list of 3000 familiar words [69].

Frequent Words Analysis

Pregnanc (stem of pregnancy) is the most frequent individual term among all the text with 344 occurrences, followed by *isotretinoin* and *studi* (stem of study, studies, etc) with 306 and 245 occurrences, respectively. *Preganc prevent* (stem of pregnancy prevention) and *birth defect* are the most recurrent 2-grams with the frequency of 74 and 63.

Table 2 shows British Columbia (BC), 1 of the 4 provinces that was included in the study, appeared 35 times in the entire corpus. However, the other study provinces (not shown in Table 2), Saskatchewan, Ontario, and Manitoba, appeared 43, 40, and 26 times, respectively.

Excluding those published by CNODES, only 2 articles (8% of the sources) mentioned or acknowledged CIHR, the study's funder. *Health Canada* appeared in 13 and some variant of the phrase *conflict of interest* occurred in only 1 article beyond the CNODES articles.

Table 2. Top 10 most frequent vocabulary terms (1-grams and 2-grams).

1-grams	Frequency	Ratio	2-grams	Frequency	Ratio
pregnanc	344	0.031	pregnanc prevent	74	0.007
isotretinoin	306	0.027	birth defect	63	0.006
studi	245	0.022	birth control	48	0.004
drug	226	0.020	pregnanc test	40	0.004
women	188	0.017	women take	39	0.003
us	165	0.015	prevent program	37	0.003
birth	163	0.014	British Columbia	35	0.003
research	135	0.012	live birth	33	0.003
treatment	123	0.011	pregnanc rate	33	0.003
acn	118	0.010	isotretinoin user	31	0.003

Similarity and Cluster Analysis

The resulting values of cosine similarity calculations and HAC are presented in Figure 2. In the similarity matrix, green cells represent higher values of similarity (maximum of 1.0) between the articles; the similarity decreases as we move to the red side of the spectrum (minimum of 0.0). Using the similarity matrix and the dendrogram, we chose a cutoff in the dendrogram of 0.5, resulting in 3 distinct clusters. As the similarity values show, articles 28 and 29 are not significantly similar to any of the articles in the corpus. Consequently, they do not fit in any clusters. Articles 24 to 27 are similar to each other (with similarity values of 0.68 and above) but different from the remaining articles. Articles 19 to 23 are highly similar to each other, and articles 1 to 15 have higher values of similarity. These groups of articles were combined using HAC and form the 3 clusters: Cluster 1 (with 18 articles), Cluster 2 (with 5 articles), and Cluster 3 (with 4 articles).

Further examination of the nature of the articles in each cluster showed Cluster 1, in addition to the 3 CNODES publications, included national and international news websites such as Reuters, CBC, The Globe and Mail, National Post, and CTV. Cluster 1 also included health-specific websites such as Medical Daily, Medical News Today, MD Magazine, and Medscape Medical News. The articles composing Cluster 3 were from regional news websites including CBC British Columbia and The Globe and Mail British Columbia. Articles in Cluster 2 did not include traditional news media outlets, but rather health-related and general interest websites (Science Daily, Parent Herald, and Science 2.0).

Figure 2 also shows that the 3 CNODES publications—the CMAJ article, podcast, and press release—are highly similar to each other, with similarity values of 0.81 and above. Because of that degree of resemblance, the media articles maintain the same trend of similarity to the CNODES publications—an article which is similar to any of the 3 CNODES publications is similar to the other 2 and vice versa. Figure 3 depicts this steady trend of similarity by comparing the similarity of each media article to the CNODES publications separately.

Figure 2. Cosine similarity values (between 0 and 1) between the media articles and CNODES publications, including CMAJ article, podcast, and press release article using TF-IDF calculations. Resulting dendrogram of hierarchical agglomerative clustering. Three clusters and 2 singletons, resulting from a cutoff point of 0.5. CMAJ: *Canadian Medical Association Journal*; CNODES: Canadian Network for Observational Drug Effect Studies; TF-IDF: term frequency-inverse document frequency.

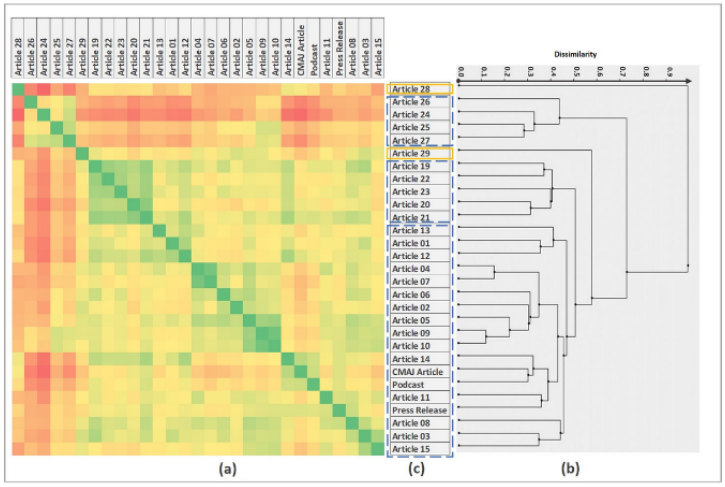
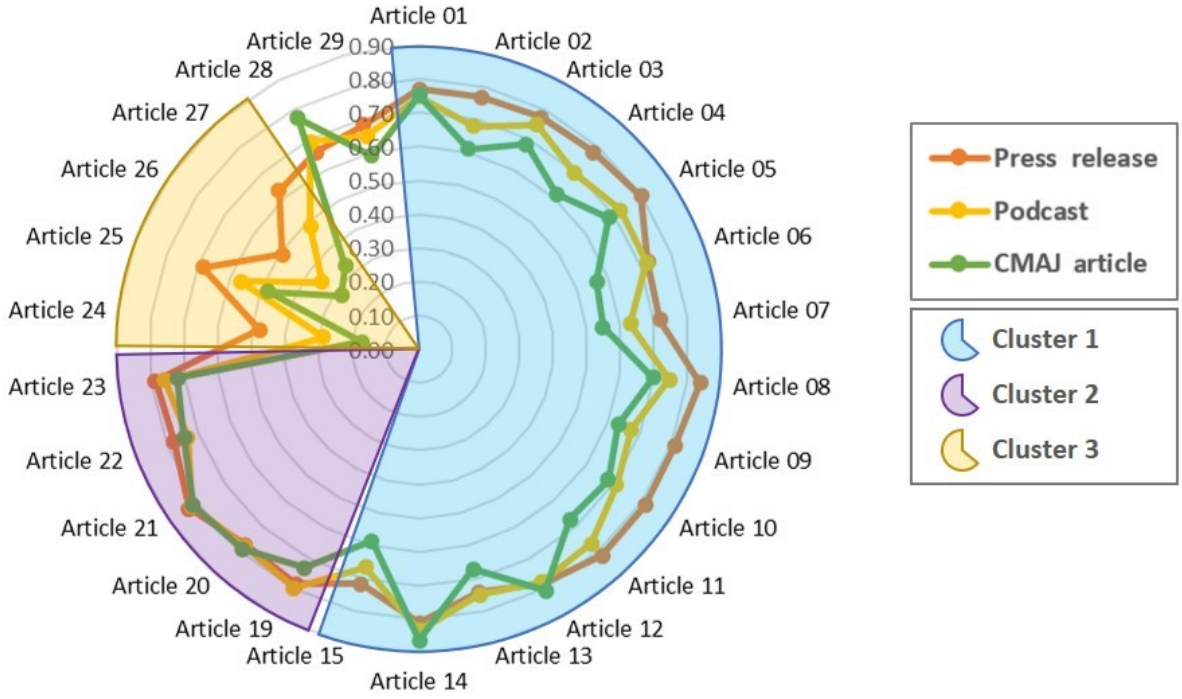


Figure 3. Trend of similarity (cosine similarity) between the media articles and the CNODES publications: CMAJ article, podcast, and press release.



Frequent Words Analysis Within the Clusters

In addition to studying the nature of the websites that published the media articles, we found that analysis of the frequent words within the clusters provides insight into how and to what extent the clusters are different. Table 3 shows the 5 most common terms within each cluster, along with specific clinical terms that we selected *a priori* to measure across the clusters.

Pregnancy and *isotretinoin* are the most common terms in the articles of Clusters 1 and 2, while these 2 terms are not among the top 10 frequent terms of Cluster 3. In addition, Clusters 1 and 2 have 6 frequent terms in common, while only 2 frequent terms of Cluster 3 (*studi* and *drug*) appear in the top 10 frequent terms of Clusters 2 and 3. Frequent words analysis within the clusters, in accordance with the similarity matrix (see Figure 2), implies Clusters 1 and 2 are more similar to each other than to Cluster 3.

Table 3 reveals the articles in Clusters 1 and 2 preferred to use *isotretinoin* (ranked 2) rather than Accutan (ranked 32 and 20, respectively), which is a brand name of *isotretinoin*; *isotretinoin* and *Accutan* were the 54th and 12th most frequent words, respectively, among the articles in Cluster 3. These rankings show the articles in Cluster 3 have chosen to focus on the brand name of the drug, rather than its generic name.

Table 3 shows Clusters 1 and 2 have focused on *patient* and *treatment*, while these concepts are not in a high position in the articles of Cluster 3. *Birth defect* has a relatively constant focus across the clusters. Cluster 3 did not discuss *fetal*, *fetal risk*, *fetal abnormality*, or *miscarriage* at all. *Acne* is in a significantly lower position for Cluster 3 (ranked 60th).

There is an overlap between the clinically important terms and the most frequent terms for each cluster. Hence, the top 5 most frequent terms of each cluster include the phrases that are not already mentioned in the 5 clinically most important terms. For example, since the 1st, 2nd, 3rd, and 7th most frequent terms of Cluster 1 are among the top 5 clinically important terms, the top 5 most frequent terms of Cluster 1 include the next 5 most frequent terms (the 4th, 5th, 6th, 8th, and 9th frequent terms of the cluster).

Table 3. Most common terms, both overall and within each cluster.

Cluster[a]	Cluster 1	Cluster 2	Cluster 3	Singleton 28	Singleton 29
5 clinically most important terms					
Isotretinoin	240 (2)[b]	49 (2)	6 (48)	7 (2)	4 (7)
Accutan[c]	46 (32)	12 (20)	17 (11)	—[d]	3 (12)
pregnanc	263 (1)	57 (1)	8 (33)	12 (1)	5 (3)
drug	166 (3)	28 (6)	23 (7)	1 (50)	8 (1)
birth	127 (7)	22 (9)	8 (33)	1 (50)	5 (3)
Top 5 most frequent terms[a] of cluster 1					
studi	160 (4)	31 (3)	42 (2)	6 (3)	6 (2)
Us	142 (5)	18 (12)	3 (107)	—	2 (17)
women	139 (6)	30 (4)	14 (14)	—	5 (3)
treatment	101 (8)	16 (14)	3 (107)	2 (16)	1 (39)
patient	94 (9)	11 (24)	9 (27)	2 (16)	1 (39)
Top 5 most frequent terms[a] of cluster 2					
studi	160 (4)	31 (3)	42 (2)	6 (3)	6 (2)
women	139 (6)	30 (4)	14 (14)	—	5 (3)
prevent	72 (16)	30 (4)	4 (74)	5 (4)	2 (17)
canadian	62 (22)	27 (7)	6 (48)	2 (16)	1 (39)
take	55 (28)	24 (8)	9 (27)	—	3 (12)
Top 5 most frequent terms[a] of cluster 3					
research	82 (13)	9 (27)	43 (1)	—	1 (39)
studi	160 (4)	31 (3)	42 (2)	6 (3)	6 (2)
health	66 (19)	1 (411)	38 (3)	—	—
Data	35 (44)	—	38 (3)	—	—
said	56 (27)	7 (41)	33 (5)	—	4 (7)

[a]The terms in the table are stemmed versions of the actual terms (for example, us represents various forms of the verb use, and pregnanc stands for pregnancy).

[b]Top 5 most frequent terms of each cluster exclude the 5 clinically important terms.

[c]The first number in the cells shows the frequency of occurrence of the term, and the second number in the parenthesis shows the ranking of the terms among all the termt in that cluster.

[d]Empty cells (represented with a —) are the terms that do not appear in the respective cluster/singleton.

Readability Analysis

Overall, 9 readability formulas were calculated for each article in the corpus. Different readability formulas consider different variables in the calculations and measure readability from distinct perspectives (see Table 1).

All calculated readability scores are above United States grade 10. Text standard scores, which represent the most prevalent reading level among all the formulas, ranged between 12 and 18, except for one article with a readability level of 9. Figure 4 demonstrates the distribution of readability levels of articles based on text-standard measure.

Table 4 shows reading ease based on calculating the average of each readability score for the articles within the clusters. On average, the articles in Cluster 3 were the easiest to read, followed by the articles in Clusters 1 and 2.

Figure 4. Distribution of readability levels of articles based on text-standard measure.

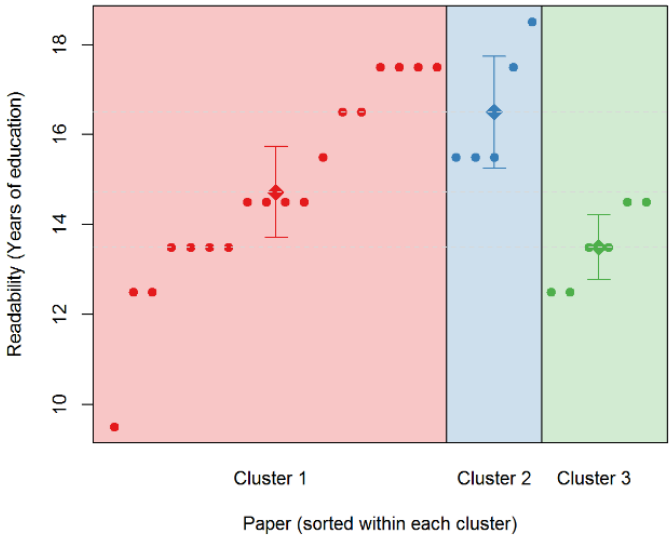


Table 4. Average readability level of each cluster.

Cluster.	Flesch Reading Ease	Flesch-Kincaid Grade	Gunning Fog Index	SMOG Index	Automated Readability Index	Coleman Liau Index	Linsear Write Index	Dale-Chall Readability Score	Text Standard
Cluster 1	40.78	13.02	15.19	15.58	15.21	14.47	13.27	9.87	16th grade
Cluster 2	29.89	14.74	16.59	16.92	16.76	15.97	10.62	10.67	17th grade
Cluster 3	49.19	11.35	13.75	14.33	13.35	13.32	8.85	9.39	14th grade
Singleton 28	36.79	12.50	12.99	15.90	15.20	16.82	13.75	8.82	12th grade
Singleton 29	49.55	11.70	15.11	15.00	15.40	14.74	8.08	9.87	14th grade

Discussion

Overall Results

Our NLP analysis of media coverage showed that the interpretation of the CNODES isotretinoin study [16] was diverse, with significant variations in content, language, areas of focus, and reading level. The primary focus of the media coverage was pregnancy and pregnancy prevention, but this focus was not consistent across all articles. Some articles focused more on the disease, drug, and treatment, while others emphasized the study and the related government regulations.

Regardless of the method used to calculate reading level, the overall reading levels were too high for the average North American reader, where the target reading level should be grades 6-8 [64-66]. Consequently, these media stories may have failed to reach many potential isotretinoin users of child-bearing potential. Even when the reading level calculations were re-run under different scenarios, such as reducing the complexity of complex words (eg, isotretinoin) through substitutions with shorter terms (eg, drug), the reading levels remained well above recommended reading levels.

Our results were similar to other studies which documented high reading levels for plain language communications of scientific advice. For example, in a study of 53 qualified health claims on food and dietary supplement labels, which are regulated by the United States Food and Drug Administration, the Flesch-Kincaid grade level ranged from 5.37 to 30.30, with 77% above a grade 9 reading level [70].

Overall disclosure of funders was low, with only 2 media articles naming CIHR as the funding organization. Financial disclosure is especially important in journalism covering pharmaceuticals where various conflicts of interest may exist [71,72].

The CNODES study was covered by the Canadian newspaper, The Globe and Mail, which averages 3.1 million print and digital readers on a typical weekday. It received coverage from both national television (CBC and CTV) and more specialized media with niche audiences such as iPolitics, which covers federal, provincial, and international politics and policies. The study also received international coverage from Thomson Reuters (www.thomsonreuters.com), which covers a broad range of topics in media markets around the world. The articles varied in length, ranging from approximately 200 to 1000 words, in large part due to standard word limits set by each media outlet [73].

Words Used

We had expected a significant overlap between some of the articles, with the potential for articles to be reprinted in different venues; overall, the words used in each media report were less similar than expected. Although there were commonalities between the articles, there was little evidence of republication or wholesale duplication of articles. We were not able to easily discern if certain articles were informed by others. Although the original CNODES source material did seem to influence the content of each article, each article author (or set of authors) clearly applied their own spin to the content. It is possible that if there had been more media coverage, patterns of duplication might have emerged. However, we have no evidence to suggest there were any patterns of reprinting in this corpus.

The clusters varied in the extent of overlap with our original press release and the top words used. Documents 28 and 29 had less similarity to the other articles in the corpus. It is interesting that document 28 was the American Pharmacist, which would likely employ science writers, and document 29 was the CBC in Saskatchewan, where they had direct access to one of the authors of the study who resided in Saskatchewan and was able to provide additional information from the Saskatchewan perspective. It has been noted that several publications reprint the press releases they receive without additional comment or contextualization and many media outlets are vertically integrated, although these integrations were not reflected in our analysis. It is interesting that the 10th most frequent 2-gram was *isotretinoin user*, which is an epidemiologic term and comes directly from the research study with specific definitions. Of note, health care providers (eg, physicians, pharmacists, and nurses) did not come up in the top 10 words. Instead, the focus seemed to be on women using isotretinoin, many of whom were not also dispensed birth control pills, and the protective actions they should be taking rather than on what health care providers or policymakers should be doing.

Table 3 shows the words by cluster. It is interesting that acn (stem of acne) came up in the top 10 only in Cluster 1. In media articles, it is useful to set the context: isotretinoin is approved only for severe cystic acne, although it is frequently used off-label. The top words in Cluster 2 were isotretinoin and pregnancy, so perhaps they were focusing more on the effects of isotretinoin than the purpose of it. Cluster 3 had research and study as their top 2 results, reflecting that they are focusing on reporting the results of the study conducted, rather than trying to consume and translate the results themselves. Clusters 1 and 2 used isotretinoin more frequently than Accutane (a common brand name for the isotretinoin product), while Cluster 3 used Accutane more frequently, reflecting different approaches on how to communicate the drug to the audience.

Omission of specific parts of the media release were surprising, such as the lack of disclosure around study funding (CIHR) and potential conflicts of interest. Although many of the articles did mention Health Canada, better reporting about the study team would have provided better context for the research and information on potential competing interests.

Table 4 shows the variability of reading levels, both between equations and across clusters. Regardless of which readability measure was used, each cluster showed a readability level that was too high, making it difficult for some patients to comprehend the material. The National Institutes of Health and American Medical Association suggest that health education material be written at a 6th to 8th grade level [64,74]. Readability calculations like these are not the only approach to measuring health literacy and are known to have shortcomings [10,67,75]. We looked at readability but not a reader's motivation to read one of the media documents or their ability to comprehend it [67]. We also did not examine numeracy, which is critical in the drug safety literature. In future, we will broaden our investigations of other aspects of health literacy, combining readability with the ability to find, process, and understand information, and to integrate these concepts with other sources of information to support health decision making [3,76]. Finally, although we looked at digital media coverage and examined specific aspects of health literacy, we did not examine electronic health literacy, which is an important concept.

Limitations

Our study takes a novel approach to tracking the media coverage of academic research after it has been published and is an important part of growing the knowledge translation component of the CNODES project, but it has its shortcomings. Our search, although comprehensive from a keyword perspective, was limited to media outlets that published on the internet. We did not search the websites of individual newspapers, with the assumption that our general Google News search would capture all relevant mentions. We did not evaluate pictures that were associated with the media articles, the way in which numbers were reported, or links to other resources. We did not consider the expertise of the journalists, specifically, whether there was a difference in the reporting between health journalists and general assignment reporters. We did not examine the length of the media article beyond its influences on reading level, so there may be further insights to be gleaned from comparing article length with specific aspects such as funding source and article positioning (eg, front page). Finally, although we believe we have captured all meaningful media coverage of our study, our data capture window was relatively short, we did not use a commercial news aggregator, and we did not specifically examine gray literature, so there is always the potential that we have missed some media articles.

We are currently not able to speak to who the articles may have deemed responsible for the original study results (ie, poor pregnancy prevention guideline adherence) or to determine the quality of the media report [8]. This type of insight is nuanced and difficult to achieve using NLP techniques, but should be explored more in future work as these insights would be valuable. We have also not analyzed the way in which the media stories were received, understood, and used by patients, health care providers, and policymakers, nor what additional information these individuals may have used to support their decision making [3].

There are many known limitations to using reading-level metrics [10,67,75]; thus, it is possible we are overestimating how difficult it may be to read the media coverage. It is important

to understand that reading level is only one way to evaluate readability, and only one aspect of many to consider when communicating health information effectively [77].

Placement within the media content is an important determinant of consumption and could provide an indication of an article's perceived value. In a digital age, these factors can change significantly over time and between users. We were unable to process this information. We did not specifically examine if independent sources (such as other researchers) were used by journalists to inform context and study validity, or whether patients, voluntary health organizations, or drug regulatory agencies provided their perspectives. We were unable to identify if the journalist was an employee of the news organization or if the article came from a news wire service or syndicated service. We also did not examine if a link to the original CMAJ article was provided.

We did not consider the quality of the coverage in terms of source. Although we subjectively evaluated the coverage to deem it as relevant or not, an objective measure of quality (such as the DISCERN tool [78]) or popularity could both assess the quality of the coverage and provide another document-level metric to understand the full extent of media coverage. Future work in this area should consider these factors.

Recommendations and Implications for Practice

It is important for researchers to understand how their research is presented by the media. Our analysis demonstrates that there is little consistency in how this is done using a peer-reviewed research article, even when accompanied by a crafted press release and outreach by the primary authors. If there are potentially controversial or sensitive issues arising from the research that need to be presented carefully, then the narrative around these issues should be appropriately constructed in the wording of the press releases and an effort needs to be made to monitor how the information is being translated in real time as it is disseminated. The reading levels of the media covering research can be quite high; more efforts should be made to simplify the press releases and other knowledge translation materials generated from the research so that journalists can more easily present the research in an accessible manner. Researchers can assist journalists by identifying other aspects of their research such as broader context and limitations [13].

Future Study

Improving the reading levels of CNODES' dissemination efforts, particularly outside of academic literature, could improve the ability of CNODES to reach key target audiences (eg, health care providers, decision makers). Further work is needed to develop automated media coverage analysis so that researchers can quickly and efficiently identify how their research is being covered and what is and is not being consumed, with the potential to react to it in real time and correct any potential misinterpretations by media outlets. Future research will need to augment readability approaches with other approaches, such as the use of mental model research [79], to inform communications strategies. Expanding on the analysis with sentiment and qualitative analyses would also be valuable as there are insights into sentiment and attribution that were not explored in this paper. The approach to document similarity we took in this paper considered the documents as a whole, but there is potential for articles to overlap in content from certain sections of the document, while adding their own local or audience-specific context to a common theme. Future research into topic modeling [80] could help identify themes that are common across documents, to contrast with document-specific themes.

Although this study focused solely on the content of the words presented in the articles, future research should incorporate the use of photos, captions, hyperlinks, and multimedia to form a more complete picture of how a study was presented. Due to the changing and various ways of presenting information on the Web, this kind of project would require careful and deliberate planning and would be difficult to do on a retrospective basis.

Extending this study to social media coverage would be a valuable addition; there are large and meaningful discussion sections accompanying some of the articles in this study (eg, doc09). Our research group has studied the altmetrics of our research on social media [81]. Combining these two research arms in a single stream could provide more nuanced results.

Conclusions

This study has demonstrated that NLP can be a valuable tool in understanding how research is conveyed to the public through digital media. Through NLP, we identified significant variations in the coverage of our research and what parts of our publications journalists focused on. We demonstrated how readability calculations can be applied to media coverage. Our future work will look at expanding our methods to better understand how our research is consumed by the media.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

List of articles (26 media articles, 3 Canadian Network for Observational Drug Effect Studies reference publications).
[DOCX File , 26 KB - formative_v4i1e13296_app1.docx]

Multimedia Appendix 2
Readability scales.
[DOCX File , 16 KB - formative_v4i1e13296_app2.docx]

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Abbreviations

BC: British Columbia
CIHR: Canadian Institutes of Health Research
CMAJ: Canadian Medical Association Journal
CNODES: Canadian Network for Observational Drug Effect Studies
HAC: hierarchical agglomerative clustering
NLP: natural language processing
TF-IDF: term frequency-inverse document frequency
VSM: vector space model

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Original Paper

A Smartphone App Designed to Help Cancer Patients Stop Smoking: Results From a Pilot Randomized Trial on Feasibility, Acceptability, and Effectiveness

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Abstract

Background: Persistent smoking after a cancer diagnosis predicts worse treatment outcomes and mortality, but access to effective smoking cessation interventions is limited. Smartphone apps can address this problem by providing a highly accessible, low-cost smoking cessation intervention designed for patients with a recent cancer diagnosis.

Objective: This study aimed to summarize our development process and report the trial design, feasibility, participant acceptability, preliminary effectiveness, and impact on processes of change (eg, cancer stigma) of the first-known smoking cessation smartphone app targeted for cancer patients.

Methods: We used an agile, user-centered design framework to develop a fully automated smartphone app called Quit2Heal that provided skills training and stories from cancer survivors focusing on coping with internalized shame, cancer stigma, depression, and anxiety as core triggers of smoking. Quit2Heal was compared with the National Cancer Institute's QuitGuide, a widely used stop smoking app for the general population, in a pilot double-blinded randomized trial with a 2-month follow-up period. Participants were 59 adult smokers diagnosed with cancer within the past 12 months and recruited through 2 cancer center care networks and social media over a 12-month period. The most common types of cancer diagnosed were lung (21/59, 36%) and breast (10/59, 17%) cancers. The 2-month follow-up survey retention rate was 92% (54/59) and did not differ by study arm (P=.15).

Results: Compared with QuitGuide participants, Quit2Heal participants were more satisfied with their assigned app (90% [19/21] for Quit2Heal vs 65% [17/26] for QuitGuide; P=.047) and were more likely to report that the app assigned to them was made for someone like them (86% [18/21] for Quit2Heal vs 62% [16/26] for QuitGuide; P=.04). Quit2Heal participants opened their app a greater number of times during the 2-month trial period, although this difference was not statistically significant (mean 10.0, SD 14.40 for Quit2Heal vs mean 6.1, SD 5.3 for QuitGuide; P=.33). Self-reported 30-day point prevalence quit rates at the 2-month follow-up were 20% (5/25) for Quit2Heal versus 7% (2/29) for QuitGuide (odds ratio 5.16, 95% CI 0.71-37.29; P=.10). Quit2Heal participants also showed greater improvement in internalized shame, cancer stigma, depression, and anxiety, although these were not statistically significant (all P>.05).

Conclusions: In a pilot randomized trial with a high short-term retention rate, Quit2Heal showed promising acceptability and effectiveness for helping cancer patients stop smoking. Testing in a full-scale randomized controlled trial with a longer follow-up

period and a larger sample size is required to test the effectiveness, mediators, and moderators of this promising digital cessation intervention.

Trial Registration: ClinicalTrials.gov NCT03600038; https://clinicaltrials.gov/ct2/show/NCT03600038

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KEYWORDS

smartphone app; mHealth; tobacco; smoking; cancer patient

Introduction

In the United States, 15% to 54% of cancer patients are cigarette smokers at the time of their diagnosis [1-4]. Compared with patients who quit smoking after their diagnosis, cancer patients who remain smokers have worse treatment outcomes, including 2 to 4 times higher risk of nonresponse to radiation [5-7], decreased efficacy and tolerance of chemotherapy [8,9], and 2 to 3.5 times higher risk of postoperative complications such as necrosis [10]. Regardless of the type of cancer diagnoses, patients who continue to smoke after diagnosis have 1.5 to 4 times higher risk of a second primary oral, oropharyngeal, esophageal, stomach, lung, or hematological cancer [11,12]. Finally, the mortality rate among cancer patients who continue smoking is 1.3 to 2.4 times higher across all types of cancer [5,13,14]. In contrast, quitting smoking after receiving a cancer diagnosis greatly reduces the risk of poor treatment outcomes [5,15] and of a second primary cancer [11,12] and lowers the mortality rates [5,13,14]. This broad body of evidence has contributed to the Surgeon General's conclusion that quitting smoking after a diagnosis will vastly improve the prognosis of patients with cancer [16] and to the National Comprehensive Cancer Network's (NCCN's) recommendation that every cancer patient who smokes must be offered evidence-based cessation intervention [17].

Unfortunately, up to 80% of smokers with cancer continue to smoke after their diagnosis [2,18-20]. Moreover, 15% to 25% of those who do quit after a cancer diagnosis will return to smoking within 12 months [4,21,22]. Despite the NCCN recommendation, tobacco treatment delivery for cancer patients in the Unites States is inadequate because of several barriers that limit patients' access to cessation treatment. For example, only 39% of oncologists routinely provide tobacco cessation treatment to patients or at least refer them to a tobacco treatment program [23]. Moreover, only 20% of the National Cancer Institute (NCI)–designated cancer centers have a tobacco treatment provider [24]. Barriers to access also include the lack of insurance coverage; the lack of clinical staff training and time; and the lack of systems for universal assessment, referral, and integration of cessation service into routine cancer care [23,24].

In direct response to this need, the US NCI created a Moonshot-funded Cancer Center Cessation Initiative (C3I) to support the implementation of evidence-based cessation interventions at 42 NCI-designated cancer centers [25]. The C3I is making progress in implementing treatment programs within the 42 participating NCI cancer centers [26] but is hindered by the complex tobacco treatment delivery challenges of limited hospital resources, inadequate clinical staff training, and clinic workflows [26]. The much larger challenge is the fact that a mere 15% of cancer patients receive their cancer treatment at NCI-designated cancer centers [27]. Overall, these challenges demonstrate the need for broader methods to reach cancer patients who smoke.

One method for all smokers with cancer to access effective and low-cost smoking cessation treatment is via smartphone-based smoking cessation software apps [28-30]. Apps do not require provider training, reimbursement for cessation interventions, or integration into complex hospital systems (eg, apps can be freely accessed on an app store), and they are available anytime at arm's reach [28-30]. Apps have potentially high population-level reach to cancer patients—especially given that over three-quarters (76%) of all smokers own smartphones, and 68% of adults aged 55 to 74 years own smartphones [31,32].

Smartphone apps for smoking cessation are showing solid promise among the general population of smokers [33]. For example, a 4-country trial (N=684), with 85% outcome data retention at the 6-month follow-up, showed that an app combining provision of quitting options with supportive and motivational messages and a quitting benefits tracker was over 2 times more effective than an informational cessation app without these features (10.2% quit rate vs 4.8% quit rate; risk ratio=2.02; 95% CI 1.08-3.81) [34]. Building on the promise of apps for the general population of smokers, a targeted intervention can address the unique processes that impede cessation among cancer patients, including shame about being a smoker, cancer stigma (feeling socially rejected for having caused one's cancer), depression, and anxiety [35-44]. However, there are no randomized trials evaluating the efficacy of *any* smoking cessation smartphone app among adult cancer patients who smoke.

To address this knowledge gap, we developed a smartphone app, called Quit2Heal, that is specifically designed to help cancer patients stop smoking. Quit2Heal was compared with NCI's QuitGuide, a widely used stop smoking app, in a pilot randomized trial of 59 US adult smokers recently diagnosed with cancer. The objective of this study was to summarize our development process and report the pilot trial recruitment, retention, participant acceptability, preliminary effectiveness, and impact on the hypothesized processes of change (eg, cancer stigma) of the first-known smoking cessation smartphone app targeted for cancer patients.

Methods

Development of Quit2Heal—A Smartphone App Designed to Help Cancer Patients Stop Smoking

We used an iterative, user-centered design approach [45] to develop an app designed to help cancer patients quit smoking. Our starting point for the development work was a smartphone app called iCanQuit, which we are currently testing in a large randomized trial for smoking cessation in a general population of adult smokers (NCT02724462). iCanQuit teaches skills for coping with smoking urges, staying motivated, and preventing relapse. To guide the adaptation of iCanQuit for cancer patients who smoke, we interviewed smoking cessation clinicians at 4 NCI-designated cancer centers across the United States and reviewed (1) the empirical studies on the factors that influence quitting smoking in cancer patients (ie, shame, stigma, depression, and anxiety [35-37]), (2) the NCCN Clinical Practice Guidelines in Oncology for smoking cessation [17], (3) the intervention content from published protocols and trials for smoking cessation of cancer patients [41,46-49], and (4) clinical intervention protocols of smoking cessation of cancer patients. We then conducted in-depth, in-person interviews of 6 smokers currently in treatment for cancer (2 attributable and 4 not attributable to smoking) and 3 caregivers of current cancer patients who smoke. The major themes derived from these interviews were lack of knowledge regarding the effects of smoking on cancer-related outcomes, mental health problems (ie, depression and anxiety) associated with smoking and cancer, shame about smoking, feeling stigmatized about being a cancer patient who smoked, and fears of seeking support from and/or discomfort discussing smoking and quitting with cancer treatment providers.

Our formative research led us to iteratively develop content on the (1) consequences of continued smoking versus quitting smoking for health domains such as daily functioning and cancer treatment outcomes, (2) skills for coping with depression and anxiety often associated with a cancer diagnosis, (3) self-compassion exercises for coping with cancer-related stigma and internalized shame, (4) advice on how to seek support for quitting smoking from cancer treatment providers (eg, oncologist), and (5) testimonials from cancer survivors describing how quitting smoking has allowed them to live more meaningful lives. The wireframes created by our user experience designer were iterated upon by our team. The content was user tested with 13 smokers currently receiving cancer treatment to get feedback on usability and content in 3 iterative rounds of testing. Our user testing also identified the cancer patients' choice of the best name for the app, Quit2Heal. After our developer created an alpha version of the Quit2Heal app, the study team identified edits for the content and features as well as any technical bugs.

Our review yielded a beta version that was tested in a 7-day diary study with 5 adult smokers (3 women and 2 men) currently receiving cancer treatment who had varying levels of technical ability and confidence in quitting smoking. The diary study included a 30-min onboarding session, 7 nightly 10-min surveys about each participant's experience of the app that day, a 10-min call on day 4 to discuss their impressions of the app so far, and a 45-min exit interview about their overall experience and the usability of the app. All participants rated the app as highly useful overall, were very satisfied overall, and would recommend the app to other cancer patients who smoke. They all liked the 5 content areas created specifically for cancer patients who smoke. The major problem area was that they were not clear where to start the app's program. Our remedies included (1) adding an introduction with screenshots showing how to begin the program and (2) graying out the sections that come later in the program until they become available. After minor usability concerns were remedied, the final version of Quit2Heal was ready for testing in the pilot randomized controlled trial (RCT) described herein.

Participants, Recruitment, and Enrollment

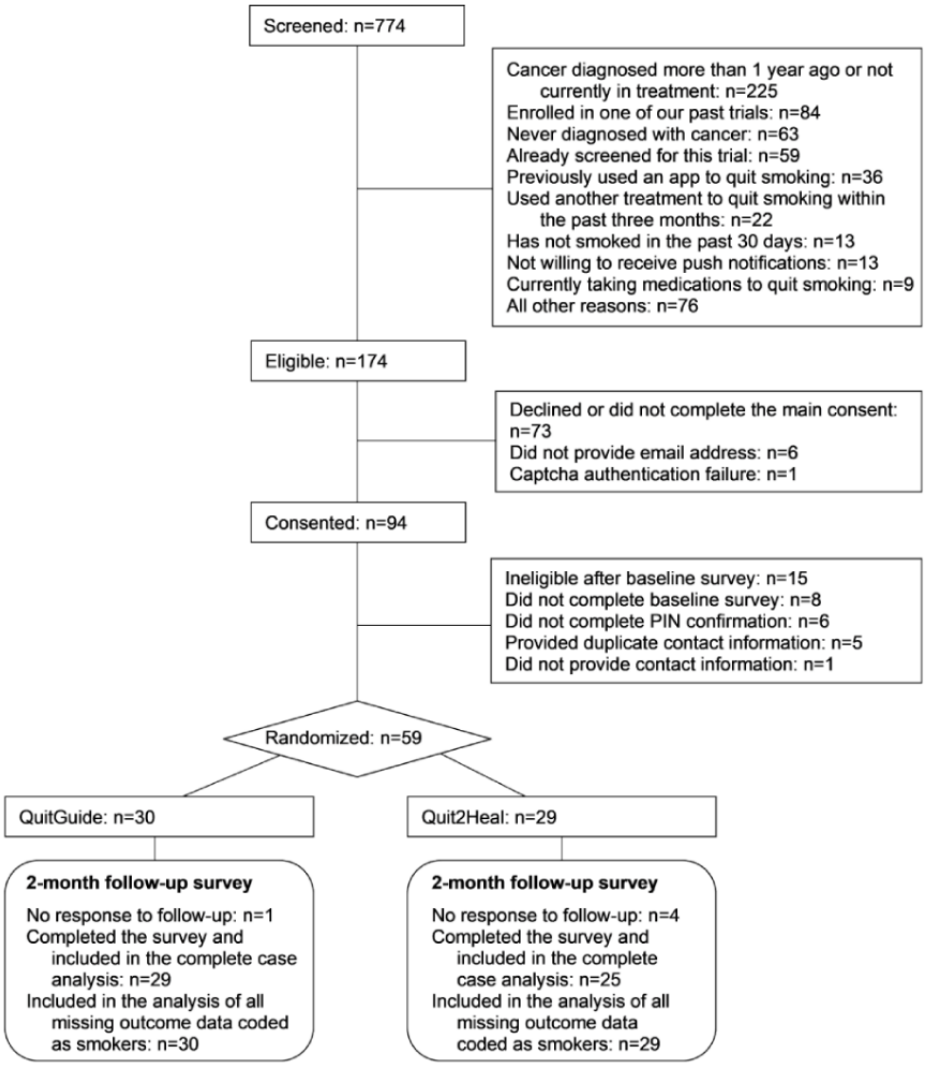
Participants with the following eligibility criteria were included in the study: (1) aged 18 years or above, (2) diagnosed with cancer within the past 12 months or currently receiving cancer treatment or planning to receive cancer treatment in the next 3 months (consistent with prior trials of smoking cessation in cancer patients [46,50]), (3) smoked a cigarette (even a puff) in the past 30 days, (4) interested in learning skills to quit smoking, (5) willing to be randomly assigned to either smartphone app, (6) living in the United States and planning to remain for the next 2 months, (7) having at least daily access to their own smartphone, (8) knowing how to download a smartphone app, (9) willing and able to read English, (10) not currently using smoking cessation medications or enrolled in another smoking cessation program, and (11) have never used the NCI's QuitGuide app, (12) willingness to complete 1 survey at the 2-month follow-up, and (13) provision of email address, phone number, and mailing address. (Criterion 12 and 13 were included to increase follow-up retention.)

The study participant flow diagram is shown in Figure 1. Participants were recruited nationally over a 12-month period from April 2, 2018, to April 1, 2019, through social media (primarily Facebook Ads) and 2 US cancer centers (Memorial Sloan Kettering Cancer Center and Seattle Cancer Care Alliance [SCCA]/Fred Hutch Cancer Research Center and their affiliated clinics) via clinic flyers, brochures, waiting room television (TV) screen ticker-tape messages, and emailing the study flyer to current cancer patients who smoke (identified through electronic medical records). Some Facebook Ads were designed for racial and ethnic minorities as well as men. Enrollment was limited to no more than 80% (47/59) non-Hispanic white and 75% (44/59) female participants to ensure the inclusion of racial/ethnic minority and male participants. All interested individuals were directed to the study website to learn more about the study and complete an encrypted Web-based screening survey. Those who were eligible were instantly sent an email inviting them to provide informed consent and complete the encrypted baseline assessment. As the enrollment occurred via the Web, additional actions were taken to ensure that the enrollees were actually eligible for participating in the study. These included CAPTCHA (Completely Automated Public Turing test to tell Computers and Humans Apart) authentication, review of Internet Protocol addresses for duplicates or non-US origin, review of survey logs for suspicious response times (<90

seconds to complete screening or <10 min to complete baseline survey), and review of mailing addresses and phone numbers to check for prior enrollment in one of our previous studies. Those not eligible were not enrolled.

Our original recruitment goal was 200 participants (100 per arm) based on our experience with recruiting 200 participants in prior pilot randomized trials of mobile health (mHealth) and electronic health (eHealth) for smoking cessation for the *general* population of smokers [51,52]. However, by 2 months into this pilot trial's recruitment period, the Facebook Ad algorithms determined that the cost of Facebook Ads to randomize each cancer patient who smokes was 16 times higher than the cost of Facebook Ads to randomize each smoker from the general population (ie, US $213.25 vs US $13.60). Consequently, to meet our limited pilot budget and complete the recruitment within the funding period, we downward adjusted our recruitment goal to 60. The recruitment sources for the enrolled sample of 59 participants were as follows: 36 participants from Facebook Ads, 3 from all other social media (eg, Craigslist), 1 from a TV news segment, and 19 from cancer care clinics. For reporting readily comparable Facebook recruitment metrics [53,54], the Facebook cost per click, result rate (formerly called *conversion rate*), and impressions were US $0.52, 0.003%, and 714,862, respectively.

Figure 1. Participant flow diagram.



A total of 2 reminder emails were sent over a 14-day period to individuals who did not respond to the initial email invitation. Individuals who did not consent or complete the enrollment process within the 14-day period were sent an email indicating that they were not enrolled. Participants not enrolled (or ineligible) were referred to *Smokefree.gov* and *800-QUIT-NOW*. Participants randomized to the trial were emailed a secured link to download their randomly assigned app (either Quit2Heal or QuitGuide) on either an Android smartphone or an iPhone. All study activities were reviewed and approved by the institutional review boards of the Fred Hutchinson Cancer Research Center and Memorial Sloan Kettering Cancer Center. The trial was registered on ClinicalTrials.gov (registration number NCT03600038).

Randomization Procedures

The enrolled participants were randomized (1:1) to either the experimental intervention (Quit2Heal, n=29) or the control intervention (QuitGuide, n=30). We used computer-generated randomly permuted block randomization, stratified by Heaviness of Smoking Index (score>4 [55]), confidence in being smoke-free >70 (on a scale of 0-100), and recruitment method

(ie, clinic vs social media). The randomization assignment was concealed from participants throughout the entire trial. Neither the research staff nor the study participants had access to the upcoming randomized study arm assignments. The study staff and investigators were blind to the random assignment throughout the trial.

To ensure participants were blinded to their assigned intervention, each app was branded as Quit2Heal. Contamination between the interventions was avoided with a unique username and password provided only to the study participant and by having an eligibility criterion of not having family, friends, or other household members participating.

Experimental Intervention

Quit2Heal [56,57] is specifically designed to help cancer patients stop smoking by providing skills to cope with cancer-related shame, stigma, depression, anxiety, and cancer-specific health consequences of continued smoking versus quitting. After setting up a personalized quit plan where users can learn about the Food and Drug Administration (FDA)–approved cessation medications they can obtain on their own, users are taken to the home screen where they can progress through all 9 levels of the intervention content, receive on-demand help in coping with smoking urges, track the number of cigarettes smoked daily, and track how many urges they let pass without smoking. The program is self-paced, and the content is unlocked in a sequential manner. For the first 5 levels, exercises are unlocked immediately after the prior exercise is complete. For the last 4 levels, the next level will not unlock until users record 7 consecutive smoke-free days. If a participant lapses (eg, records having smoked a cigarette), the program encourages (but will not require) the participant to set a new quit date and return to the first 5 levels for preparation.

The first 5 levels contain content and exercises designed to prepare the users for their chosen quit day. Level 1, *Becoming an Urge Expert*, introduces the main features of the app and introduces a fictional tobacco treatment *guide* who specializes in helping cancer patients quit smoking. The guide navigates the user through the app and teaches skills for coping with cancer-related depression, anxiety, shame, stigma, and common triggers to smoke (eg, being around other smokers). An example of a skill for coping with cancer-related depression is having the user track small things that the user was grateful for on that day (eg, less pain and being able to attend a child's birthday party). Levels 2 to 4 contain 26 exercises teaching skills to cope with cravings, emotions, and thoughts that trigger smoking. Level 5, *Becoming a Kindness Expert* contains 9 exercises designed to help the users develop self-compassion for themselves for shame and stigma about being a cancer patient who smokes. An example of the skill for coping with shame is an exercise to forgive the user's younger self for choosing to start smoking. An example of the skill for coping with stigma is an exercise in shifting perspective, having kind words for the people who the user perceives had stigmatized them.

The last 4 levels contain content and exercises designed to help the user stay smoke-free after their quit date. These levels contain 25 exercises that focus on coping with cancer-related depression and anxiety, withdrawal symptoms, slips, and potential weight gain and building smoke-free life activities. All levels contain at least one *user story* (testimonial) presented by fictitious cancer patients who quit smoking; how they overcame challenges, including cancer-related shame and stigma; and how quitting has helped them live more meaningful lives (eg, spending more time with family).

Through the main menu, participants access the education section, which has 3 components. The first component educates on the negative consequences of continuing to smoke after a cancer diagnosis: (1) impacts on radiation, chemotherapy, and postsurgical recovery; (2) risk of second primary cancers; and (3) mortality. The second component educates on the positive consequences of quitting smoking after a cancer diagnosis: (1) improved treatment outcomes, (2) lesser chance of a second primary cancer, and (3) lower chance of mortality. The third section contains education on how to talk to a cancer care provider about the user's smoking and ask for the provider's assistance and support in quitting—which can help reduce shame and stigma. The participants can edit their quit plan, review their progress (eg, smoke-free days), and view the badges they earned for making progress in the program.

Comparison Intervention

The comparison was NCI's QuitGuide app [58,59] which, with the NCI's permission, we posted on the Google Play and Apple Store in a blinded format branded as Quit2Heal. We selected QuitGuide as the comparison because (1) QuitGuide is a smartphone app—the treatment delivery modality identical to our experimental Quit2Heal app and, thus, avoids confounding treatment *content* with treatment delivery *modality*; (2) QuitGuide's content is based directly on the NCI's Smokefree.gov website, a well-established eHealth intervention resource recommended by the NCCN Clinical Practice Guidelines for cancer patients' smoking cessation [17]; (3) QuitGuide is one of the few apps (of over 500 available) that follow the US Clinical Practice Guidelines [60]; and (4) QuitGuide is nonproprietary and free to the public, providing maximal transparency, accessibility, and replicability.

QuitGuide is a *non-targeted* smoking cessation app designed for the *general population of smokers*, with 4 sections of content: (1) *Thinking about quitting*, which focuses on motivations to quit by encouraging the users to list reasons for quitting and providing information on the general health consequences of smoking and quitting; (2) *Preparing to Quit*, which helps users develop a customized quit plan; identify smoking behavior, triggers, and reasons for being smoke-free; and identify social support for quitting and provides information on FDA-approved medications to quit smoking; (3) *Quitting*, which teaches skills for avoiding cravings to smoke, such as finding replacement behaviors (eg, chewing on carrot sticks) and staying busy; and (4) *Staying Quit*, which presents tips, motivations, and actions to stay smoke-free and skills for coping with slips via fighting cravings and trying to be positive.

Both interventions were available for log in at any time after randomization. Neither was modified during the study (the apps used in this study are available for download, with tester usernames and passwords available upon request [56-59]).

Follow-Up Data Collection

The procedures for follow-up data collection were modeled after the procedures that have been successful in our previous trials at maximizing data retention [52,61,62]. Specifically, at 2 months post randomization, participants received US $25 for completing the follow-up survey and an additional US $10 bonus if the encrypted online survey was completed within 24 hours of the initial email invitation to complete the survey. Participants who did not complete the survey online within 12 days were sequentially offered opportunities to do so by phone, mailed survey, and finally, for main outcomes only, by postcard.

Measures

Baseline Measures

At baseline, participants reported their demographics, cancer (eg, type and stage), alcohol use (Quick Drinking Screen [63]), current and past tobacco use, nicotine dependence (Fagerstrom Test for Nicotine Dependence; FTND [64]), confidence in quitting, and smoking in the social environment.

Treatment Utilization

Utilization was assessed via data logged automatically by the secured server on how many times the app was opened during the 60 days after randomization. Owing to a database error, these data were only available from the 32 participants who were randomized after June 29, 2018.

Treatment Satisfaction

Treatment satisfaction outcomes were the extent to which a participant (1) was overall satisfied with the assigned app, (2) would recommend the assigned app to a friend, and (3) believed that the assigned app was made for someone like them. The response choices for all items ranged from *not at all* (1) to *very much* (5) and were dichotomized such that a threshold of *somewhat* (3) or higher represented satisfaction.

Process Measures

The brief process measures, assessed at baseline and the 2-month follow-up, were internalized shame (5-item internalized shame subscale of the Social Impact Scale [65]), internalized stigma (9-item internalized stigma subscale of the Lung Cancer Stigma Inventory [35]), depression (10-item Center for Epidemiologic Studies Depression Scale; CES-D [66]), and generalized anxiety (7-item Generalized Anxiety Disorder; GAD-7 [67]). Internalized shame refers to the perception that one's illness sets one apart from others who are well and feeling a need for secrecy about the illness [65]. A sample scale item is "I feel a need to keep my illness secret." Internalized stigma refers to the internalized experience of rejection, blame, and devaluation based on the assumption that one has caused one's illness [35]. We modified the internalized stigma subscale of the Lung Cancer Stigma Inventory so that it focused on cancer broadly (rather than only lung cancer). A sample scale item is "I blame myself for having cancer."

Smoking Cessation

For scientific rigor and comparability with other low-intensity behavioral intervention trials [68,69], the cessation outcome was self-reported 30-day point prevalence abstinence (ie, no smoking at all in the past 30 days), which was calculated based on the response to the question "When was the last time you smoked, or even tried, a cigarette?" Owing to the cost and low demand characteristics for false reporting, the Society for Research on Nicotine and Tobacco Subcommittee on Biochemical Verification recommends that biochemical confirmation is unnecessary in population-based studies with limited face-to-face contact and in studies where the optimal data collection methods are remote (eg, telephone) [70]. Self-reported smoking is a standard method for assessing the efficacy of low-intensity interventions [68,69].

Statistical Analysis

The demographic characteristics, smoking behavior, and process measures at baseline were compared between the study groups using 2-sample *t* tests for continuous variables and Fisher exact test for binary variables. All participants were analyzed using intent to treat in the study arm to which they were randomized. The abstinence outcomes were calculated as both complete case and missing equals smoking imputation.

We used logistic regression models to analyze the differences between the treatment arms on binary cessation and satisfaction outcomes. A negative binomial model was used to analyze the right-skewed app utilization data. Linear models were used to analyze the changes in process indicator measures, adjusting for baseline value of the measure. All models were adjusted for the 3 variables used in stratified randomization. The models were also adjusted for any baseline characteristic that was both imbalanced between the study arms at baseline (ie, $P<.10$) and associated with the outcome of interest. Statistical tests were 2-sided, with alpha=.05. Analyses were completed using R version 3.6.1 [71] and R library MASS [72].

Results

Baseline Characteristics, Balance, and Follow-Up Retention

As shown in Table 1, the overall sample was aged 45.2 years on average and comprised 25% (15/59) male, 78% (46/59) white, 29% (17/59) with high school or less education, and 22% (13/59) who identified as lesbian, gay, or bisexual (LGB). The rates of positive screen for depression (CES-D≥10) and anxiety (GAD-7≥10) were 73% and 39%, respectively. The most common primary cancer diagnoses were lung (21/59, 36%) and breast (10/59, 17%) cancers. The most common stages of cancer were stage I (17/47, 36%) and stage II (14/47, 30%). With regard to smoking characteristics, 51% (30/59) of the sample had high nicotine dependence (ie, FTND score ≥6 [64]) and 56% (33/59) smoked more than half a pack of cigarettes per day. About one-third (19/59, 32%) lived with a partner who smoked. The 2-month follow-up survey retention rate was 92% (54/59) and did not differ by study arm ($P=.15$). Although none of the measured baseline characteristics significantly differed between the study arms (all $P>.05$), the level of education completed trended toward an imbalance ($P=.07$) and was predictive of the cessation outcome; therefore, we adjusted for this variable in subsequent analyses.

Table 1. Baseline characteristics of Quit2Heal study participants.

	Total (N=59)[a]	QuitGuide (N=30)[a]	Quit2Heal (N=29)[a]	*P* value
Age (years), mean (SD)	45.2 (12.9)	47.3 (13.5)	42.9 (12.0)	.19
Male, % (n/N)	25 (15/59)	30 (9/30)	21 (6/29)	.60
Race, % (n/N)				**.29[b]**
White	78 (46/59)	77 (23/30)	79 (23/29)	
Black or African American	12 (7/59)	10 (3/30)	14 (4/29)	
Native American	2 (1/59)	3 (1/30)	0 (0/29)	
Asian	2 (1/59)	3 (1/30)	0 (0/29)	
More than 1 race	3 (2/59)	7 (2/30)	0 (0/29)	
Unknown race	3 (2/59)	0 (0/30)	7 (2/29)	
Hispanic	7 (4/59)	3 (1/30)	10 (3/29)	.58
Married, % (n/N)	44 (26/59)	40 (12/30)	48 (14/29)	.71
Working, % (n/N)	46 (27/59)	40 (12/30)	52 (15/29)	.52
High school or less education, % (n/N)	29 (17/59)	17 (5/30)	41 (12/29)	.07
Lesbian, Gay, or Bisexual % (n/N)	22 (13/59)	20 (6/30)	7 (24)	.95
Mental health				
Positive depression screen, % (n/N)	73 (43/59)	70 (21/30)	76 (22/29)	.83
Positive anxiety screen, % (n/N)	39 (23/59)	30 (9/30)	48 (14/29)	.24
Internalized shame[c], mean (SD)	11.3 (4.2)	11.5 (3.8)	11.2 (4.7)	.77
Cancer-related stigma[d], mean (SD)	30.1 (11.9)	31.2 (10.4)	28.9 (13.4)	.47
Cancer-related background				
Cancer diagnosis, % (n/N)				**.40[e]**
Lung	36 (21/59)	30 (9/30)	41 (12/29)	
Breast	17 (10/59)	20 (6/30)	14 (4/29)	
Skin	7 (4/59)	10 (3/30)	3 (1/29)	
Cervical	5 (3/59)	3 (1/30)	7 (2/29)	
Colorectal	3 (2/59)	3 (1/30)	3 (1/29)	
Leukemia	3 (2/59)	0 (0/30)	7 (2/29)	
Non-Hodgkin lymphoma	3 (2/59)	0 (0/30)	7 (2/29)	
Pancreatic	3 (2/59)	7 (2/30)	0 (0/29)	
Esophageal	2 (1/59)	3 (1/30)	0 (0/29)	
Liver	2 (1/59)	3 (1/30)	0 (0/29)	
Prostate	2 (1/59)	0 (0/30)	3 (1/29)	
Stomach	2 (1/59)	0 (0/30)	3 (1/29)	
Throat	2 (1/59)	3 (1/30)	0 (0/29)	
All others	14 (8/59)	17 (5/30)	10 (3/29)	
Stage of cancer, % (n/N)				**.41[f]**
0	11 (5/47)	5 (1/21)	15 (4/26)	
I	36 (17/47)	48 (10/21)	27 (7/26)	
II	30 (14/47)	19 (4/21)	38 (10/26)	
III	11 (5/47)	5 (1/21)	15 (4/26)	

	Total (N=59)[a]	QuitGuide (N=30)[a]	Quit2Heal (N=29)[a]	*P* value
IV	13 (6/47)	24 (5/21)	4 (1/26)	
Months since initial diagnosis, mean (SD)	4.7 (3.5)	4.2 (3.7)	5.3 (3.3)	.23
Type of standard cancer treatment completed, % (n/N)				
Chemotherapy	51 (21/41)	48 (10/21)	55 (11/20)	.87
Radiation	41 (17/41)	38 (8/21)	45 (9/20)	.90
Surgery	44 (18/41)	38 (8/21)	50 (10/20)	.65
Hormone therapy	12 (5/41)	14 (3/21)	10 (2/20)	>.99
Stem cell transplant	0 (0/41)	0 (0/21)	0 (0/20)	>.99
Immunotherapy	0 (0/41)	0 (0/21)	0 (0/20)	>.99
Smoking behavior				
Fagerstrom Test of Nicotine Dependence score, mean (SD)	5.3 (2.2)	5.4 (2.1)	5.1 (2.4)	.69
High nicotine dependence (FTND ≥6), % (n/N)	51 (30/59)	57 (17/30)	45 (13/29)	.52
Smokes more than half a pack of cigarettes per day, % (n/N)	56 (33/59)	53 (16/30)	59 (17/29)	.88
Smoked for 10 or more years, % (n/N)	92 (54/59)	93 (28/30)	90 (26/29)	.97
Used electronic cigarettes at least once in the past month, % (n/N)	29 (17/59)	37 (11/30)	21 (6/29)	.29
Made at least one attempt to quit smoking in the past 12 months, % (n/N)	60 (35/58)	69 (20/29)	52 (15/29)	.28
Number of attempts to quit smoking in the past 12 months, mean (SD)	2.1 (3.3)	2.6 (4.0)	1.6 (2.3)	.25
Confidence of being smoke-free, mean (SD)	71.7 (25.7)	70.7 (26.5)	72.8 (25.3)	.76
Friend and partner smoke				
Number of close friends who smoke, mean (SD)	2.1 (1.8)	2.3 (1.8)	2.0 (1.9)	.53
Number of adults at home who smoke, mean (SD)	1.4 (1.1)	1.5 (1.2)	1.3 (1.1)	.52
Living with partner who smokes, % (n/N)	32 (19/59)	37 (11/30)	28 (8/29)	.64
Heavy alcohol drinker, % (n/N)	5 (3/57)	11 (3/28)	0 (0/29)	.22

[a]Sample size, unless otherwise indicated in the cell.

[b]*P* value from a chi-square test compares distribution of all races between arms. This is an omnibus test, so *P* values for each race are not applicable.

[c]Internalized shame scores range from 5 to 20.

[d]Cancer-related stigma scores range from 9 to 45.

[e]*P* value from a chi-square test compares distribution of all cancer diagnoses between arms. This is an omnibus test, so *P* values for each diagnosis are not applicable.

[f]Numbers shown indicate that not all participants provided the stage of cancer. *P* value from a Wilcoxon rank sum test compares cancer stage between arms.

Participant Utilization and Satisfaction

Summarizing from Table 2, compared with QuitGuide participants, Quit2Heal participants (1) opened their app a greater number of times during the 2-month trial period, although this difference was not statistically significant (mean 10.0, SD 14.4 vs mean 6.1, SD 5.3; *P*=.33); (2) used the app for more minutes per session, although this was also not statistically significant (mean 3.9, SD 3.2 vs mean 2.7, SD 2.1; *P*=.07); (3) were more satisfied with their assigned app (19/21, 90% vs 17/26, 65%; *P*=.047); and (4) were more likely to report that their assigned app was made for someone like them (18/21, 86% vs 16/26, 62%; *P*=.04).

Table 2. Primary and secondary study outcomes.

	QuitGuide (N=30)[a]	Quit2Heal (N=29)[a]	*P* value[b]
Utilization			
Logged in at least once, % (n/N)	97 (29/30)	93 (27/29)	.43
Number of times the app was opened[c,d], Mean (SD)	6.1 (5.3)[e]	10.0 (14.4)[f]	.33
Time spent per log in (in min)	2.7 (2.1)[e]	3.9 (3.2)[e]	.07
Number of days from the first use to the last use[c], Mean (SD)	19.8 (22.6)[e]	25.1 (19.8)[f]	.32
Participant acceptability, % (n/N)			
Satisfied overall[g]	65 (17/26)	90 (19/21)	.047
Will recommend to a friend	57 (16/28)	74 (17/23)	.21
App was made for someone like to me[g]	62 (16/26)	86 (18/21)	.04
Smoking outcomes at 2 months, % (n/N)			
30-day quit rate, using all available outcome data[d]	7 (2/29)	20 (5/25)	.10
30-day quit rate, missing outcomes coded as smoking[d]	7 (2/30)	17 (5/29)	.17
Process indicators[h], Mean (SD)			
Change in internalized shame	0.2 (3.5)[i]	−0.5 (4.7)[j]	.27
Change in cancer-related stigma	−1.3 (8.8)[i]	−3.0 (9.9)[k]	.48
Change in depression score	−0.9 (6.5)[l]	−3.5 (5.0)[k]	.38
Change in anxiety score	0.0 (5.6)[m]	−2.8 (6.8)[j]	.56

[a]Sample size, unless otherwise indicated in the cell.

[b]Two-sided *P* values were calculated from regression models adjusted for 3 factors used in stratified randomization: Heaviness of Smoking Index >4, confidence of being smoke-free >70, and recruitment method (clinical vs nonclinical). Unadjusted 2-sided *P* values were very similar.

[c]App opening data are limited to a subset of participants for whom the objective utilization data were available. Owing to a technical error, automatic recording of the utilization data began 2 months after the beginning of the trial recruitment period.

[d]Regression model was adjusted for high school or less education because of its association with the outcome and slight imbalance between arms.

[e]N=15.

[f]N=17.

[g]Responses were dichotomized as “somewhat,” “mostly,” or “very much” versus “not at all” or “a little.”

[h]Process indicators were calculated as follow-up score minus baseline score.

[i]N=29.

[j]N=25.

[k]N=24.

[l]N=27.

[m]N=28.

Smoking Outcomes

The self-reported 30-day point prevalence quit rate for those who completed the 2-month follow-up was 20% (5/25) for Quit2Heal versus 7% (2/29) for QuitGuide (odds ratio [OR] 5.16, 95% CI 0.71-37.29; *P*=.10). Assuming that the 4 participants missing the 2-month outcome data were smoking (ie, missing=smoking), the 30-day adjusted point prevalence quit rate was 17% (5/29) for Quit2Heal versus 7% (2/30) for QuitGuide (OR 3.87, 95% CI 0.57-26.16; *P*=.17).

Processes of Change

From baseline to the 2-month follow-up, Quit2Heal participants also reported greater improvement in internalized shame, cancer stigma, depression, and anxiety, although none of these changes were significant (all *P*>.05).

Use of Outside Treatment

The use of outside treatments to quit smoking during the 2-month study period did not differ by study arm: nicotine patch (20% for Quit2Heal vs 31% for QuitGuide; *P*=.34), nicotine gum (12% for Quit2Heal vs 17% for QuitGuide; *P*=.59), varenicline (16% for Quit2Heal vs 17% for QuitGuide; *P*=.89), bupropion (4% for Quit2Heal vs 7% for QuitGuide; *P*=.65), and any behavioral program (4% for Quit2Heal vs 0% for QuitGuide; *P*=.94).

Discussion

Study Summary

This paper reports the trial recruitment, retention, participant acceptability, preliminary effectiveness, and impact on processes of change of the first-known smoking cessation smartphone app targeted for cancer patients. In general, the results supported all the aims of the pilot study.

Recruitment, Retention, and Sample Diversity

The trial provided useful information on recruitment sourcing and budgeting. Social media (primarily Facebook Ads) yielded 66% (39/59) of the study sample, which showed that it was an effective method for recruiting cancer patients who smoke for an mHealth intervention trial. Recruitment of this population via Facebook was worth the investment because it was highly useful for recruitment, and an intervention, if proven effective, could be broadly disseminated through Facebook given its high reach to this population.

The outcome data collection protocol yielded a strong overall retention rate of 92%, which is consistent with our past experience with this protocol [62] and affirms its value for future trials of cancer patients who smoke.

The recruitment methods yielded demographics broadly representative of adult cancer patients. There was variability of cancer diagnoses, including cancer diagnoses not typically thought of as caused by smoking but whose treatment would greatly benefit from quitting smoking (eg, breast cancer). In a fully powered trial, it would be worth exploring whether patients with cancers known to be attributable to smoking (eg, lung/head and neck cancers vs patients with all other cancers) are more likely to respond to an app targeted to cancer patients who smoke. The rates of inclusion of participants with mental health problems (eg, depression) and participants who belonged to racial or ethnic minority, were male, identified themselves as LGB, and had high school or less education were encouraging. These sociodemographic groups are typically underrepresented in eHealth and mHealth smoking cessation research [73], although they experience significant disparities in the prevalence and negative health consequences of smoking [74].

Participant Receptivity and Satisfaction

Although not statistically significant, among those with available log-in data, Quit2Heal participants opened their app more often than QuitGuide participants. Quit2Heal participants were highly satisfied with their app on multiple indicators—substantially more than the QuitGuide participants. Particularly encouraging was the finding that, as an app targeted for cancer patients, 86% of the assigned study participants rated Quit2Heal as being made for someone like them. Taken together, these results suggest that the Quit2Heal content was engaging, acceptable, and seen as relevant by cancer patients.

Smoking Cessation

Tests of the encouraging quit rates were underpowered as this was a pilot trial. Indeed, the 95% CIs for the ORs for the comparison of quit rates were wide, which is expected in pilot trials with low sample sizes. However, if similar quit rates are found in a fully powered RCT, the overall effect size could have high public health significance.

Impact on Cancer Patients' Smoking Processes

The results from Quit2Heal on improvements in internalized shame, cancer stigma, depression, and anxiety are important. They suggest that Quit2Heal may have impacted the processes hypothesized to impede smoking cessation among cancer patients. A future larger trial can determine the extent to which these processes mediate the effects of Quit2Heal on smoking cessation.

Limitations

The study has several important limitations. As a pilot randomized trial, the sample size was not powered to detect statistically significant differences in quit rates or to conduct formal moderation or mediation analysis of the hypothesized treatment effects. Moreover, substantial smoking relapse naturally occurs after a 2-month follow-up [69,75], especially among cancer patients who smoke, and therefore, a longer-term follow-up (eg, 12 months) is recommended. Owing to a technical error, automatic recording of utilization data did not occur until 2 months after the beginning of the trial recruitment period. Finally, we relied exclusively on the self-reported abstinence in our estimate of 30-day point prevalence abstinence.

Future Directions

The study results suggest 3 main lines of future research: (1) provide a definitive test of the effectiveness of smoking cessation of smartphone-delivered Quit2Heal compared with QuitGuide—an app that follows US Clinical Practice Guidelines, (2) demonstrate that the smoking cessation outcomes of Quit2Heal are mediated by processes that impede cancer patients' cessation (eg, internalized shame and cancer stigma), and (3) explore the baseline moderators of treatment effectiveness.

Conclusions

In a pilot trial with a high short-term follow-up rate, Quit2Heal showed promising acceptability and effectiveness for helping cancer patients stop smoking. Testing in a full-scale RCT is required to definitively determine the effectiveness of Quit2Heal for smoking cessation.

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Conflicts of Interest

In the past, JB has served on the Scientific Advisory Board of Chrono Therapeutics. JH has received research support from Pfizer. Other authors have no declarations.

Multimedia Appendix 1
CONSORT-EHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 1871 KB - formative_v4i1e16652_app1.pdf]

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Abbreviations

C3I: Cancer Center Cessation Initiative
CAPTCHA: Completely Automated Public Turing test to tell Computers and Humans Apart
CES-D: Center for Epidemiologic Studies
eHealth: electronic health
FDA: Food and Drug Administration
FTND: Fagerstrom Test of Nicotine Dependence
GAD-7: Generalized Anxiety Disorder-7
LGB: lesbian, gay, or bisexual
mHealth: mobile health
NCCN: National Comprehensive Cancer Network
NCI: National Cancer Institute
OR: odds ratio
RCT: randomized controlled trial
SCCA: Seattle Cancer Care Alliance
TV: television

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Original Paper

A Web-Based Communication Platform to Improve Home Care Services in Norway (DigiHelse): Pilot Study

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Abstract

Background: Home care service in Norway is struggling to meet the increasing demand for health care under restricted budget constraints, although one-fourth of municipal budgets are dedicated to health services. The integration of Web-based technology in at-home care is expected to enhance communication and patient involvement, increase efficiency and reduce cost. DigiHelse is a Web-based platform designed to reinforce home care service in Norway and is currently undergoing a development process to meet the predefined needs of the country's municipalities. Some of the main features of the platform are digital messages between residents and the home care service, highlighting information on planned and completed visits, the opportunity to cancel visits, and notifications for completed visits.

Objective: This study aimed to test the usability and economic feasibility of adopting DigiHelse in four districts in Oslo by applying registry and behavioral data collected throughout a one-year pilot study. Early health technology assessment was used to estimate the potential future value of DigiHelse, including the predictive value of behavior data.

Methods: Outcome measures identified by stakeholder insights and scenario drafting in the project's concept phase were used to assess potential socioeconomic benefits. Aggregated data were collected to assess changes in health consumption at baseline, and then 15 and 52 weeks after DigiHelse was implemented. The present value calculation was updated with data from four intervention groups and one control group. A quasi-experimental difference-in-difference design was applied to estimate the causal effect. Descriptive behavioral data from the digital platform was applied to assess the usability of the platform.

Results: Over the total study period (52 weeks), rates increased for all outcome estimates: the number of visits (rate ratio=1.04; *P*=.10), unnecessary trips (rate ratio=1.37; *P*=.26), and phone calls (rate ratio=1.24; *P*=.08). A significant gap was found between the estimated value of DigiHelse in the concept phase and after the one-year pilot. In the present pilot assessment, costs are expected to exceed potential savings by €67 million (US $75 million) over ten years, as compared to the corresponding concept estimates of a potential gain of €172.6 million (US $193.6 million). Interestingly, behavioral data from the digital platform revealed that only 3.55% (121/3405) of recipients actively used the platform after one year.

Conclusions: Behavioral data provides a valuable source for assessing usability. In this pilot study, the low adoption rate may, at least in part, explain the inability of DigiHelse to perform as expected. This study points to an early assessment of behavioral data as an opportunity to identify inefficiencies and direct digital development. For DigiHelse, insight into why the recipients in Oslo have not made greater use of the Web-based platform seems to be the next step in ensuring the right improvement measures for the home care service.

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KEYWORDS

early health technology assessment; eHealth; primary care; innovation; behavioral data

Introduction

The era of digital health and the demand for health information technology (HIT) brings enormous opportunities for both patients and professional users [1]. While HIT is the technology used in electronic health (eHealth) services, eHealth itself is defined as the interaction between medical informatics, public health, and businesses, referring to health services and information delivered or enhanced through the internet and related technologies [2]. One promise of eHealth solutions is that, through enhanced communication and patient involvement, and increased efficiency, reduced costs for the health care service may be achieved. It is also assumed that eHealth may enhance the quality of care by increasing transparency and availability between different health suppliers. There is, however, a discrepancy between the expected value of such interventions and the empirically demonstrated benefits [3,4]. There is a lack of case studies demonstrating the assumed cost-effectiveness and efficacy of eHealth solutions, and research to promote value-based health care in this field has been requested [3,5].

Web-based communication platforms are intended to enhance health in both somatic and mental health care [6-8]. Such platforms have shown success in reaching individuals who are hard to contact, in lifestyle behavior change, and the delivery of individualized online care [7,9,10]. For chronic illnesses, enabling people to administer their treatment and care may increase compliance to treatment regimens and improve quality of life. The translation of the Diabetes Prevention Program to online treatment is one such example [11]. The failure of adoption by end-users, however, is a challenge faced by these Web-based interventions. Accordingly, end-user engagement in the development of these interventions has been recognized as essential to increase adoption rates when they are introduced [12,13].

A health service characterized by efficiency and high quality can only be achieved if patient outcomes and costs of delivery are addressed [14]. When facing the complex health care system, not only do technical and legal issues appear, but so do organizational, economic, and social aspects [1]. User-centric design can be employed from the earliest exploratory stages to help understand and design for the needs, goals, limitations, capabilities, and preferences of all stakeholders [15]. Recommendations from an international workshop in the United Kingdom on how to create, evaluate, and implement effective eHealth interventions highlights new evaluative challenges in the field. Due to the swiftly changing technological landscape, these UK authors emphasized challenges such as continuous technological adaption and problems identifying valid outcome measures for assessment of costs and patient benefits [16]. Thus, to adjust to the rapidly changing context, standard methods for development and assessment will benefit from including the whole development cycle. Access to data and valid information from a conceptual stage of development may, however, be demanding, which could explain the lack of empirical evidence concerning the effect of eHealth interventions [3,17].

Health technology assessment (HTA) is traditionally used to provide decision support in the implementation phase of new or current health technology. HTA is defined as an interdisciplinary process for synthesizing information about medical, social, economic, and ethical issues related to the introduction of a new health technology [18]. To improve the pace and efficiency of the development and assessment of health innovation, new methods for early HTA are emerging in the literature [19]. Early HTA is a form of HTA that evaluates technologies still in development and can be defined as the initial examination of the medical, economic, social, and ethical implications of a health intervention to determine the potential of its incremental value in health care [20,21]. A standard model for early HTA is yet to be established, so research is needed to validate the proposed approaches to early HTA emerging in the literature [22].

DigiHelse is an intervention designed to reinforce the home care service in Norway and is currently undergoing a procurement process in the county's municipalities. This is the second of a series of two studies reporting on the effects of implementing the Web-based communication platform, and the first study reported on the early assessment of potential socioeconomic value in the concept stage of the project. DigiHelse was designed and developed to integrate a national Web-based communication platform for recipients of home care services. The main features of the platform were digital messages between residents and the home care service, visualizing agreed upon and completed visits with their associated information, the option to cancel visits, and final notifications of completed visits. In the concept stage of development, data was collected from stakeholders and experts to build scenarios to show the potential value of the intervention. Based on the findings, the project was granted additional funding and proceeded to its pilot phase in four districts in Oslo. Throughout this pilot study, the project needed to collect evidence on its potential benefits to ease the procurement process in other municipalities in the country.

DigiHelse is an example of an eHealth intervention still in development; thus, there is an opportunity to perform assessments on the different stages of the development cycle. A stepwise decision process with several evaluation points and iterative adoptions of the solution has been incorporated in the implementation plan to ensure that the final solution meets the needs of the end-users. This study aimed to test the usability and economic feasibility of adopting DigiHelse in four districts in Oslo by applying registry and behavioral data collected throughout a one-year pilot. Early HTA was used to estimate the potential future value of DigiHelse, including the predictive value of behavior data.

Methods

Population

The target population for the intervention is composed of all the recipients of the home care service in Norway, their next of kin, and the service providers of the home care service. The home care service in Norway is a part of the country's primary health care service. Norway has 426 municipalities that are responsible for the provision of services in primary care. Operations directed under primary care are typically health services provided outside an institution (with a preferred emphasis on health promotion and preventive work), general medical care (general practitioner), and nursing services outside the hospital. Nurses and doctors in preventive and long-term care services are usually employed in municipal health care [23]. Although the municipalities in Norway dedicate a significant part of their budgets to health services (about one quarter), the home care service struggles to meet an increasing demand for health care under the constraints of a restricted budget [24]. During 2016, there were 355,635 unique recipients of nursing and care services nationally, which equates to 6.7% of the Norwegian population. Of the unique recipients of nursing and care services, 85% received home-based services, and about 2.7 million visits ware performed every week [25].

The Intervention

This study was set in Oslo in 2018. The purpose of DigiHelse was to digitalize the dialogue between recipients and professionals in home care services in Norway through the development and implementation of a national Web-based platform. All recipients of home care services in four districts in Oslo were offered DigiHelse, in addition to regular services, in a one-year pilot project from autumn 2017 to the next year. The utilization of DigiHelse was completely voluntary. The project is based on the existing "Helsenorge.no" platform from the Norwegian Directorate of e-Health, which provides national digital health services. The realization of digital services in this project supports the overall objective of the development of information and communication technology in the health care sector to provide citizens with access to simple and secure digital services [26].

The intervention intends to cover the following objectives and needs:

- Support relatives who are involved in care tasks and strengthen the interaction between service providers and relatives through the possibility of secure digital dialogue and an overview of visits.
- Support service recipients in enhanced coping, safety, and involvement in their daily lives by providing an overview of visits and facilitating dialogue with the home care service, so that they can express their experiences and needs.
- Ensure that the home service can organize tasks more rationally and cooperate better with service recipients and relatives.
- Ensure that messages from relatives and recipients are captured and followed up with appropriately, such that phone inquiries are reduced, tasks can be registered at a more favorable time, and unnecessary trips to the recipient can be reduced.

Choice of Health Outcomes

Summary

In the concept stage of DigiHelse, a multidisciplinary team of stakeholders managed to identify both quantitative and qualitative outcome measures comparing the new solution to the current situation. Through scenario building, a present value calculation on socioeconomic impact was carried out. The outcome measures, based on each scenario elaborated on in the previous study of DigiHelse, are presented below.

Increased Predictability for Recipients

Notifications of appointments and any delays might give recipients a greater sense of predictability and greater confidence in the home care services. Digital services may also provide better information security for recipients than email and texting, thus more thoroughly safeguarding the privacy of the recipients. In the concept assessment, increased predictability gave a predicted annual value of €408.4 million (US $458.3 million) per year. This was based on the assumption that if the recipients knew the exact arrival time of their home service care, an hour waiting time per visit might be saved. This effect was not included in the present value calculation as the value of free time is debatable.

Increased Involvement From Relatives and Volunteers

Improved communication between relatives and the home service was assumed to amount to savings of €13.8 million (US $15.5 million) a year. For relatively self-sufficient recipients, relatives and volunteers may carry out one visit per month on average.

Increased Predictability of the Home Care Service

The assumption in the concept stage was that the staff in the home care service might be able to better manage their workday by using digital channels rather than the telephone. They may experience reduced time consumption for administrative tasks and have more time for preventive work. Increased predictability of the home service may also result in fewer unnecessary trips to the users, as unwanted visits may be easily canceled in the portal. With the ability of the user to digitally cancel and postpone visits, a reduction of 30% of unnecessary trips was estimated, which results in assumed savings of €3.8 million (US $4.3 million) a year.

Greater Dialogue Efficiency and Time Management

Through interviews with professionals from the home services, the stakeholders estimated potential administrative time savings in administrative time of 30 minutes per day, with an hourly rate of €46 (US $51.60) with digital communication, resulting in savings of €7.1 million (US $8 million) a year.

Reduced Phone Inquiries

The estimated impact of reduced phone inquiries may amount to €1 million (US $1.2 million) per year on a national basis. To assess whether the intervention may reduce phone inquiries that otherwise could be solved digitally, the project group conducted

a phone survey in Oslo and Bergen. After the survey, a scenario where digital communication could reduce phone inquiries to the home service by 40% was built.

Provide a Technical Basis for Developing Digital Services

Providing a technological basis for developing digital services may result in a one-time saving of €18.25 million (US $20.5 million). If 50% of the municipalities in Norway each procure a platform, they will, on average, consume €100,000 (US $110,000) each, including procurement, infrastructure, licenses/rent, etc. This effect was not included in the present value calculation because the digitalization of home services is still not statutory in the country's municipalities.

In the present study, three outcomes (increased involvement from relatives and volunteers, increased predictability of the home care service, and reduced phone inquiries) were reassessed using empirical data from the one-year pilot in four districts in Oslo, and a control district. The remaining outcome measures will appear unchanged in the present value calculation, as will the unit costs of investment, training, and maintenance.

Data Sources

In this pilot assessment, descriptive behavioral data from the Web-based platform was collected to study the usability of the platform. Data points, such as the number of digital users, digital inquiries, and active users, were retrieved from the platform's server. In this study, we used behavioral data on the number of active users to study usability. All recipients in the intervention districts were offered the chance to log into the platform and create a profile. The number of active users is defined as the number of users who not only created a profile but also had interactions with the home care service in the platform. Aggregated data from the electronic patient record (EPR) system Gerica was retrieved to study changes in health consumption in the home care service in the four intervention districts and one control district in Oslo. Data collection was performed through three measurement points in time: at baseline (the week before the intervention), during the short period (15 weeks after the intervention), and over the total study period (52 weeks after the intervention). Data was collected on the number of visits of the home service to the recipient to assess if the intervention may give an incentive to increase involvement from relatives and volunteers in the care of recipients.

Further, to assess if the option to cancel unwanted trips in the portal may result in fewer unnecessary trips and increased predictability of the service, data was also collected on the number of unnecessary trips by the home care service to the recipient. An unnecessary trip is when the home service arrives at a recipient's home for a planned visit, and the recipient does not answer the door. Finally, to study if digital dialogue may reduce the number of phone calls to the home service, phone calls to the service were registered during the three measurement points. Input variables on the cost of the present value calculation are shown in Multimedia Appendix 1.

Data Analysis

A 10-year present value calculation model with a discount rate of 4% was used to estimate the potential value of the intervention. The potential value was first estimated every year, and by employing the cost of investment, training, and implementation pace, the overall value was calculated over ten years. The assumption of the 10-year life cycle is based on national recommendations from the Directorate for Financial Management [27]. The data from the intervention and control group was analyzed using the quasi-experimental difference-in-difference design to estimate the causal effect and to update the present value calculation. Such a design is typically used to estimate the effect of an intervention by comparing the changes in outcomes over time between a population exposed to the intervention (intervention group) and a population not exposed (control group) [28]. A Poisson regression analysis was used to fit the model, as the dependent variables are counts of events.

First, to test for an effect of the intervention, interaction models with dummy variables were used for the intervention and the period. To assess both the short-term and long-term effects, analyses were done separately for time points one week before the intervention versus 15 weeks after, and before intervention versus 52 weeks after. The number of those exposed to the intervention in the model corresponded to the number of home care recipients (user base) in each group because all recipients in the intervention group had, in principle, access to DigiHelse, and all analyses are based on aggregate data. The interaction coefficient between the intervention and the time period dummies indicates the effect of the intervention. Second, to assess the effect of the proportion of active users in the intervention districts, an interaction model with continuous-time and continuous rates of digital users was used in each district. Different rates of active digital users were then extrapolated to assess how this would influence the rates for visits, unnecessary trips, and phone calls, and thereby, the costs in the present value analysis. All calculations were done in kr and converted to euros based on the exchange rate from May 2018 (9.54) [29]. All analyses were performed in Stata 15.1 (StataCorp, College Station, Texas, United States) and Excel 2010 (Microsoft, Redmond, Washington, United States).

Results

Study Parameters

Table 1 and Table 2 show the demographic distribution and aggregate data from the EPR system Gerica for each of the intervention districts and the control district. District 2 has the highest percentage of active digital users. This district has a relatively high percentage of immigrants, but the lowest percentage of people under retirement age. The user base is the number of recipients of home care services in each district, and the digital users are the recipients who have logged in to the digital platform. The active digital users are the recipients who use the portal to actively administer their services and contact with the home care service. Finally, the demographic data shows the composition of people over retirement age and immigrants of the total population in each district.

Table 3 shows the rates for the number of visits, the number of unnecessary trips, and the number of phone calls extracted from the EPR system for every ten users. The rates in the intervention and control groups at baseline, after 15 weeks (short period), and after 52 weeks (total study period), with their associated percentage changes compared to baseline, are presented. Also presented are *P* values for whether the difference over time is significantly different between intervention and control, which corresponds to whether the intervention has an effect.

The intervention group had a 12% (8.32/69.33) higher rate for the number of visits at baseline (77.65) compared to the control group (69.33). After 15 weeks (short period), the rate for the number of visits in the control group increased by 7% (4.97/74.30). In the same period, the rate for the number of visits also increased in the intervention group by 6% (4.26/81.91; rate ratio=1.06; *P*=.59). In the total study period (after 52 weeks), the rate for the number of visits increased in the control group by 7% (5.05/74.38), but by 11% (8.77/86.42) in the intervention group (rate ratio=1.04; *P*=.10). Both unnecessary trips and phone calls had a lower rate at baseline in the intervention group (19%) compared to the control group (28%) at baseline. However, over time the rates were further reduced in the control group compared to the intervention group for both unnecessary trips and phone calls.

Over the 52 total weeks of the study period, unnecessary trips decreased in the control group by 33% (–0.21/0.42), and the rate for unnecessary trips reduced in the intervention group by 10% (–0.05/0.46). This is still less than in the control group, with a rate ratio of 1.37 *(P*=.26*)*. Phone calls were reduced in the control group by 2% (–0.05/2.66) and increased in the intervention group by 22% (0.42/2.36), by a rate ratio of 1.24 (*P*=.08*)*. In conclusion, all point estimates indicate that the intervention increases the rates for all outcomes, although none of the intervention effects were significant.

Table 1. Description of user base.

Users	District 1	District 2	District 3	District 4	Control
User base, n					
Baseline	812	667	746	1073	590
Short period	874	684	741	1064	607
Long period	863	662	802	1078	600
Digital users, n					
Baseline	0	0	0	0	0
Short period	19	46	32	33	0
Long period	442	269	382	351	0
Active digital users, n					
Baseline	0	0	0	0	0
Short period	7	15	23	21	0
Long period	21	21	36	43	0

Table 2. Demographic data of user base.

District	Population, N	Over retirement age, n (%)	Immigrants, n (%)
1	57,000	6954 (12.2)	15,960 (28)
2	36,000	1836 (5.1)	12,600 (35)
3	49,200	5806 (11.8)	17,220 (35)
4	49,800	6823 (13.7)	8964 (18)
Control	51,400	2878 (5.6)	20,046 (39)

Table 3. Outcome rates in the intervention and control groups for every ten users.

Outcome	Baseline (week 0)	Short period after intervention (after 15 weeks)	Short period change, rate (%)	*P* value	Total study period (after 52 weeks)	Long-period change, rate (%)	*P* value
Rate of visits							
Intervention	77.65	81.91	4.26 (6)	—	86.42	8.77 (11)	—
Control	69.33	74.30	4.97 (7)	.59	74.38	5.05 (7)	.10
Rate of unnecessary trips							
Intervention	0.51	0.41	–0.1 (–20)	—	0.46	–0.05 (–10)	—
Control	0.63	0.48	–0.15 (–24)	.83	0.42	–0.21 (–33)	.26
Rate of phone calls							
Intervention	1.94	1.81	–0.13 (–7)	—	2.36	0.42 (22)	—
Control	2.71	2.64	–0.07 (–3)	.75	2.66	–0.05 (–2)	.08

Incremental Costs and Outcomes

In the prior concept stage assessment of the project, a 90% adoption rate of the digital portal DigiHelse was assumed. Applying behavioral data made available from the platform's server revealed that the adoption rate after the one-year pilot was not as expected. Only 3.55% (121/3405) of active users were registered in the data, which makes it a challenge to both predict whether the precision and the fit of the concept model were good and compare the present value calculation with and without empirical pilot data. As such, the present analysis may only show that the control district improved over time compared to the intervention districts and that the adoption rate of the intervention was considerably lower than expected. From the difference-in-difference analysis, a 37% (0.46/0.34) increase in the rate of unnecessary trips in the intervention group was found, but this was given the observed adoption rates of around 3.55% (121/3405). Using continuous-time and adoption rates in the model and extrapolation to 50% active digital users, the effect of the intervention would have been a 128-fold yearly increased rate of unnecessary trips. The same trend was found for the number of visits. When extrapolating for 50% of active digital users, the effect of the intervention would be a 1.04 times higher increase in the intervention group compared to the control group. Finally, if there were 50% active users, the effect of the intervention would be a 55-fold increase in the phone call rate.

When including the outputs from the difference-in-difference model comparing the intervention and control group into the present value calculation model from the concept stage, the estimated value of the intervention changes radically (see Multimedia Appendix 2). The net present value of the intervention after adding data form the pilot is reduced by €241.8 million (US $271.3 million) over ten years from the first assessment, resulting in a loss of €62.2 million (US $69.8 million) over ten years. Based on the present pilot assessment, costs are expected to exceed potential savings by €67 million (US $ 75.2 million) over ten years, compared to potential gains of €172.6 million (US $ 193.7 million) from the prior concept assessment.

Discussion

Primary Findings

Through a case of early HTA employing empirical data from a pilot study, the present study updated effect estimates made in the concept stage of the development of DigiHelse. Based on the present pilot assessment, costs are expected to exceed potential savings by €67 million (US $75.2 million) over ten years, compared to potential gains of €172.6 million (US $193.7 million) from the first assessment. After one year, only 3.55% (121/3405) of recipients used the platform actively. The prior socioeconomic analysis, conducted in the concept stage of DigiHelse, was based on stakeholder insight and scenario drafting. Collecting empirical data from the one-year pilot of DigiHelse, the present study evaluated the potential value of the intervention and assessed the precision of early HTA using stakeholder analysis and scenario drafting. Three of the outcome measures identified in the first study constituted the basis for the difference-in-difference analysis, and related costs were analyzed using a 10-year present value calculation with a rate of 4%. We found a significant gap between the estimated value in the concept stage of DigiHelse and the estimated value using empirical data from the one-year pilot.

This may indicate that early assessment using stakeholder insight and scenario drafting applied in the concept stage was less precise than expected. Another explanation may be, at least in part, suboptimal pilot implementation, as it is known that adoption and diffusion of eHealth solutions may be time-consuming and require significant adaptation of work practices [30]. However, by assessing behavioral data on the actual use of the platform, an important issue likely to affect the outcome of the assessment was found: a very low rate of DigiHelse users among recipients of home care services. This may explain why there was no significant change in the outcome measures between the control and the intervention districts after the pilot.

A review study highlighting methodological challenges in early HTA emphasizes both the lack of proof on the efficacy of the methods and the absence of a standardized framework for early assessments [20]. Empirical and theoretical attempts have been

made to fill the evidence gaps in early assessment modeling, with theoretical recommendations on the use of sophisticated mathematical techniques such as Bayesian modeling or Markov modeling [31-34]. Empirical models based on scenario drafting and expert elicitation have also been used to compensate for the lack of data and steer the innovation in the right direction [31,35-38].

Findings from the review showed how stakeholder insights and scenario drafting might be used in an early phase to collect data on patient outcomes and effects on costs [17,39,40]. However, there are some presented concerns are, such as the high uncertainty regarding the availability of adequate data sources for modeling outcomes and that the models suffer from the precision required for data input [31,41]. Although a strength of the present study was the availability of concept stage assumptions and assessment based on stakeholder insights and scenario drafting when empirical data from the present pilot were analyzed, lack of precision was found. In line with similar research on the subject, we found that early-stage analyses may suffer from loss of information, as they are unable to reflect all possible outcomes [39,42]. Further, it cannot be excluded that stakeholders may be positively biased towards the value of the technology in which they have a particular interest [43]. This may explain the identified gap between the estimated socioeconomic value and the value assessment based on empirical pilot data in the present study.

While the low acceptability rate among recipients of the home care service in Oslo was an important concern found in the present study, other studies addressing the acceptance of eHealth solutions tested in clinical settings have indicated high patient acceptability rates [44-46]. However, it is unclear how the adoption rate of eHealth solutions may be affected once the technology is moved outside the boundaries of the clinic and is implemented in users' homes. Discrepancies in access to the internet and technological literacy in different subgroups may influence the adoption rate and, thus, the estimated improvement in efficiency and cost reduction expected from the implementation of eHealth [47-49]. Identified subgroups that are especially challenged by eHealth solutions are the elderly [47,48], minorities [49], and the socioeconomically disadvantaged [48,49].

Effective adoption among users is a prerequisite for successful implementation, and the effectiveness of eHealth is compromised if the solutions are suboptimally implemented. Discomfort with the new technology and a preference for well-known, earlier provided services are reasons reported to influence the adoption of eHealth technologies [50,51]. Qualitative methods are needed to explore the experienced discomfort about or preference for existing analog health services. Such methods are increasingly being explored to accompany quantitative assessments of complex innovations to provide a deeper understanding of the adoption of eHealth [52]. While quantitative methods explore relationships between digitalization and disease outcomes, qualitative methods may provide a deeper understanding of contextual factors influencing these relationships, such as information on drivers and barriers to technological implementation [53].

The engagement of end-users in collaboration with product developers may succeed in increasing acceptability in particularly vulnerable groups by incorporating favorable eHealth designs to overcome barriers, although this may not be sufficient [54]. Predictive behavioral data represents another important tool, as it provides valuable information on the usability of a digitalized service and its corresponding population, and thus may determine whether the predefined intent of the new service is met. The digitalization of services in health care provides a new, potentially valuable data source as real-time data can be extracted and analyzed at any time [55]. According to the Lean Startup framework, behavioral data from initial testing provides essential information on how the market will respond to a service or a product [56]. Measuring quantifiable behavioral data outcomes provides an opportunity to assess usability [57]. Qualitative information on the directions of the developmental improvements of services may then be assembled from the same study sample. This allows for iterative modifications and adaptations at the initial project phase to avoid the implementation of ineffective services. Through this process, the likelihood of developing a user-centric service which complies with market expectations may increase as the early assessment of behavioral data provides the ability to test whether the service meets its initial intent and contributes to value-based health care [56].

Limitations

There are several limitations of this study. Firstly, health economic analysis commonly presents results as cost per patient. The present analysis applied the net present value of the presented investment, weighting potential benefits against investment costs. In this case, the model was chosen due to the significant heterogeneity among recipients receiving home services and the early nature of the analysis.

Further, a quasi-experimental design was used. This means that many confounders may affect the results, such as changes over time independent of the intervention, aging in the population, and heterogeneity between the intervention and control groups. The homogeneity of the districts in the analysis may also be questioned due to the baseline data. To increase the representativeness of the selected control group, data could preferably have been collected from more than one control district. An increased number of measurement points before the intervention would have provided an opportunity to assess trend assumptions between the control and intervention group, which is crucial for difference-in-difference analyses.

Further, if the behavioral data had shown a higher adoption rate, both these issues would have been resolved before the difference-in-difference analysis. In addition to empirical results, the present value model could have been used to predict the socioeconomic outcomes if the adoption rate was 90%. However, given the unexpectedly low adoption rate, collecting more measurement points, and performing a sensitivity analysis of the findings was deemed futile. It should also be taken into consideration that the value of DigiHelse was calculated on a national basis, although, due to the Norwegian municipal health budget autonomy, it is uncertain whether all municipalities will implement the service. A final limitation of this study is that

the analyses are based on aggregated numbers and not individual data. On the positive side, the database is larger than typical pilot studies; however, it comes with an inability to connect data sources to adjust for confounders on the individual level.

Conclusion

Measuring objective behavioral data provides an important source to assess usability. This study reported on the attempt to evaluate methods for early HTA by reassessing DigiHelse by comparing pilot intervention data to a corresponding control group. In this pilot study, the low adoption rate may, at least in part, explain the inability of the DigiHelse pilot to perform as expected. This study points to an early assessment of behavioral data as an opportunity to identify inefficiencies and direct digital development. Implementing eHealth solutions is known to be challenging and time-consuming. To ensure adoption, effective diffusion strategies are needed, including user training programs. For DigiHelse, learning strategies may be targeted to increase adoption in the next phase.

The integration of behavioral data in early planning and assessment provides an opportunity to address implementation challenges and user adherence, where early HTA modeling has a purpose. For DigiHelse, insight into why the recipients in Oslo have not made greater use of the Web-based platform seems to be the next step in ensuring the right improvement measures for the home care service. We encourage more research on early HTA and the use of behavioral data in case studies as tools to empirically demonstrate eHealth intervention benefits.

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Authors' Contributions

LNS and TM conceived, designed, and performed the experiments. LNS and TM analyzed the data. LNS authored the manuscript. KJK and KK critically reviewed the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Summary of cost units.
[DOCX File , 18 KB - formative_v4i1e14780_app1.docx]

Multimedia Appendix 2
Summary of priced effects in the concept phase and after the pilot phase.
[DOCX File , 18 KB - formative_v4i1e14780_app2.docx]

Multimedia Appendix 3
CONSORT ‐ EHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 3533 KB - formative_v4i1e14780_app3.pdf]

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Abbreviations

eHealth: electronic health
EPR: electronic patient record
HIT: health information technology
HTA: health technology assessment

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Original Paper

The Use and Effects of an App-Based Physical Activity Intervention "Active2Gether" in Young Adults: Quasi-Experimental Trial

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Abstract

Background: Insufficient physical activity (PA) is highly prevalent and associated with adverse health conditions and the risk of noncommunicable diseases. To increase levels of PA, effective interventions to promote PA are needed. Present-day technologies such as smartphones, smartphone apps, and activity trackers offer several possibilities in health promotion.

Objective: This study aimed to explore the use and short-term effects of an app-based intervention (Active2Gether) to increase the levels of PA in young adults.

Methods: Young adults aged 18-30 years were recruited (N=104) using diverse recruitment strategies. The participants were allocated to the Active2Gether-Full condition (tailored coaching messages, self-monitoring, and social comparison), Active2Gether-Light condition (self-monitoring and social comparison), and the Fitbit-only control condition (self-monitoring). All participants received a Fitbit One activity tracker, which could be synchronized with the intervention apps, to monitor PA behavior. A 12-week quasi-experimental trial was conducted to explore the intervention effects on weekly moderate-to-vigorous PA (MVPA) and relevant behavioral determinants (ie, self-efficacy, outcome expectations, social norm, intentions, satisfaction, perceived barriers, and long-term goals). The ActiGraph wGT3XBT and GT3X+ were used to assess baseline and postintervention follow-up PA.

Results: Compared with the Fitbit condition, the Active2Gether-Light condition showed larger effect sizes for minutes of MVPA per day (regression coefficient B=3.1; 95% CI −6.7 to 12.9), and comparatively smaller effect sizes were seen for the Active2Gether-Full condition (B=1.2; 95% CI −8.7 to 11.1). Linear and logistic regression analyses for the intervention effects on the behavioral determinants at postintervention follow-up showed no significant intervention effects of the Active2Gether-Full and Active2Gether-Light conditions. The overall engagement with the Fitbit activity tracker was high (median 88% (74/84) of the days), but lower in the Fitbit condition. Participants in the Active2Gether conditions reported more technical problems than those in the Fitbit condition.

Conclusions: This study showed no statistically significant differences in MVPA or determinants of MVPA after exposure to the Active2Gether-Full condition compared with the Active2Gether-Light or Fitbit condition. This might partly be explained by the small sample size and the low rates of satisfaction in the participants in the two Active2Gether conditions that might be because of the high rates of technical problems.

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KEYWORDS

physical activity; smartphone; mobile app

Introduction

Insufficient physical activity (PA) is associated with adverse health conditions and noncommunicable diseases such as cardiovascular diseases, cancer, and diabetes [1,2]. Worldwide, approximately 25% of the adult population does not meet the recommended guidelines for PA [3]. In Western countries such as the United States and the Netherlands, approximately 50% of the population does not meet the guidelines [4]. Moreover, engagement in moderate-to-vigorous PA (MVPA) decreases with age, in particular, when transitioning from adolescence to (young) adulthood [5,6].

To increase the levels of PA, effective interventions to promote PA are needed. Research has shown that interventions are more likely to be effective when established behavior change techniques, such as self-monitoring, goal setting, and providing feedback on performance, are incorporated [7]. Systematic reviews further showed that individually tailored interventions are superior to generic interventions in promoting PA in effects as well as user engagement and appreciation [8-14]. Moreover, Krebs et al [10] demonstrated that dynamic tailoring (ie, iteratively assessing and providing feedback) was associated with larger effect sizes compared with static tailoring (ie, all feedback is based on one baseline assessment).

Present-day technologies such as smartphones, smartphone apps, and activity trackers offer possibilities to deliver theory-based, dynamically tailored interventions that include effective behavior change techniques. The high adoption rate of smartphones (97% among adults aged 20-29 years in the Netherlands) and the popularity of health and fitness apps and activity trackers [15] suggest that young adults may appreciate and adopt app-based PA interventions. Moreover, systematic reviews show that app-based interventions show promising results on changing health behavior, including PA [16-18]. Furthermore, the majority of interventions that reported significant changes in behaviors and health-related outcomes included behavior change techniques such as goal setting, self-monitoring, and feedback on the performance [16].

In this context, we developed the *Active2Gether* intervention. A systematic and stepwise approach was used to develop the Active2Gether intervention guided by health behavior theory and scientific evidence [19]. This resulted in the development of an app suitable for providing highly tailored coaching messages that are framed in an autonomy-supportive style. These coaching messages include behavior change techniques aiming to address relevant behavioral determinants (ie, self-efficacy, outcome expectations, intentions, impediments, long-term goals, social norm, satisfaction, and self-regulation skills) and are partly context specific. A fundamental component of the intervention is the model-based reasoning engine, that is, a software system that generates conclusions from information stored in the database using logical techniques and a mathematical model that is used to predict behaviors by computer simulations. The reasoning engine is used to tailor the intervention with respect to the type of support provided by the app, to send relevant and context-specific messages to the user, and to tailor the graphs displayed in the app. Detailed information on the development and technical design of the Active2Gether intervention can be found elsewhere [19,20].

The primary objective of the Active2Gether intervention was to increase the total time spent in MVPA for participants who do not meet the Dutch guidelines, to maintain PA levels of those who meet the guideline, or to further increase the PA levels if they indicate that they want to improve further. The secondary aims were (1) to increase the underlying specific categories of MVPA, that is, minutes of weekly sports participation, weekly numbers of stairs climbed, or weekly minutes of active transport and (2) to enhance the underlying determinants of the PA behaviors.

The aim of this study was to explore the use and effects of the Active2Gether intervention on increased weekly levels of MVPA and psychosocial determinants of MVPA in adults aged 18-30 years compared with two control groups in a quasi-experiment. As we could not achieve a sufficiently valid and powered research design, this paper is an exploratory study.

Methods

Design

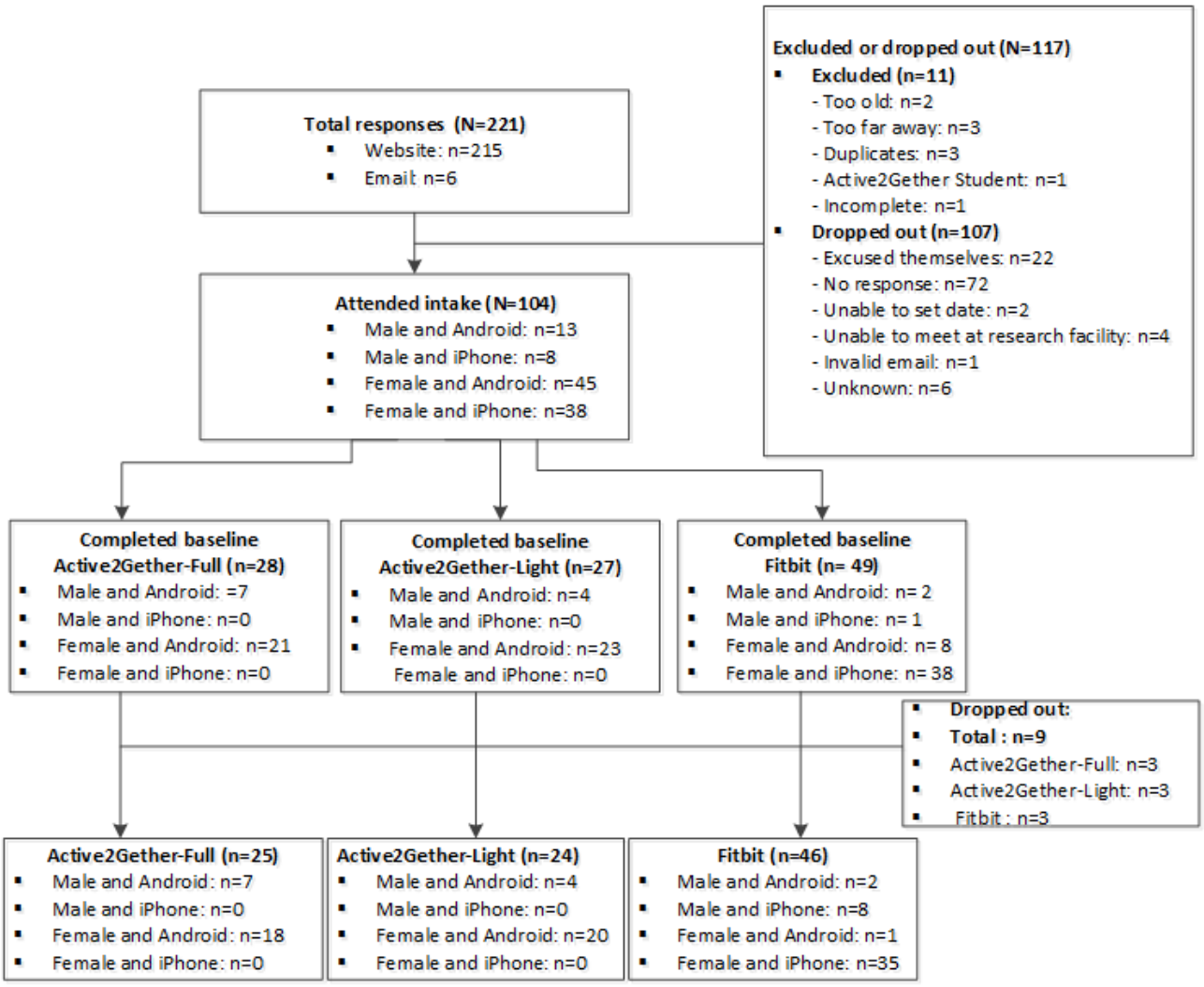
A three-arm quasi-experimental trial was conducted to evaluate the short-term effects of the Active2Gether intervention. The trial included baseline, mid-intervention (6 weeks), and postintervention assessments. Data were collected between March 2016 and October 2016. The trial was registered (Dutch Trial Registry registration number NTR5630), and the project protocol was approved by the ethics committee of the VU Medical Center, Amsterdam. All participants provided written informed consent. The development of the Active2Gether intervention and evaluation plan are described in more detail in an earlier publication [19].

Participants

Young adults were recruited by flyers, posters, social media, personal contacts, and snowball strategies. The majority of the participants were recruited through social media (48.4%, 42/104), other participants (23.1%, 24/104), and flyers and advertisement (11.5%, 12/104) in the regions of Amsterdam, Leiden, and Utrecht in the Netherlands.

Participants registered for the trial through the Active2Gether website by completing a Web form asking information about gender, age, and type of smartphone they owned (ie, Android [Google Inc] or iOS [Apple Inc]). Regarding eligibility criteria, participants were considered eligible for the study if they were (1) aged 18-30 years at the time of registration, (2) in possession of a suitable smartphone running on Android or iOS, (3) apparently healthy, (4) Dutch speaking, and (5) signed the informed consent form. Participants were excluded if they were unable to visit the research facilities for the intake procedure. Figure 1 shows a flow diagram that outlines the reasons for exclusion or withdrawing from the study.

Figure 1. Flow diagram of the participants that were excluded or dropped out.



Group Allocation

Stratified group allocation was applied, stratified by type of smartphone and gender. As the Active2Gether app only runs on Android, iPhone users were automatically assigned to the Fitbit condition, whereas Android phone users were randomly allocated to one of the 2 Active2Gether conditions after stratification by gender. The aim was to divide men and women with an Android phone equally over the 2 Active2Gether conditions and to allocate friends to the same condition. This was done by applying a 1:1 ratio to the order of registration. As a result, one Android user was allocated to the Fitbit condition. Randomization of Android users after gender stratification was performed before the participants visited the research facilities.

Intervention

As described above, the participants were allocated to one of the three conditions: (1) the Active2Gether-*Full* condition, (2) the Active2Gether-*Light* condition, and (3) the *Fitbit* condition.

The participants in the Active2Gether-*Full* condition received an Android app that provided tailored advice aiming to increase weekly levels of MVPA. For this purpose, participants were coached on sports participation, taking the stairs, or active transport. Every week, the participants were asked to choose their coaching domain and set a weekly goal. Participants received a suggestion for a coaching domain and a weekly goal based on their previous behavior, but the final decision was up to the user. The participants received a Fitbit One (Fitbit Inc) activity tracker that could be synchronized to the app and allowed the participants to monitor their PA behavior. The app sent (daily) coaching messages addressing relevant behavioral determinants, that is, self-efficacy, outcome expectations, intentions, satisfaction, barriers, and self-regulation skills. The content of the messages was tailored to the user's behavioral determinants, occupational status, and weather. The participants could receive up to three messages a day. Finally, the app displayed the activity data of the participant, including a graph displaying the activity data of six other participants, preferably friends. The graph with the activity data of others ranked the participants based on their weekly step activity and the user's preferences for social comparison, that is, upward or downward comparison. Detailed information on the development and the technical design of the Active2Gether intervention can be found elsewhere [19,20].

The participants in the Active2Gether-*Light* condition received a slimmed-down version of the Active2Gether-Full app. Similar to the Active2Gether-Full condition, the participants received a Fitbit One tracker that could be synchronized to the app and

allowed the participants to monitor their PA behavior. In addition, activity data of six other participants were shown in the same way as in the Active2Gether-Full condition. However, this variant of the Active2Gether app did not send tailored coaching messages.

The participants in the *Fitbit* condition only received a Fitbit One tracker and the Fitbit app. The Fitbit app is a publicly available—compatible with iPhones and Android phones—and enabled participants to monitor their step activity and set activity goals, that is, goals for the number of steps and flights of stairs [21]. Participants did not receive weekly emails (with a weekly summary of the progress and congratulations on earning badges) that Fitbit sends to its users.

Procedure

A total of three rounds of assessments were conducted: at baseline, at 6-week follow-up (mid-trial), and after completion of the 12-week intervention period. For the majority of the participants, the postintervention measurement was delayed because of absence during the summer holidays. Participants completed a Web-based questionnaire at all points and wore an ActiGraph accelerometer at baseline and postintervention follow-up, providing objective measurements on the levels of PA.

After registering through the Active2Gether website, participants received an email providing detailed information about the study. Participants were asked to visit the research facilities once for an intake of about 1 hour. During the intake, participants again received detailed information about the study, and they signed an informed consent form, completed the baseline survey, installed the app(s) that were needed, and received a Fitbit One tracker. To complete the baseline measurements, participants were asked to wear an ActiGraph accelerometer for 1 week to objectively assess their baseline PA levels. During that week, no coaching messages were sent. After 6 weeks, participants received an automatically generated email inviting them to complete the online follow-up questionnaire. At the end of the study, after 12 weeks, participants were asked to complete the final online questionnaire (the link was automatically sent after 12 weeks) and to wear the ActiGraph accelerometer for another week. The participants did not have to visit the research facilities for the 6-week and postintervention follow-up assessments: After 6 weeks, the participants received an email with a link to the 6-week follow-up questionnaire; and after 12 weeks, participants received an email with a link to the postintervention follow-up questionnaire and were asked to briefly meet one of the researchers in Amsterdam or Utrecht for handing over the ActiGraph and Fitbit devices. Participants who were not able to meet the researchers in person returned the ActiGraph and Fitbit by mail.

Participants ($N_{baseline}$=13 [Active2Gether-Full=2, Active2Gether-Light=2, and Fitbit=9; mean delay of 7.5 days after end of previous measurement] and $N_{postintervention}$=14 [Active2Gether-Full=0, Active2Gether-Light=3, and Fitbi*t* =11; mean delay of 24.4 days]) with insufficient ActiGraph data were asked to wear the accelerometer for another week. After completing the postintervention follow-up assessment and returning the devices, the participants received a voucher of €20 as an incentive for participating and an additional €5 for each participant they brought into the study, ranging from 0 to 15 additional euros.

Measurements

Physical Activity

PA was assessed using 2 different assessment methods. The ActiGraph accelerometer was used to objectively measure the levels of PA to assess intervention effects. The Fitbit One also assesses PA objectively and was primarily used to allow participants to (self-)monitor their PA behavior, but the data were also used to explore possible intervention effects and to examine the levels of engagement.

Baseline and postintervention follow-up measurements were conducted using the ActiGraph GT3X+ (N=8) and ActiGraph wGT3XBT (N=32; ActiGraph Inc), and data were downloaded with the software ActiLife version 6.10.4. The ActiGraph GT3X has moderate validity and high reliability and is commonly used to assess PA in daily life [22-24]. The ActiGraph is a triaxial accelerometer that can convert accelerations to step counts. The sampling rate was set at 100 Hz, and afterward, data were aggregated to 1-min epochs. Participants were instructed to wear the accelerometer on the right hip using an elastic belt for 7 consecutive days during waking hours. Furthermore, they were instructed to remove the accelerometer during water activities and sleep. The accelerometer was set up with the specific information—gender, age, height, and weight—of the participant. Participants received a daily email containing a link to an online form asking to fill in the wear time of the day before.

Choi's definitions and the *physical activity* R package were used to identify nonwear time (eg, periods of consecutive strings of 0s for at least 90 min; the time window for detecting and handling artifactual movement was set the default at 2 min). Interruptions up to 100 counts per minute within the string of 0s were filtered out [25].

Troiano's definitions [26] were used to calculate the time spent per activity level using data from the three axes—vector magnitude score—of the ActiGraph; sedentary (<100 counts per minute), light (100-2019 counts per minute), moderate (2020-5998 counts per minute), vigorous (≥5999 counts per minute), and moderate-to-vigorous (≥2020 counts per minute) physical activities. To adjust for wear time, weekly minutes of MVPA—the sum of all minutes spent in MVPA during the assessment week—was divided by wear time, resulting in an average number of MVPA per day during the assessment week.

Participants were asked to wear a Fitbit One during 12 weeks to (self-)monitor their PA behavior. The Fitbit One (Fitbit Inc, San Francisco, California) tracker is a lightweight triaxial accelerometer with a built-in altitude monitor [21]. The Fitbit One assesses the step activity, active minutes, number of floors ascended, distance walked, and number of calories burned. The Fitbit One can be considered a valid device to assess daily step activity and step activity by using smaller time epochs and thus can be used for real-time minute-by-minute self-monitoring,

although an overestimation of 677 steps per day by the Fitbit should be taken into account [27-30]. As there is no algorithm to define nonwear time for the Fitbit data, daily steps less than 1000 were treated as nonwear time [31-33]. Thus, only days with 1000 steps or more were included when Fitbit data were used to assess intervention effects and the levels of engagement.

Behavioral Determinants

Behavioral determinants that were addressed in the intervention were assessed with an online questionnaire at baseline, 6-week follow-up, and postintervention follow-up. Questionnaires that were used to assess the behavioral determinants were mainly based on existing and previously validated questionnaires.

Outcome Expectations

PA outcome expectations were assessed with 6 items using a 4-point Likert scale (1 [*I do not agree at all*] to 4 [*I totally agree*]). The statements captured expected outcome of PA with respect to health, appearance, weight, feeling fit, relaxation, and stress relief [34]. A sum score (range 6-24) was computed for each time point.

Self-Efficacy

Self-efficacy for PA was assessed with 13 items using a 5-point Likert scale (1 [*I know I can't do it*] to 5 [*I am sure I can do it*]). The questionnaire was developed by Sallis et al [35] and translated into Dutch and used by Van Sluijs et al [36]. A sum score (range 13-65) was computed for each time point.

Barriers

Barriers for sports participation (N=12), active transport (N=7), and taking the stairs (N=4) were assessed using a 5-point Likert scale (1 [*never*] to 5 [*Very often*]) [34,37]. The list of barriers that was assessed was based on an existing questionnaire and previous focus group discussions with the target population [38]. A sum score was computed, summing the mean values of the three types of barriers—barriers for sports participation, active transport, and taking the stairs—(range 3-15) for each time point.

Intention

Intentions were assessed with three items using a 5-point Likert scale (1 [*very certainly not*] to 5 [*very certainly yes*]). Questions assessed the intentions to be physically active within the next week/month/6 months [34,37]. For the analysis, intentions to be physically active within the next month and the next 6 months were used.

Social Norm

Injunctive and descriptive social norms were assessed, where injunctive norms refer to the perceptions of what others think you are supposed to do, and descriptive norms refer to the perceptions of what others do [39]. Injunctive social norm was assessed with three items stated as "My sibling(s)/fellow students/friends think that I should be sufficiently physically active." A 6-point Likert scale (1 [*I do not agree at all*] to 5 [*I totally agree*] and 6 [*not applicable*]) was used, and *not applicable* was coded as missing variables. A sum score (range 3-15) was computed for each time point.

Descriptive social norm was assessed with four items stated as "How often are your friends/fellow students/parents/siblings physically active?" A 6-point Likert scale (1 [*never*] to 5 [*very often*] and 6 [*not applicable*]) was used, and *not applicable* was coded as missing variables. A sum score (range 4-20) was computed for each time point.

Self-Regulation Skills

Self-regulation skills were assessed with seven items assessing exercise planning and scheduling and how the user keeps track of his/her activity and self-determined goals [40]. A 5-point Likert scale (1 [*never*] to 5 [*very often*]) was used. A sum score (range 7-35) was computed for each time point.

Satisfaction

Satisfaction was assessed using one item stating, "How satisfied are you with respect to how physically active you are on a scale from 0 to 10?"

Long-Term Goals

Satisfaction was assessed using one item stating, "How motivated are you to be (more) physically active on a scale from 0 to 10?"

Engagement and Usability

Engagement with the intervention was assessed using a number of coaching messages—only for the Active2Gether-Full condition—and Fitbit usage. As all participants were asked to wear the Fitbit during the intervention, we used the number of valid days the Fitbit was worn during 12 weeks (ie, 84 days).

A purpose-designed feedback questionnaire was used to examine the usability of the intervention. Users' previous experiences with apps or activity trackers, self-reported usage of the Active2Gether app, and several aspects of user satisfaction—including encountering technical problems with the Active2Gether or Fitbit app—were assessed at postintervention follow-up.

Previous experiences with apps were assessed with a single question ("Did you have previous experience with PA apps prior to the current study?") with three response options ("Yes, I use a PA app"; "Yes, I used to use a PA app, but now I don't"; and "No, I have no previous experience with PA apps"). For the analyses, the variable was dichotomized ("Yes, have previous experiences" and "No, I don't have any previous experience").

Previous experiences with activity trackers were assessed with a single question ("Did you have previous experience with activity trackers prior to the current study?") with three response options ("'Yes, I use an activity tracker"; "Yes, I used to make use of an activity tracker, but now I don't"; and "No, I have no previous experience with activity trackers"). For the analyses, the variable was dichotomized ("Yes, have previous experiences" and "No, I don't have any previous experience").

Usage of the Active2Gether app was assessed for the 2 Active2Gether conditions using a single question ("How often did you use the Active2Gether app?"), with an 8-point Likert scale (1 [*multiple times per day*] to 8 [*never*]). For the analyses, the variable was dichotomized (*multiple times per day*, *once*

per day, and *multiple times per week* were coded as 1, whereas the options *once per week*, *multiple times per month*, *once per month*, *rarely*, and *never* were coded as 0).

Participants were asked how satisfied they were with the app they used (either 1 of the 2 versions of the Active2Gether app or the Fitbit app). A 7-point Likert scale was used to assess the level of agreement with the statement, "I am pleased with the app" (1 [*I do not agree at all*] to 7 [*I completely agree*]). For the analyses, the variable was categorized (*I do not agree at all* and *disagree* were coded as 1, *neutral* was coded as 2, and *I somewhat agree* and *I completely agree* were coded as 3).

Participants were asked whether they experienced technical problems with the app they used by asking the level of agreement with the statement, "I experienced technical problems with the app" on a 7-point Likert scale (1 [*I do not agree at all*] to 7 [*I completely agree*]). For the analyses, the variable was categorized (*I do not agree at all* and *disagree* were coded as 1, *neutral* was coded as 2, and *I somewhat agree* and *I completely agree* were coded as 3).

Demographics

Information on age, gender, and type of smartphone (iPhone/Android phone) was collected at registration through the Active2Gether website. Data on height (self-report), weight (self-report), and student status (yes/no) were requested at baseline during the intake session. Height and weight were used to calculate the body mass index (BMI).

Sample Size

We used the G*Power software [41] and calculated the required sample size for a design with three groups (*F* test and analysis of variance [ANOVA]). As input, we used an effect size of 0.25, which is considered a medium effect size, an alpha of 5%, and a power of 80%. On the basis of these considerations, approximately 53 participants per group were required. Therefore, we aimed to include 159-200 participants, taking into account dropout and missing data.

Statistical Analyses

Intervention Effects

Primary outcome variables were levels of PA at postintervention follow-up (ie, mean minutes of MVPA per day and mean steps per day), as measured by the ActiGraph. Secondary outcome variables were scores of behavioral determinants (ie, outcome expectations, self-efficacy, barriers, social norm, intentions, self-regulation skills, satisfaction, and long-term goals) at postintervention follow-up. Descriptive analyses were conducted for all variables—means and SDs (continuous variables) or frequencies and proportions (categorical variables). Chi-square tests (categorical variables) and one-way ANOVAs (continuous variables) were conducted to test for differences between groups at baseline.

For the analyses, the two intervention groups—the Active2Gether-Full and Active2Gether-Light conditions—were compared against a publicly available app, that is, the Fitbit app. This comparison will provide information on the effectiveness of the Active2Gether conditions compared with an existing *usual care* app. In addition, this design gives us the opportunity to compare the two Active2Gether conditions. As the difference between these two conditions is the inclusion or absence of the coaching, this comparison will provide information on the efficacy of the coaching part of the Active2Gether app. As participants with an iPhone were automatically assigned to the Fitbit condition and could not be randomly assigned to one of the two Active2Gether conditions, additional analyses were conducted to test for differences in intervention effects between the two Active2Gether conditions only. Furthermore, there were large differences in the duration of time between the start of the intervention and the postintervention follow-up measurements (ie, between 12 and 24 weeks). Thus, to examine the intervention effects at exactly 12-week follow-up, additional analyses were conducted using the Fitbit data (ie, step activity) instead of the ActiGraph data and the Fitbit data from the baseline week and 12-week follow-up were used.

For all analyses, regression techniques (linear and logistic) were used to examine the intervention effects. For this purpose, the assumptions were checked, and when necessary, variables were dichotomized.

In a first step, analyses were conducted to examine the efficacy of the intervention to increase weekly minutes of MVPA and weekly number of steps at postintervention follow-up. Associations were analyzed using linear regression analyses with the intervention conditions entered as dummy variables—the Fitbit condition was coded as the reference group—adjusting for baseline PA (ie, minutes of MVPA or number of steps) and time between baseline and postintervention follow-up. In a second step, analyses were conducted to examine the efficacy of the intervention to improve relevant behavioral determinants at postintervention follow-up. Linear regression analyses with the different determinants as dependent variables, while adjusting for baseline scores and time between baseline and postintervention measurements, were used. For dichotomous determinant variables (intentions and satisfaction), logistic regression analyses were conducted. These variables were dichotomized, as the residuals from the linear regression analyses when using the continuous variables were not normally distributed. All analyses were checked for outliers (≥3 SDs of the residuals), and when necessary, sensitivity analyses were conducted without outliers. The final analyses were conducted without outliers. A total of four models were run for each outcome variable (ie, levels of PA and scores of behavioral determinants): (0) a minimal adjusted model (only adjusted for baseline values and time between baseline and postintervention measurements), (1) a model additionally adjusted for BMI, (2) a model additionally adjusted for student status, (3) BMI models—(a) a model additionally adjusted for BMI and student status (for the intervention effects on PA only) and (b) a model adjusted for BMI and meeting the PA guidelines (for the intervention effects on behavioral determinants only). Owing to the small sample size, no further potential confounders were added to the final model.

Levels of Engagement and Usability

Exploratory analyses were conducted to evaluate how the users rated various aspects of the app they had used.

Descriptive statistics were provided for previous experiences with apps or activity trackers, usage of the Active2Gether app, satisfaction with the Active2Gether or Fitbit app, and encountering technical problems. Chi-square tests were used to examine differences in these variables between the groups.

Nonresponse Analyses

Nonresponse analyses were conducted to examine differences among those who had no PA data (assessed with the ActiGraph) for baseline and postintervention follow-up, those who only had baseline PA data, and those who had valid data at both baseline and postintervention follow-up. No significant differences between the groups were found with respect to age, BMI, student status, and all secondary outcome variables.

All analyses were conducted in STATA 14 (StataCorp, College Station, Texas).

Results

Baseline Characteristics

The baseline characteristics have been described in Table 1. A total of 104 participants (83 women) attended the intake session and completed the baseline questionnaire, and 98 participants had valid PA data for the baseline week. Figure 1 shows a flow diagram of the participants who dropped out, including reasons for dropping out. On average, participants were aged 23.4 years and had a BMI of 22.8 kg/m^2; 69.2% (72/104) were students, 79.8% (83/104) were women, and 31.7% (33/104) had previous experiences with PA apps. At baseline, participants were, on average, moderately to vigorously active for 267.7 min per week. No significant differences between the Active2Gether conditions and Fitbit condition were found for the baseline characteristics.

Table 1. Baseline characteristics of participants in the Active2Gether-Full, Active2Gether-Light, and Fitbit conditions.

Characteristics	Overall	Active2Gether-Full	Active2Gether-Light	Fitbit	*P* value[a]
Participants, n (%)	104 (100)	28 (26.9)	27 (26.0)	49 (47.1)	N/A[b]
Female, n (%)	83 (79.8)	21 (75.0)	23 (85.2)	39 (79.6)	.96
Age (years), mean (SD)	23.4 (3.0)	23.7 (3.2)	22.8 (2.8)	23.5 (3.1)	.46
Body mass index (kg/m^2), mean (SD)	22.8 (3.4)	23.8 (3.7)	22.6 (3.3)	22.3 (3.3)	.77
Student, n (%)	72 (69.2)	17 (60.7)	22 (81.5)	33 (67.3)	.69
Android phone, n (%)	57 (54.8)	28 (100)	27 (100)	3 (6.1)	<.001
Previous experience with physical activity apps (yes), n (%)	33 (31.7)	8 (28.6)	7 (25.9)	18 (36.7)	.46
Minutes of moderate-to-vigorous physical activity per week[c], mean (SD)	267.7 (163.8)	234.9 (107.4)	258.8 (202.2)	293.1 (168.5)	.15
Step count using ActiGraph[c], mean (SD)	8177.6 (3272.0)	7519.3 (2884.3)	7847.8 (3546.6)	8770.4 (3307.5)	.10
Step count using Fitbit[c], mean (SD)	9008.9 (3722.8)	8179.9 (2415.9)	9190.7 (4610.6)	9535.5 (3878.0)	.30
Wear time for ActiGraph (minutes/day), mean (SD)	861.9 (61.3)	861.3 (50.5)	865.0 (58.8)	860.5 (69.6)	.84
Time between baseline and postintervention follow-up (days), mean (SD)[d]	103.4 (19.5)	106.5 (23.9)	109.0 (21.6)	97.7 (12.6)	.56

[a]Pearson Chi-square test with *P* value for frequencies and one-way analysis of variance for means for differences between Active2Gether-Full and Active2Gether-Light and Fitbit conditions.

[b]N/A: not applicable

[c]Baseline minutes of moderate-to-vigorous physical activity; number of steps and wear time were summed for the week and divided by the number of valid days to adjust for wear time.

[d]Intervention duration is the number of days between the start of the baseline assessment (day 1) and the last day of the postintervention follow-up assessment.

Intervention Effects on Physical Activity

PA data (assessed with the ActiGraph) for baseline and postintervention follow-up were available for 88 participants ($N_{Active2Gether-Full}$=25, $N_{Active2Gether-Light}$=25, and N_{Fitbit}=38). Table 2 shows the means and SDs for the outcome measurements for baseline and postintervention follow-up.

All results of the intervention effect on PA are discussed based on model 3a (adjustment for baseline PA, intervention duration, BMI, and student status).

Regression analyses showed no significant intervention effects of the Active2Gether-Full and Active2Gether-Light conditions on levels of PA (minutes of MVPA and steps) compared with the Fitbit condition. Effect sizes were small for average minutes of MVPA per day and smallest for the Active2Gether-Full

condition (B=1.2; 95% CI −8.7 to 11.1). Thus, the Active2Gether-Full condition reported, on average, 1.2 min of MVPA per day more compared with the Fitbit condition. Table 3 shows the results of the regression analyses.

Additional regression analyses using the ActiGraph data showed a group difference of 2.8 min (95% CI −12.2 to 6.7) of MVPA per day between the Active2Gether-Full and Active2Gether-Light conditions in favor of the Active2Gether-Light condition (Multimedia Appendix 1). The same regression analyses, but using the Fitbit data at baseline and 12-week follow-up instead, showed a group difference of 533.51 steps per day (95% CI −2334.4 to 1267.4) between the Active2Gether-Full and Active2Gether-Light conditions in favor of the Active2Gether-Light condition (Multimedia Appendix 2).

Table 2. Characteristics at baseline (T1), 6-week follow-up (T2), and postintervention follow-up (T3).

Characteristics	Active2Gether-Full, mean (SD)			Active2Gether-Light, mean (SD)			Fitbit, mean (SD)		
	T1	T2	T3	T1	T2	T3	T1	T2	T3
Physical activity measures									
Minutes of moderate-to-vigorous physical activity/day ActiGraph[a]	35.2 (15.3)	N/A[b]	39.7 (17.5)	38.6 (28.1)	N/A	42.1 (20.5)	43.5 (23.5)	N/A	44.8 (29.5)
Steps/day ActiGraph[a]	7519.3 (2884.3)	N/A	7681.5 (2463.8)	7847.8 (3546.6)	N/A	8366.0 (2637.0)	8770.4 (3307.5)	N/A	9367.6 (4537.3)
Steps/day Fitbit[c]	8179.9 (2415.9)	N/A	9392.8 (3275.7)	9190.7 (4610.6)	N/A	9567.1 (3152.2)	9535.5 (3878.0)	N/A	9968.1 (4506.2)
Behavioral determinants (range of sum score)									
Self-efficacy (13-65)	42.4 (7.6)	41.8 (7.3)	42.8 (7.6)	42.5 (8.2)	40.9 (9.4)	42.0 (8.3)	44.5 (6.2)	45.4 (7.8)	44.7 (7.4)
Outcome expectation (6-24)	20.3 (2.3)	19.7 (3.1)	19.8 (3.1)	20.4 (2.4)	19.3 (3.1)	19.5 (2.8)	20.4 (2.4)	20.5 (2.6)	19.8 (2.7)
Social norm, injunctive (3-15)	10.7 (2.3)	10.9 (3.0)	10.3 (3.0)	9.9 (2.7)	10.2 (2.4)	9.7 (3.6)	9.9 (2.6)	9.8 (3.0)	10.8 (2.8)
Social norm, descriptive (4-20)	14.6 (2.7)	14.9 (2.3)	14.8 (2.7)	13.4 (2.8)	13.2 (3.5)	13.2 (2.9)	13.9 (2.6)	13.8 (2.5)	13.2 (2.7)
Intention in 1 month (1-5)	4.1 (0.7)	3.6 (1.0)	3.5 (1.0)	3.7 (1.1)	3.1 (1.3)	3.4 (1.2)	3.9 (0.8)	3.4 (1.0)	3.3 (1.0)
Intention in 6 months (1-5)	4.4 (0.8)	3.8 (0.8)	3.9 (0.9)	4.1 (0.9)	3.7 (1.1)	3.7 (0.9)	4.2 (0.7)	3.6 (0.9)	3.5 (1.0)
Barriers (3-15)	8.4 (1.7)	8.3 (1.9)	8.2 (1.9)	7.9 (1.5)	7.8 (1.4)	7.9 (1.5)	7.7 (1.7)	7.7 (1.9)	7.7 (1.7)
Self-regulation skills (5-25)	18.8 (4.3)	19.4 (3.2)	19.3 (3.8)	19.0 (5.5)	20.1 (5.5)	19.3 (5.0)	20.9 (4.6)	21.0 (4.4)	20.8 (4.4)
Satisfaction (0-10)	5.5 (1.8)	6.0 (1.7)	5.9 (2.0)	5.5 (1.8)	5.5 (1.8)	5.7 (1.7)	6.0 (1.7)	6.2 (1.9)	6.3 (1.9)

[a]Minutes of moderate-to-vigorous physical activity and number of steps per day assessed with ActiGraph.

[b]Not applicable.

[c]Number of steps per day assessed with Fitbit.

Table 3. Results of the regression analyses to evaluate the intervention effects of the Active2Gether-Full and Active2Gether-Light condition on levels of physical activity at postintervention follow-up compared with the Fitbit condition.

Parameter[a] and condition	Model 0[b]		Model 1[c]: BMI[d]		Model 2[e]: student		Model 3a[f]: BMI-student	
	B	95% CI	B	95% CI	B	95% CI	B	95% CI
Average minutes of moderate-to-vigorous physical activity per day								
Fitbit	Reference	Reference	Reference	Reference	Reference	Reference	Reference	Reference
Active2Gether-Full	0.82	−8.82 to 10.46	1.16	−8.73 to 11.04	0.92	−8.70 to 10.54	1.20	−8.66 to 11.07
Active2Gether-Light	1.99	−7.56 to 11.55	2.14	−7.51 to 11.78	3.00	−6.68 to 12.67	3.10	−6.66 to 12.87
Average number of steps per day								
Fitbit	Reference	Reference	Reference	Reference	Reference	Reference	Reference	Reference
Active2Gether-Full	−577.42	−1913.68 to 758.85	−387.88	−1742.21 to 966.44	−575.76	−1918.33 to 766.82	−388.95	−1750.20 to 972.31
Active2Gether-Light	−128.54	−1447.23 to 1190.16	−45.56	−1361.36 to 1270.24	−70.37	−1413.70 to 1272.96	5.21	−1334.82 to 1345.25

[a]Linear regression analyses are presented with regression coefficient (B) and 95% CI, and all analyses were adjusted for levels of physical activity at baseline and time between baseline and postintervention follow-up.

[b]Model 0: $y=B_0+B_1\times$physical activity at postintervention$+B_2\times$physical activity at baseline$+B_3\times$time until postintervention follow-up (days).

[c]Model 1: Model 0$+B_4\times$BMI (kg/m^2).

[d]BMI: body mass index.

[e]Model 2: Model 0$+B_4\times$student (yes/no).

[f]Model 3: Model 0$+B_4\times$BMI (kg/m^2)$+B_5\times$student (yes/no).

Intervention Effects on Behavioral Determinants

Survey data for baseline and 12-week follow-up were available for 92 participants ($N_{Active2Gether-Full}$=24, $N_{Active2Gether-Light}$=23, and N_{Fitbit}=45). Table 2 shows the mean and SD for behavioral determinant scores for baseline, 6-week follow-up, and postintervention follow-up.

Linear and logistic regression analyses for the intervention effects on the sum score of the behavioral determinants at postintervention follow-up showed no significant intervention effects of the Active2Gether-Full and Active2Gether-Light conditions compared with the Fitbit condition. For all analyses, small effect sizes were found, except for intentions to be physically active within 6 months (Model 3b: odds ratio $[OR]_{Active2Gether-Full}$=2.13, 95% CI 0.59-7.75; $OR_{Active2Gether-Light}$ 3.57, 95% CI 0.93-13.72). Thus, participants in the Active2Gether-Full condition have an OR of 2.13 to have high intentions to be physically active at 6 months compared with the Fitbit condition, whereas participants in the Active2Gether-Light condition have an OR of 3.57. Table 4 shows the results of the regression analyses. Additional analyses showed that participants in the Active2Gether-Full condition have an OR of 0.72 (95% CI 0.15-3.51) to have high intentions to be physically active at 6 months compared with the Active2Gether-Light condition (Multimedia Appendix 3).

Table 4. Results of the linear and logistic regression analyses to evaluate the intervention effects of the Active2Gether-Full and Active2Gether-Light conditions on behavioral determinants at postintervention follow-up compared with the Fitbit condition.

Outcome measurement[a] and condition	Model 0[b]	Model 1[c]: BMI[d]	Model 2[e]: student	Model 3b[f]: BMI-PA
Self-efficacy, B (95% CI)[g]				
Fitbit	Reference	Reference	Reference	Reference
Active2Gether-Full	0.03 (−2.88 to 2.94)	0.74 (−2.15 to 3.63)	0.14 (−2.73 to 3.00)	0.62 (−2.24 to 3.49)
Active2Gether-Light	−1.52 (−4.40 to 1.36)	−1.28 (−4.08 to 1.52)	−0.92 (−3.81 to 1.98)	−1.54 (−4.34 to 1.25)
Outcome expectations, B (95% CI)[g]				
Fitbit	Reference	Reference	Reference	Reference
Active2Gether-Full	0.44 (−0.59 to 1.47)	0.43 (−0.63 to 1.50)	0.40 (−0.61 to 1.41)	0.41 (−0.66 to 1.47)
Active2Gether-Light	0.07 (−0.95 to 1.10)	0.07 (−0.97 to 1.11)	−0.12 (−1.15 to 0.91)	0.02 (−1.02 to 1.07)
Social norm, descriptive, B (95% CI)[g]				
Fitbit	Reference	Reference	Reference	Reference
Active2Gether-Full	1.18 (0.15 to 2.20)	1.11 (0.05 to 2.16)	1.26 (0.24 to 2.29)	1.12 (0.08 to 2.16)
Active2Gether-Light	−0.14 (−1.13 to 0.86)	−0.16 (−1.16 to 0.84)	0.02 (−1.00 to 1.03)	−0.06 (−1.05 to 0.94)
Social norm, injunctive, B (95% CI)[g]				
Fitbit	Reference	Reference	Reference	Reference
Active2Gether-Full	0.11 (−1.64 to 1.85)	0.27 (−1.53 to 2.06)	0.26 (−1.47 to 2.00)	0.03 (−1.73 to 1.80)
Active2Gether-Light	−0.45 (−2.05 to 1.16)	−0.33 (−1.97 to 1.30)	−0.09 (−1.74 to 1.56)	−0.42 (−2.01 to 1.18)
Intention in 1 month, OR (95% CI)[h]				
Fitbit	Reference	Reference	Reference	Reference
Active2Gether-Full	1.01 (0.33 to 3.06)	0.91 (0.29 to 2.85)	1.01 (0.33 to 3.06)	0.92 (0.29 to 2.90)
Active2Gether-Light	1.37 (0.45 to 4.13)	1.32 (−0.43 to 4.02)	1.38 (0.45 to 4.24)	1.39 (0.45 to 4.33)
Intention in 6 months, OR (95% CI)[h]				
Fitbit	Reference	Reference	Reference	Reference
Active2Gether-Full	2.66 (0.77 to 9.23)	2.08 (0.58 to 7.50)	2.66 (0.77 to 9.22)	2.13 (0.59 to 7.75)
Active2Gether-Light	3.28 (0.92 to 11.76)	3.30 (0.88 to 12.38)	3.24 (0.87 to 12.04)	3.57 (0.93 to 13.72)
Barriers, B (95% CI)[g]				
Fitbit	Reference	Reference	Reference	Reference
Active2Gether-Full	−0.01 (−0.60 to 0.58)	−0.20 (−0.77 to 0.37)	0.03 (−0.54 to 0.61)	−0.20 (−0.77 to 0.37)
Active2Gether-Light	0.06 (−0.53 to 0.64)	−0.00 (−0.55 to 0.54)	0.16 (−0.41 to 0.73)	0.00 (−0.56 to 0.56)
Self-regulation skills, B (95% CI)[g]				
Fitbit	Reference	Reference	Reference	Reference
Active2Gether-Full	0.78 (−0.94 to 2.50)	0.80 (−0.96 to 2.56)	0.82 (−0.90 to 2.54)	0.83 (−0.94 to 2.60)
Active2Gether-Light	0.01 (−1.68 to 1.69)	0.02 (−1.69 to 1.72)	0.20 (−1.53 to 1.93)	0.09 (−1.63 to 1.80)
Satisfaction, OR (95% CI)[h]				
Fitbit	Reference	Reference	Reference	Reference
Active2Gether-Full	0.69 (0.19 to 2.52)	0.88 (0.23 to 3.40)	0.81 (0.22 to 3.03)	0.88 (0.23 to 3.42)
Active2Gether-Light	0.49 (0.14 to 1.75)	0.51 (0.14 to 1.87)	0.65 (0.18 to 2.30)	0.50 (0.13 to 1.85)

[a]All analyses were adjusted for baseline scores of the determinant and time between baseline and postintervention follow-up.

[b]Model 0: $y=B_0+B_1\times$determinant at postintervention$+B_2\times$determinant at baseline$+B_3\times$time until postintervention follow-up (days).

[c]Model 1: Model 0$+B_4\times$BMI (kg/m^2).

[d]BMI: body mass index.

[e]Model 2: Model 0+B_4×student (yes/no).

[f]Model 3: Model 0+B_4×student (yes/no)+B_5×meeting physical activity guidelines at baseline (yes/no).

[g]Linear regression analyses are presented with regression coefficient (B; 95% CI).

[h]Logistic regression analyses with odds ratio (OR; 95% CI).

Levels of Engagement and Usability

For the Active2Gether-Full condition, 1429 messages were derived, 1381 messages (ie, 97% (1381/1429) of the messages) were sent, and 1324 messages were successfully received. For 5 of the 24 users, a derived message was not sent at some point, which could indicate that the app was removed before the end of the study. For nine users, a sent message was not received by phone, and one user did not receive any messages at all.

For participants in the Active2Gether-Full and Fitbit conditions, a decrease was observed (from day 1 to day 84 of the intervention) in the number of participants who recorded valid step activity (>1000 steps per day) assessed with the Fitbit. At the 6-week follow-up (ie, after 42 days), 68% (19/28) of the Active2Gether-Full condition, 70% (19/27) of the Active2Gether-Light condition, and 51% (25/49) of the Fitbit condition were still using the Fitbit. At 12-week follow-up (ie, after 84 days), 50% (14/28) of the Active2Gether-Full condition, 74% of the Active2Gether-Light condition, and 38% (19/49) of the Fitbit condition were still using the Fitbit. Figure 2 shows the number of participants who logged step activity per intervention condition, and a steeper decrease was seen for the Fitbit condition relative to the 2 Active2Gether conditions.

The majority (58% (14/28) and 82% (18/22)) of the participants in the Active2Gether-Full and Active2Gether-Light conditions, respectively, reported that they used the app at least several times per week or more frequently (Figure 3); for the Fitbit condition, this value was 73% (33/45). Significant differences were found in how satisfied the participants were with the app they used during the intervention. The majority of participants in the two Active2Gether conditions were not satisfied with the app (Active2Gether-Full=67% (16/24) and Active2Gether-Light=64% (14/22)), whereas 22% of the participants in the Fitbit condition were not satisfied with the Fitbit app. More participants in the two Active2Gether conditions (Active2Gether-Full=54% (13/24) and Active2Gether-Light=45%) experienced technical problems with the app compared with the Fitbit condition (23% (10/44)). Table 5 shows the scores on the user evaluations.

A more detailed evaluation of the user experience of the Active2Gether intervention can be found elsewhere [42].

Figure 2. Fitbit usage in the participants who used the Fitbit throughout the intervention period of 12 weeks. This figure shows the proportions of participants who recorded step activity (>1000 steps per day) assessed with the Fitbit for the three conditions: Active2Gether-Full (A2G-Full), Active2Gether-Light (A2G-Light), and Fitbit.

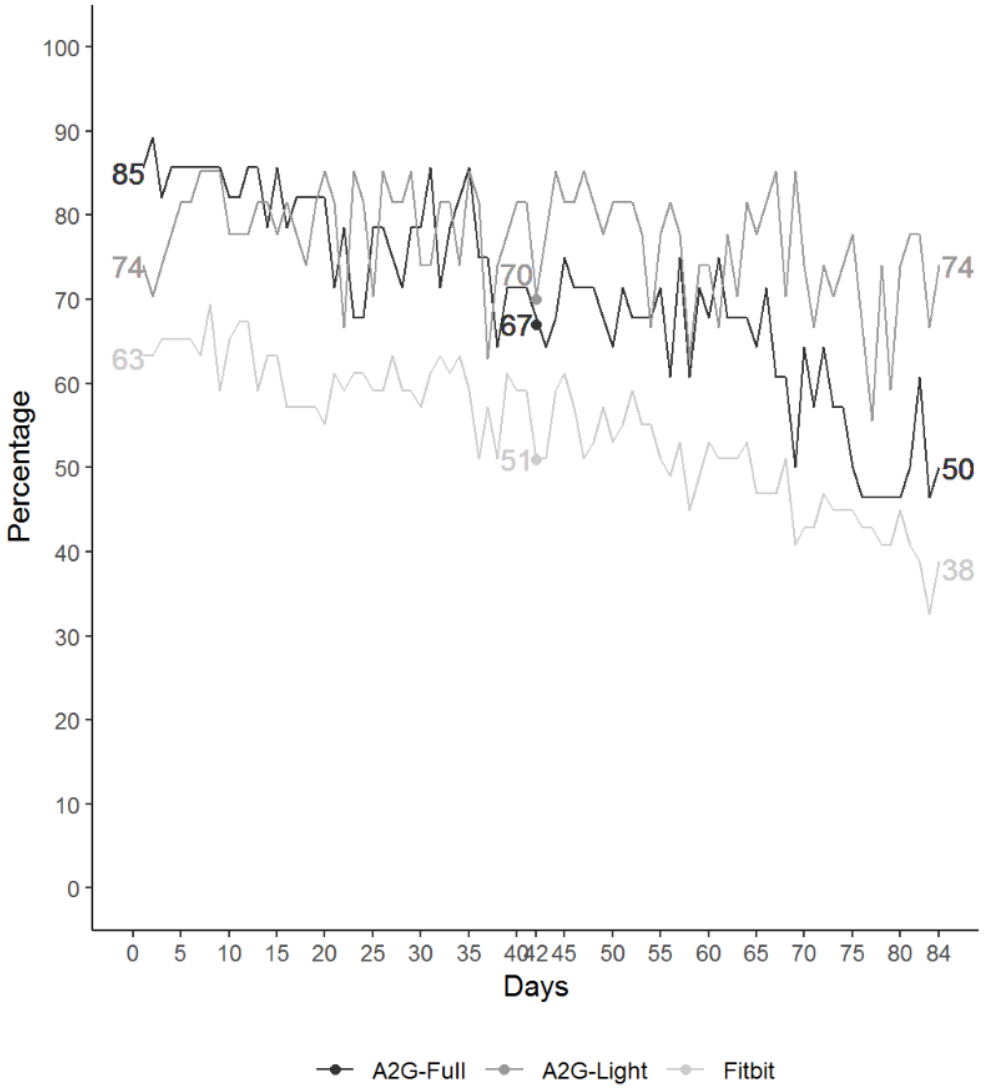


Figure 3. Frequency plot for app usage during the intervention period per intervention group. A2G: Active2Gether. App usage scores: 1, never; 2, rarely; 3, once a month; 4, several times per month; 5, once per week; 6, several times per week; 7, once a day; and 8, several times per day.

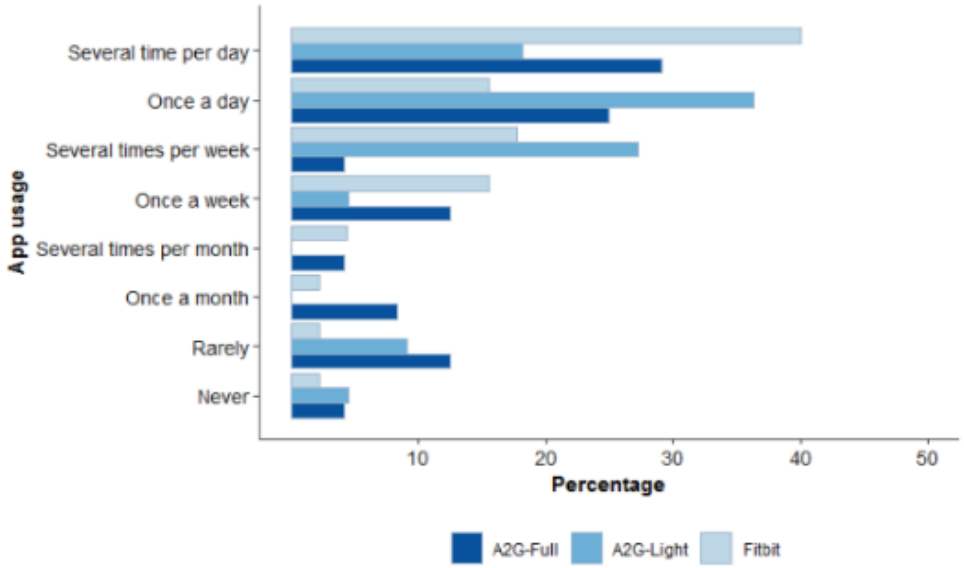


Table 5. User engagement and usability of the Active2Gether-Full, Active2Gether-Light, and Fitbit apps assessed at the postintervention follow-up.

Measurement of engagement and usability	Overall	Active2Gether-Full	Active2Gether-Light	Fitbit	*P* value[a]
Fitbit usage, median percentage of days used[b] (range)	88 (0-100)	86(10-100)	95 (4-100)	84 (0-100)	.13
Previous experience with physical activity apps[c] , n (%)					
Yes	33 (36)	8 (33)	7 (32)	18 (40)	.47
Previous experience with activity trackers[c], n (%)					
Yes	17 (19)	6 (25)	4 (18)	7 (16)	.45
Satisfied with the Active2Gether or Fitbit app[d], n (%)					
Yes	36 (40)	5 (21)	5 (23)	26 (58)	<.001
Neutral	15 (16)	3 (13)	3 (14)	9 (20)	<.001
No	40 (44)	16 (67)	14 (64)	10 (22)	<.001
Experienced technical problems with the app[d], n (%)					
Yes	33 (37)	13 (54)	10 (45)	10 (23)	.009
Neutral	3 (3)	0 (0)	0 (0)	3 (7)	.009
No	54 (60)	11(46)	12 (55)	31 (70)	.009
App usage[e], n (%)					
Often	76 (84)	14 (63)	18 (82)	33 (73)	.69

[a]*P* value is the result of a chi-square test between Active2Gether users (Full and Light version) versus Fitbit users.

[b]Percentage of days used=number of days the Fitbit was used (steps>1000)/84 days×100.

[c]The score was dichotomized: Yes=Yes, I'm currently using one and Yes, in the past and No=No, no experience.

[d]The score was categorized: Yes=agree, somewhat agree, and totally agree; Neutral=neutral; and No=completely disagree, somewhat disagree, and disagree.

[e]The score was dichotomized: rarely=never, rarely, once a month, multiple times per month, and once per week; and often=multiple times per week, once a day, and multiple times per day.

Discussion

Principal Findings

This study aimed to explore whether two versions of the Active2Gether app—a tailored app-based intervention to promote PA—appeared to be more effective in increasing the levels of PA among young adults than an existing self-monitoring app. The secondary aims of the study were to examine and explore whether the intervention was effective in changing the levels of relevant behavioral determinants of PA and how participants used and evaluated the app. No evidence for significant intervention effects on increased PA or more positive determinants of PA were found. Most Active2Gether app users used the app at least several times per week and were not satisfied with the app, and a substantial number of participants experienced technical problems.

This study was originally designed and planned as a randomized controlled trial (RCT) with 159 to 200 participants and a follow-up measurement for all participants at 12 weeks, that is, immediately after the envisioned intervention period. Owing to the practicalities and challenges encountered, the study conducted differed substantially from the original protocol. Despite these explicitly acknowledged suboptimal design and power, we wish to share our results with the scientific community to contribute to the further development of artificial intelligence–supported, individually tailored health behavior promoting interventions and to help avoid publication bias.

First, the number of participants was lower than that envisioned in the study protocol. Despite our efforts for participant recruitment, fewer people than expected were willing to participate because of a lack of interest, a lack of time, and the perceived burden for the participants. Owing to the smaller sample, the statistical power of the results was lower than that according to protocol.

In addition, participants were not assigned to the three conditions based on true randomization. One reason for this is that the two versions of the Active2Gether app (Active2Gether-Full and Active2Gether-Light) could not be made available for iPhone users; therefore, iPhone users were automatically assigned to the Fitbit condition. In addition, the proportion of Android users who registered for the study was lower than expected; therefore, to maintain a balance between the three conditions, they were randomized over the two Active2Gether conditions only, rather than over all three conditions. Therefore, the study would ideally only include Android users, or the Active2Gether intervention should have been made available for iPhones as well.

Third, owing to the difficulties with recruiting participants from the target population, the inclusion of the participants was spread over 3 months. Consequently, some participants were included just at the end of the academic year and the beginning of the summer holidays. As a result, the 12-week follow-up measurements were due in the middle of their summer holiday for the majority of the participants. Therefore, the postintervention measures were delayed, and the time between the baseline and postintervention follow-up varied widely among the participants.

Finally, due to the malfunction of the PA assessment with the ActiGraph, the baseline measurement had to be redone for a number of participants. Therefore, the baseline measurement of PA for some participants took place during the intervention, rather than at the start.

Despite these major violations of the original study protocol, we want to discuss the results found in more detail, but this discussion should, of course, be read and interpreted while keeping these differences between the study designed and the one conducted in mind.

No statistically significant effects were found, and the effect sizes were small: Compared with the Active2Gether-Light condition, the Active2Gether-Full condition measured, on average, 2.76 min of MVPA less per day, accounting to 19.32 min of MVPA per week. In addition, based on Fitbit registrations, the Active2Gether-Light users took 533.51 more steps per day. Earlier evaluations of app-based interventions also reported mixed results, but the majority of the studies reported significant intervention effects relative to the control group. Those studies reported changes between −15.5% and 34.8% in PA in the intervention groups, of whom the majority evaluated the intervention effects at 8-week follow-up [43-46]. However, it should be noted that these studies differ with respect how they assess PA: One study used the ActiGraph [43], a pedometer to assess step activity [44], a validated questionnaire [40,43], and a built-in smartphone accelerometer to assess PA with an unknown validity [45]. Owing to the different assessment methods used in the different studies, it is difficult to compare the results. Furthermore, the participants in this study were already active and, on average, met the guidelines of 30 min MVPA per day, whereas the baseline PA levels in other studies were much lower. As it might be difficult to increase weekly levels of MVPA in an already active group, this might partially explain the lack of intervention effect.

The secondary aim of this study was to examine whether the Active2Gether-Full intervention effectively changes scores in behavioral determinants that were included in the theoretical framework. No significant intervention effects were seen in changes in scores, indicating that sending the tailored coaching messages did not lead to changes in the behavioral determinants. A meta-analysis reported significant higher effect sizes for self-efficacy and for PA in interventions for adults with obesity when prompt self-monitoring of behavioral outcome and plan social support/social change were included [47]. However, little is known about the effects of behavior change techniques on behavioral determinants for app-based interventions. Thus far, the only study examining the effects of the Fitbit app on social cognitive behavioral determinants showed no significant changes in behavioral determinants after 12 weeks [33]. Other studies using apps to change PA used of self-monitoring features, motivational messages, and prompts and offered challenges to increase the levels of PA as well but did not examine changes in behavioral determinants [43-45]. Therefore, it remains unclear whether these app-based interventions successfully changed the underlying and relevant behavioral determinants. Therefore, future research is needed to examine whether motivational messages, prompts, challenges, and social support features can be used to change behavioral determinants. For this, a more

iterative assessment of the determinants during the intervention is needed, as performed in the Active2Gether intervention. Consequently, this knowledge will contribute to further tailoring and personalizing app-based interventions to increase levels of PA.

Although 96 participants (96/104, 92.3%) participated in the postintervention follow-up assessment, lower rates of engagement with the Fitbit were seen after 12 weeks, especially for the Fitbit condition. However, the overall engagement with the Fitbit was high (median 88% of the days). This is in line with the self-reported app usage: Most participants reported that they used the appointed app several times per week or more throughout the intervention. However, about only 21.2% (22/104) and 23.1% (24/104) of the participants in the Active2Gether-Full and Active2Gether-Light condition, respectively, were satisfied with the app, whereas 57.7% (60/104) of the participants were satisfied with the Fitbit app in the control condition. Those low scores might be related to the high rates of technical problems that the participants in the Active2Gether conditions encountered and the participants' high expectations of an app. Moreover, it should be noted that the Fitbit used to monitor daily activity did not automatically synchronize with the Active2Gether apps. The participants in the 2 Active2Gether conditions needed to synchronize the Fitbit through the Fitbit app or Fitbit website. This additional step can be a burden for the users of the Active2Gether apps and might be more prone to technical errors. The Active2Gether-Full app sent the weekly questions and coaching messages via push messages, and the users could only access the app after reading the unread messages. Participants in the Active2Gether-Light condition only received daily or weekly questions via push messages. A more detailed evaluation of the participants' satisfaction in the usability of the app is published elsewhere [42].

This study compared the Active2Gether conditions to the Fitbit app. The Fitbit app enables users to monitor their activity (eg, number of steps, floors climbed, and distance walked), monitor their sleep, and set activity goals. In addition, users have the possibility to log their weight, calorie, and fluid intake. Thus, compared with both the Active2Gether conditions, the Fitbit app enables tracking of various lifestyle components instead of only tracking activity levels. Fitbit sends its users weekly emails with a weekly summary of their progress and congratulations on earning badges. However, participants were asked to register using an Active2Gether email address so that they would not receive these emails in this study. In brief, the Fitbit app included behavior change techniques that were also embedded in the Active2Gether-Full condition.

To summarize, this study showed no significant intervention effects in changes in levels of PA and behavioral determinants compared with the active control groups. Because the study conducted differed substantially from the study designed, any attempt to explain these results should be done with utmost caution. First, the lack of effects found may be because of the lack of an internally valid research design: We had nonrandom allocation between the two Active2Gether conditions and the control *Fitbit* condition. In addition, the number of participants was smaller than we aimed for based on our power analysis, and there was a large variation in at the postintervention measurement. As the effect sizes were generally small, it is unlikely that the lack of sufficient power explains the lack of statistically significant differences between the conditions, although the differences between the baseline and postintervention assessments in minutes of MVPA were 12% to 15% in the Active2Gether conditions, which may be an indication that these Active2Gether interventions do warrant further research. The lack of effect might also be because of the lack of exposure to the interventions; a large majority of the participants did not make use of the app, as we assumed was needed to have sufficient influence and impact on determinants and behavior. Such lack of true exposure to mobile health and electronic health interventions has been found before [16], and a main focus in further research should be how exposure to and actual use of such interventions can be intensified. A research by Schoeppe et al [16] suggests that the effects of app-based interventions as part of more comprehensive, multicomponent programs that may also include other forms of health education of face-to-face counseling may be more likely to be effective.

Strengths and Limitations

The main research design–related limitations of this study have already been described in the Introduction section of this paper and in the opening paragraphs of Discussion section: the lack of full randomization, the small sample size, the variation in timing of the postintervention measurement, and the fact that the baseline measurement of PA for some participants took place during intervention exposure. In addition, most participants were highly educated, female, and already more physically active than the population at large, which limits the external validity. Furthermore, about half of the participants in the Active2Gether conditions experienced technical problems with their app; however, only a few participants informed the researchers that they were having technical problems. Consequently, they might have stopped using the app without first requesting assistance with solving the problem.

Strengths of this study are the high completion rate for participants (92% (95/104)) and the fact that the experimental interventions were compared to Active2Gether with an existing app (the Fitbit app). Comparing the Active2Gether-Full app with the Active2Gether-Light version further provided information about whether sending tailored coaching messages on top of the monitoring and social comparison had an added effect on PA. Another strength was the use of the ActiGraph accelerometer—a valid and reliable accelerometer—to objectively assess baseline and postintervention follow-up PA and the use of existing questionnaires to assess the behavioral determinants. Further evaluation is needed to examine whether sending coaching messages resulted in changes in step activity throughout the study period.

Suggestions for Future Research

This study was originally designed and planned as an RCT with baseline, 6-week, and 12-week evaluations. However, as app-based interventions are relatively new in health promotion and offer the possibility to provide highly personalized and just-in-time feedback, it is necessary to evaluate the long-term effects and what parts of the intervention are effective and what

works for whom. RCTs provide information on the overall effects of the intervention, and they come with some challenges as well. First, choosing an appropriate control group: Compare the intervention to another intervention, no intervention, or a waitlist control group. Second, a truly controlled environment for a trial in real-life circumstances (ie, outside a behavior laboratory) is a challenge, as participants may use other apps or intervention activities to monitor and help them increase or maintain PA levels alongside the intervention to be tested in the study. On the other hand, such opportunities for using existing and available apps or other intervention activities are part of the real-life circumstances, and testing a new app in such circumstances will show if this app has effects additional to what is already available. Therefore, a future study should consider an RCT design with sufficient power, only after the app has been developed, and pilot a more agile developmental process.

Conclusions

This study showed no statistically significant effect of the Active2Gether-Full condition compared with the Active2Gether-Light and Fitbit conditions. Future work is needed to increase the actual use of the apps to integrate the apps in a more comprehensive, multicomponent intervention and in a study with better internal validity.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Results of the linear regression analyses (regression coefficients [B] with 95% CI) for differences in physical activity at postintervention follow-up between Active2Gether-Full and Active2Gether-Light conditions assessed with ActiGraph.
[PDF File (Adobe PDF File), 358 KB - formative_v4i1e12538_app1.pdf]

Multimedia Appendix 2
Results of the linear regression analyses (regression coefficients [B] with 95% CI) for differences in step activity at postintervention follow-up using the Fitbit data (N=63).
[PDF File (Adobe PDF File), 343 KB - formative_v4i1e12538_app2.pdf]

Multimedia Appendix 3
Linear and logistic regression analyses for differences in behavioral determinants between Active2Gether-Full and Active2Gether-Light conditions at postintervention follow-up adjusted for baseline and time between baseline and postintervention follow-up.
[PDF File (Adobe PDF File), 274 KB - formative_v4i1e12538_app3.pdf]

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Abbreviations

ANOVA: analysis of variance
BMI: body mass index
MVPA: moderate-to-vigorous physical activity

PA: physical activity
RCT: randomized controlled trial

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Original Paper

Designing a Mobile App to Enhance Parenting Skills of Latinx Parents: A Community-Based Participatory Approach

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Abstract

Background: Latinx families are among the highest users of smartphones, yet few health-focused Web programs have been developed for this audience. Parent-based smartphone apps designed for Latinx families may help increase access to evidence-informed parenting programming and ultimately reduce health disparities among children and adolescents. To maximize uptake of such apps, the Center for eHealth Research and Disease Management (CeHRes) Roadmap for electronic health (eHealth) development recommends 5 phases of development: (1) contextual inquiry, (2) value specification, (3) design, (4) operationalization, and (5) evaluation.

Objective: Guided by the CeHRes Roadmap, our objective was to apply a community-based participatory research (CBPR) approach to mobile app development. We present a formative evaluation to inform the design of an eHealth mobile app for Latinx parents of adolescents based on a face-to-face parenting program, Padres Informados/Jovenes Preparados (PIJP).

Methods: Community participants in the process included Latinx parents and stakeholders. We conducted a parent survey (N=115) and interviews (N=20) to understand the context and obtain feedback on a mockup and prototype of the app, facilitator workshops to streamline content, and stakeholder interviews (N=4) to discuss values and app requirements.

Results: We report results from the first 3 phases of the CeHRes Roadmap. In the survey, 96.5% (111/115) of parents reported they had access to a cell phone, 85.6% (89/104) reported they would use a parenting app in the next month if they had access, and 80.2% (89/111) reported intentions to use a stress reduction app. Parents reported that setting goals about parenting and tracking those goals were important potential features of an app. In logistic regression analyses, technology attitudes and barriers were not related to parent's intentions to use a parenting mobile app (95% CI 0.51-1.17 and 95% CI 0.28-2.12, respectively). Qualitative interviews confirmed Latinx parents' technology engagement and desire for education and child development information online. Stakeholder interviews identified 3 community values: familism, the promotion of adolescent health, and delivery of economic value. Community stakeholders participated in defining the mobile app requirements. On the basis of community and parent input, the mobile app prototype was designed with 3 sections: (1) 8 modules of video-based parenting

skills instruction with content from the face-to-face PIJP program, (2) breath rate information from a wearable device to support awareness of stress levels that could affect parenting, and (3) goal setting and tracking capacities.

Conclusions: The findings of this study highlight the utility of an iterative, participatory design process. The CBPR approach and community collaboration enhanced the CeHRes Roadmap by promoting power sharing, facilitating recruitment, and building trust among community members. Experiences applying community research to the initial 3 phases of the CeHRes Roadmap in a Latinx community are discussed, along with plans for the 2 final phases.

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KEYWORDS

mobile application; eHealth; community-based participatory research; Hispanic Americans, family

Introduction

Overview

Evidence-informed parenting programs have been shown to improve parenting skills and reduce youth internalizing behaviors and substance use [1,2]. However, the reach of these programs is limited, particularly among Latinx families [1]. Mobile technology has the potential to aid in the dissemination of evidence-based parenting programs [3]. As Latinx families are high users of mobile phones, more specifically smartphones, parent-focused apps designed for this population may help increase access to evidence-based programming and ultimately reduce adolescent mental health and substance use health disparities [4,5].

Background

Latinx individuals are leading users of smartphones [6]. From 2009 to 2016, the use of the internet in the United States nearly doubled among Spanish-dominant Latinxs (from 36% to 74%). In comparison, the use of the internet rose from 87% to 95% among English-dominant Latinxs and rose from 80% to 89% among whites. This narrowing of the gap in internet access is primarily because of the increased use of smartphones [6,7]. Broadband access to the internet among Spanish-dominant Latinxs was still relatively low in 2016 (ie, 21%) compared with 65% of English-dominant Latinxs and 73% of whites. These trends have prompted a call for health promotion efforts to focus on reaching immigrant Latinxs and Spanish speakers via mobile technology, especially through smartphones [5,8]. Despite the promise of mobile technology programs, 1 review of electronic health (eHealth) efforts found that less than 1% of programs were designed for Latinx communities [5], underscoring the need for research in this emerging area.

Uptake of mobile health technology is a critical concern to the success of eHealth interventions [9], and barriers to its successful uptake include low formal education levels, lack of health care access, and attitudes about technology or health, particularly for low-literacy and Spanish-speaking Latinx community members [8]. Community-based participatory research (CBPR) approaches may bridge trust gaps between the health care providers and community while marshaling support for eHealth implementation. Several key principles characterize CBPR approaches [10,11]. First, CBPR recognizes community as an entity that is a full partner at all stages of the research process [11,12]. Second, CBPR emphasizes egalitarian partnerships. Third, participatory approaches invest in change with the goal of reducing health disparities. Fourth, CBPR focuses on local problems, using a strengths-based approach. Fifth, cyclical processes are expected in CBPR research. Sixth, collaborating with different partners fosters humility, colearning, and capacity building. Seventh, CBPR includes commitment to a long-term investment with an eye toward sustainability. By involving end users throughout the development process, CBPR provides important strategies to build community perspectives and practical priorities into the design process, thus maximizing utility for Latinx parents [10,13]. CBPR increases translation of health equity programs into practice through participation of end users and stakeholders in the development and testing of interventions to improve their relevance, acceptability, and efficacy [14]. The CBPR approach recognizes the knowledge, expertise, and resources of communities.

This Paper

In this paper, we apply a CBPR approach to the Center for eHealth Research and Disease Management (CeHRes) Roadmap for designing eHealth technology [13]. In particular, we illustrate the design of a smartphone app for parents, with the long-term goal of reducing internalizing symptoms and substance use among Latinx youth. We present the process of designing the PIJP mobile app, guided by the CeHRes Roadmap. The CeHRes Roadmap is a framework based on 16 models of eHealth development, incorporating an iterative process of design by integrating feedback from stakeholders and end users [13]. This makes it a human-centered process rather than a technology-centered process. Feedback should be recorded, and flexibly should be incorporated into the design of the app at every step of the process [15]. The CeHRes Roadmap outlines 5 phases of design for eHealth development [13]—contextual inquiry, value specification, design, operationalization, and evaluation (see Table 1). This has been described as a *participatory development approach* [13].

Table 1. Phases of Center for eHealth Research and Disease Management Roadmap: Application of community-based participatory research to Padres Informados/Jovenes Preparados app development.

CeHRes[a] Roadmap phase of design	Phase description	CBPR[b] application: PIJP[c] app development	Progress
1. Contextual inquiry	• Exploration of needs and strengths of users and community [13] • Inclusion of multiple community viewpoints	• We began with a commitment to understanding social, structural, and economic factors of the community [16]. • A CBPR partnership comprised of representatives of the Latinx-serving community and researchers identified the need to have an app for parents [11,17]. • A survey (N=115) and subsets of contextual interviews (n=20) were conducted to understand parents' use of technology and needs and desires.	Complete (1-12 months)
2. Value specification	• Documentation of stakeholders and potential users' social and economic values [18] • Translation of values into design and implementation considerations [13]	• Via stakeholder interviews (N=4) and results of parent surveys and interviews, we identified familism and reducing adolescent health disparities as key social values. Increasing access to resources and keeping costs low were key economic values. • Stakeholders agreed that an app provided a cost-effective means of disseminating the PIJP program. We chose a commercial rather than a research-focused wearable device because it was affordable.	Complete (3-12 months)
3. Design	• Creation of a simple prototype or mockup of the proposed technology • Iterative process of getting community feedback early and often on prototypes or mockups [13] • Development of a business plan for disseminating the technology	• We first created an interactive mockup using a tool called PopApp. The mockup was revised integrating results of the first set of contextual interviews with parents, and then, we created a prototype of the app. • Community facilitators were cocreators in the translation of the content to short videos for the app [16]. In the second set of interviews, parents and community stakeholders gave feedback on the app prototype. • We engaged in the initial business plan ideas to attain the CBPR goal of sustainability [10]. Ongoing discussions regarding this theme have continued.	In progress (6-18 months)
4. Operationalization	• Implementation of the program, which may begin with pilot testing [13] • Includes a plan for adoption in the community	• Within the CBPR framework, community members, community organizations, and researchers will contribute to research design, recruitment, and evaluation [11,14]. • Community members, including parents, will participate in an advisory board to successfully launch the app.	In planning (18-30 months)
5. Summative evaluation	• Assessment of the impact of the technology on the community from a behavioral, organizational, and business perspective [8]	• We will engage a broad coalition of stakeholders and community members to participate in evaluation efforts. • Community priorities will be equally weighed with research priorities to make evaluation decisions [19].	Planned for future (30+ months)

[a]CeHRes: Center for eHealth Research and Disease Management.

[b]CBPR: community-based participatory research.

[c]PIJP: Padres Informados/Jovenes Preparados.

The purpose of this paper was to describe how a community-based participatory approach was applied to the adaptation of the face-to-face PIJP curriculum and the development of the mobile app. We had the following aims: (1) to explore Latinx parents' access to technology, current use of technology, and intentions to use a parenting app, based on a mixed methods contextual inquiry; (2) to identify the stakeholder values and parent desires for a parenting/stress reduction app and wearable device to support awareness of stress levels that could affect parenting; and (3) to synthesize and integrate parent feedback about the mobile app mockup and the working prototype into the design of the mobile app.

In this paper, we discuss the findings, as they are relevant to the 5 phases of the CeHRes Roadmap. As a method of conducting research that is rooted deeply in community involvement, CBPR naturally fits with the participatory design process of CeHRes.

Methods

The Padres Informados/Jovenes Preparados Program

The Padres Informados/Jovenes Preparados (PIJP) program was developed using a CBPR approach. The PIJP partnership began in 2007 to support parents and youth to reduce smoking by developing a culturally-grounded parenting program. The development of PIJP included Latinx-serving organizations and Latinx parents of youth who helped align parent and community priorities. Guided by social cognitive theory and positive youth development principles [20,21], PIJP focuses on core cultural values while building family relationship characteristics and parenting practices most closely associated with substance use prevention. Parenting practices include monitoring of children's whereabouts and activities as well as the use of effective and consistent discipline. As part of the face-to-face delivery of the PIJP program, parents attended 8 weekly 2-hour sessions. A total of 4 sessions of a complementary youth program were delivered conjointly with the parent sessions. The program and face-to-face delivery are described in greater detail in a study by Allen et al [22]. Results from a randomized, wait-list trial (2011 to 2013) demonstrated that the program lowered intention to smoke among youth who reported low levels of traditional Latinx cultural values. Family relational training resulted in improved family relations characterized by increased attachment, warmth, and support; decreased conflict; and increased acceptance and constructive communication [23].

Building the PIJP mobile app was part of a larger action-oriented dissemination plan—a call to action in response to community needs [11,17]. Dissemination of the PIJP program occurred through a 3-pronged approach: (1) developing a website to easily disseminate the program materials to local facilitators, (2) piloting a *train-the-trainer* model to ensure fidelity of delivery, and (3) developing a mobile app that parents could access directly. A website was developed to disseminate PIJP program materials, and the program has been disseminated using the train-the-trainer model in a metropolitan area in the Midwest of the United States. Methods to develop the mobile app are described in the following sections.

Community Stakeholders and Research Team

A multidisciplinary team of PIJP stakeholders—critical for eHealth research and development [13]—has continued to regularly attend a monthly community-participatory research meeting for over 10 years. As the dissemination phase launched 5 years ago, 2 authors (JD and JM) joined the collaborative and have led the mobile app development. The PIJP stakeholders include leadership from a local community serving agency, a physician from a Latinx-serving clinic, a public health outreach specialist, and university researchers and extension specialists.

To lay the groundwork for the PIJP app, stakeholders discussed and approved a mixed methods research plan to survey local Latinx parents, interview a subset of parents about their technology use, and obtain feedback on the app design.

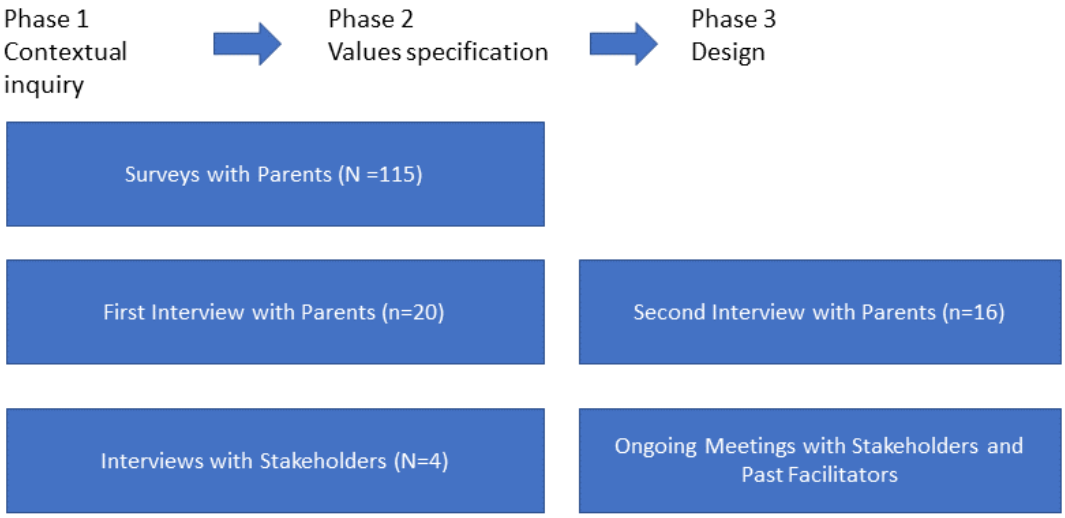
A graduate student with experience in human-computer interaction and prototyping, an undergraduate intern, and JD met with a user experience and design expert with over 15 years of experience in the industry to formulate questions and discuss how to translate requirements into design. In addition, 8 stakeholders were invited to participate in individual interviews, and 4 stakeholders participated in 1-hour interviews outside of monthly meetings to gather requirements. The graduate student interviewed stakeholders, while the undergraduate intern took notes. Stakeholders' and parents' values were translated into design requirements, keeping communication open throughout the design process so as not to isolate or lose ideas [15]. Experienced Latinx community facilitators of the PIJP program became cocreators of the content that would be selected for the mobile app version of the program. These facilitators were previously trained and had presented the face-to-face PIJP program in the community [19].

Research Design

We employed a mixed methods design for the formative evaluation to triangulate data and better understand parents' needs (see Figure 1) [13]. We conducted a quantitative survey (N=115) to achieve a big-picture overview of Latinx parents' technology use. We then conducted 2 sets of qualitative interviews to gather parent feedback on the usability of the design [24]. The first interview (approximately 60 min; n=20) covered parents' online interactions, use of technology for parenting, stress reduction resources on the Web, and feedback on the mockup of the mobile app. Our mockup was created using Pop, an app by Marvel, which allowed a simple but interactive prototype of the app using PowerPoint images.

Design of the prototype of the app began 4 months later. Applying Persuasive Systems Design (see Multimedia Appendix 1), we focused on aspects of the app design intended to increase primary task support (eg, increase the target behaviors of positive parenting), dialog support (eg, increase feedback the app gives to parents), and system credibility (eg, increase trustworthiness and real-world feel) [25]. A second interview (approximately 45 min; n=16) was conducted to gather feedback on using the mobile app prototype and parents' experience using a wearable device. We invited parents to *think out loud* about the process of navigating through the app. This method has been recognized as a tool for gathering participant feedback in the development of eHealth technologies [26] and fits with the CBPR commitment to incorporate opportunities for community members to provide meaningful input [10,16].

Figure 1. Summary of study design.



Participants

Surveys

We recruited Latinx parents (N=115) through flyers, word of mouth, tabling at community events, and face-to-face invitations to participants in classes at local agencies. Most respondents either approached our table at 3 large community events where more than 100 community members were in attendance or participated after being invited in community classes with 12 to 18 participants. Recruitment was stratified by gender with the goal of recruiting 40% of fathers. All surveys were given in Spanish, with the option to take them in English, and participants had the option to complete the surveys on paper or a tablet.

Interviews

Of the 70 survey participants who indicated in the survey that they would participate in interviews, 30 were randomly chosen and invited to meet with the outreach specialist. The first participants who were able to schedule an appointment were interviewed for both the first (n=20) and second phases (n=16) of qualitative interviews. The outreach specialist met participants for interviews at the location of participants' choice (eg, home or local cafe) to conduct 2 interviews in Spanish. Interviews were recorded, transcribed, and translated into English using an online service, and interactions with the mockup and prototype were recorded using a portable IPEVO camera.

Measures

Quantitative Measures

Stakeholder input was incorporated into survey development, and parents gave feedback on a draft of the survey. Access to mobile technology was measured by the following questions: "Do you access the internet on a cellphone?" (1=yes and 0=no) and "Do you have a data plan for your phone?" (1=yes and 0=no). Intention to use a parenting app was measured by the following question: "If a parenting/biofeedback app were available today, I predict I would use the mobile app in the next..." (1=week to 7=never). Parents indicated the importance of parenting information in response to the following question: "Which of the following things would be most important to you in a parenting app?" Responses included "Information about communication or connecting with your child"; "Information about negotiating culture and adolescent development"; "Information about discipline, monitoring my child, conflict resolution"; and "Connections to other parents." Parents indicated the importance of potential design features in response to the following question: "Which of the following things would be most important to you in a parenting app?" Responses included "Stress reduction and relaxation tips," "Personal feedback on my stress levels through a wearable," "The ability to write and track goals," and "Reminders about my goals on my phone."

Technology attitudes were measured using a 6-item scale (alpha=.62) [27]; for example, "Thinking about all the technologies you use, overall would you say these devices: 'Make your life easier' or 'Give you less control over your life'" (1=*strongly disagree* to 5=*strongly agree*). To measure perceived barriers to technology use, parents answered the question, "Which (if any) of these things make it difficult for you to use or concern you about the Internet?" [27]. A count variable was created from a checklist of 7 items, such as "I'm worried about computer viruses." Control variables included age of parents, gender (0=female and 1=male), educational attainment (1=did not go to school to 5=university), and monthly income (1=less than US $1000 per month to 5=more than US $4000 per month).

Qualitative Protocol

The first parent interview covered 4 topics: general technology use, use of technology for parenting, preferences for the app, and feedback on the mockup of the app. Interview questions are found in Multimedia Appendix 2. The first parent interview was informed by parents' responses to the quantitative survey. For example, parents emphasized making parenting goals and were enthusiastic about using an app to support parenting and

stress reduction. We asked further details about these topics in the interviews. In the second parent interview, parents reported on their preferences for 8 potential features that could be included in a parenting app. To facilitate the process of determining preferences, parents were presented features in 7 sets of 4 and instructed the following: "Think about the features in each example set of an app. Which would be the most important and least important characteristics to you?" Some example options include the following: "The app is generic—it does not display personalized information about you or your child" or "You are able to make parenting goals in the app based on the parenting module and track each day of the week." Parents indicated the most and least important features in each set. Guided by an expert in the user experience field, we took a practical approach to investigating user experience. Specifically, we conducted user testing, and participants talked out loud about their experience completing tasks in the app prototype. For example, we asked them about the first page, and before clicking on anything, participants shared their first impressions of who the app was for and the purpose of the app. Then, participants were given a series of scenarios and asked to navigate through the prototype, for example, "If you had a hard day at work and wanted to relax for two minutes before helping your child do homework, what part of the app might be helpful?" In the stakeholder interviews (N=4), we asked partners about the future of the PIJP program and collaborative, their understanding of the project to build a mobile app, the benefits of the project to the community collaborative, desired features and functionality of the app, potential problems with the app, and successful implementation of the app.

Analytic Plan

Descriptive statistics were computed on the survey data to understand parents' access to and current use of technology as well as their intentions to use a parenting app. Logistic regression analyses were conducted to assess the relationships of technology attitudes and barriers with access and use patterns. To address missing data, we conducted 25 iterations of multiple imputation in Stata.

For qualitative analyses of parent and stakeholder interviews, the first set of interviews were coded by JD and the outreach specialist to reduce the bias of 1 researcher interpreting the data [28]. We met on 2 occasions to discuss coding and reach consensus regarding themes that emerged and design implications.

Results

Survey participants (N=115) included 59.8% (64/107) of mothers. Nearly three-fourths (78/107, 72.9%) of the participants were married, and the mean age was slightly over 40 years (mean 40.6). Approximately half of the participants reported technical training or education beyond high school (56/110, 50.9%), 77.4% (89/115) were from Mexico or Central America, and 18.5% (20/108) reported being in the United States for less than 10 years. A subset of 20 survey participants were interviewed on 2 occasions. Of this subset of participants, nearly three-fourths were mothers, 68% (13/19) were married, and the mean age was slightly over 41 years (mean 41.5). Slightly more than half of the participants reported technical training or education beyond high school (12/20, 60%), 65% (13/20) were from Mexico or Central America, and 20% (4/20) reported being in the United States for less than 10 years.

Context and Values

The CBPR approach supported both quantitative data collection and 2 rounds of qualitative data collection necessary for the iterative process of design (see Table 1). In the first 2 phases of the CeHRes Roadmap, we focused on contextual inquiry and value specification.

Quantitative Survey

We found that 96.5% (111/115) of parents had access to a cell phone, whereas only 68.8% (77/112) had access to a home computer. Parents reported that 84.5% (93/110) had access to a data plan. Parents also indicated that they would use a parenting app within a month if they had access to it (89/104, 85.6%), and 80.2% (89/111) indicated that they would use a stress reduction app within a month. We conducted a logistic regression analysis to examine the relationship between technology attitudes with intentions to use a parenting app in the next month. We found no relationship (odds ratio [OR] 0.77, 95% CI 0.51-1.17). In addition, technology barriers were not related to intentions to use a parenting app (OR 0.76, 95% CI 0.28-2.12).

First Set of Parent Interviews

Some of the Latinx parents we interviewed were avid technology users, whereas some were weary of technology. However, all parents we interviewed said they used basic apps including email, WhatsApp, Google, Facebook, and banking apps. Some parents listed more than a dozen apps that they used on a regular basis to research hobbies, connect with their child's school, travel, engage in entertainment, or transfer money. Few barriers to technology were mentioned. Moreover, 1 parent mentioned a lack of access, and another mentioned privacy concerns. Some parents expressed frustration that technology is always changing, and they depended on their children to help them learn to use new devices and software. One parent said:

> *What I find difficult is when I don't use, for example an Xbox...I usually learn how to use whatever I have. And when something is very difficult, that I don't understand, I call [my children], and they make everything easier for me.*

Few parents had used wearable devices or relaxation apps. A couple who had tried relaxation or mindfulness apps for a short time did not continue using the app. For example, one said:

> *I deleted it, I got bored, I used to fall asleep.*

Other methods of relaxing using technology were common. One mother said:

> *[To relax, I use] my phone to make a call, and sometimes watch a video. I look for healthy food and exercises on Google...I like to see how to feed my family and how to feed myself, what exercises are good and how to do them.*

Others avoided technology, and another mother said:

> *When I'm stressed I prefer to get away from [technology]…For example, I read a book and stop working on the computer.*

When it came to parenting, parents saw value in technology as a parenting and education resource. Almost all parents communicated with their child's school and monitored their academic progress on the Web. Overall, they were enthusiastic about the role of technology in their children's education. A parent explained:

> *I also opened an email account for communicating with the teachers...Now with the internet, I realized that it is a big help for school because, for example, my children are learning now about math, and I remember it was more difficult for me to learn math. Instead they are like playing, counting, so math is easier.*

They saw technology as a potential way for them to learn information about parenting too. One parent said:

> *When I want to learn things, what I do is Google them; my daughter is a teenager, and there I start reading a bit more about how to handle some situations that they start having during adolescence.*

Parents also wanted information on parenting by developmental ages:

> *I think there are so many resources available on internet, but sometimes it's difficult to find them, so, I'd like a place where it only focuses on parenting, education, or children, divided by ages.*

Another parent said:

> *I would like [an app] to talk about how to help students, how to be parents, how to help each other.*

A few acknowledged the need for support as they navigate a new culture:

> *[I'd like] something that helps us to understand a little more about the culture, to help us adapt a little more to the new culture.*

Some wished that they had a way to monitor their children's use of technology. A couple said that they thought adolescents needed independence from monitoring. Overall, parents were positive about the potential for technology to support their family and parenting efforts.

Stakeholder Interviews

When stakeholders were asked the direction in which they would like the PIJP program to progress over the next few years, stakeholders articulated a goal of helping parents gain parenting skills by having access to the material they need when they need it. Stakeholders mentioned the desire to provide access and flexibility but also mentioned the need for sensitivity to family data limits. Regarding the features and functionality of the app, all 4 stakeholder participants were enthusiastic about the possibility of including breath rate feedback on stress levels to parents via a wearable device and reminders to parents through the app. One stakeholder commented, although, that "different people will have different reactions to notifications" and noted that we would need to study this further. Stakeholders also agreed on the need to have interactive audio/visual and brief time windows to present material. All stakeholders suggested promoting family connections and social support through the app, perhaps by using social media. Others suggested a hybrid program with personalized training and consultation provided alongside the app. Each stakeholder we talked to was interested in developing more specialized content on youth issues (eg, information on nutrition, sexual health, and mental health). When we asked how we could successfully implement the dissemination of the app, stakeholders mentioned "grassroots growth," recognition from local health systems, and the need for "investment from funders." Other ideas to incorporate into a business plan included conducting an initial in-person provider and parent meeting, planning for ongoing improvements to the app, leveraging the app to provide referrals to caregivers, and incorporating video conferencing into the app over time. Stakeholders not only recognized the potential value of the app in clinical practice (eg, at doctors' visits or in meetings with social workers) but also thought that "we're a long way from using this in routine clinical practice" because mobile dissemination would need to be systematically tested. Sustainability of the app economically and long-term commitment to the project and community were also valued.

Design

Stakeholder Interviews

The results of the stakeholder interviews were presented to all stakeholders (including those who did not participate in interviews) at a monthly meeting in the form of updated requirements and a proposed site map (see Multimedia Appendix 3). On the basis of stakeholder interviews, the team agreed that future releases of the app should include additional content on specialized areas of youth development and exploration of social media connections. In addition, stakeholders discussed the potential future release of a youth version of the app. Stakeholders agreed with this plan, given the limited budget for the first release. Most points of disagreement involved presentation of content (eg, the extent to which we could include gender-neutral language). Another area of some disagreement and discussion was the need for a wearable device that would be affordable for participants, rather than a costly research-grade wearable device. Some stakeholders argued that affordability was critical to sustainability of the project over time. Disagreements were resolved over several months after having discussions in monthly meetings with stakeholders and gathering opinions from community members. CBPR values of colearning, humility, and shared power were critical to resolving differences.

On the basis of stakeholder feedback, the app prototype featured a homepage that directed parents to 1 of the 3 areas: (1) parenting tools with 8 modules on parenting practices; (2) relaxation techniques, which would connect to breath rate information from a wearable device and breathing exercise apps; and (3) goals, which provided an opportunity for parents to make and track goals about parenting and relaxation practices. As stakeholders were concerned about parents not being able to stream if they did not have data, we included transcripts of videos.

Second Parent Interview: Feedback on Design

The same parents who participated in a user test of the mockup of the Padres Informados app in interview 1 were invited to provide feedback on the prototype of the Padres Informados app in interview 2 (n=16). Parents were confused by some of the labels, but most were able to complete each task (finding information on discipline, relaxation, monitoring their breath rate, and setting a goal). The only task that sometimes gave parents problems was setting up their personal preferences. During the interview, parents were asked to choose the most important and least important features of the app from a menu of 8 options presented in sets of 4. Parents indicated that the most important features of the app were setting goals (40%) and tracking on a weekly or monthly basis (40%). Parents indicated that the least important features of the app were lengthy videos (40%) and prompts to finish all 8 modules (20%).

Discussion

Principal Findings

This study supports the utility of combining the CeHRes Roadmap with CBPR methods for designing eHealth technology for Latinx families. Using mixed methods, the contextual inquiry phase of the CeHRes Roadmap included a survey of Latinx parents and interviews with a subset of parents. The findings of this study highlighted parents' engagement with technology and illustrated parents' desires to improve their parenting skills and knowledge. Latinx parents in the local community were connected to technology. Similar to national findings [7], 96.5% of parents had cell phones, and the majority of parents indicated that they would use an app for parenting (85.6%) or stress reduction (80.2%) if it were available. Technology attitudes and barriers were not associated with parent's intentions to use a parenting app or wearable device. Although 84.5% of parents reported having a plan for data usage, stakeholders who reviewed survey data were nonetheless concerned that some families would not be able to stream videos.

During qualitative interviews, parents indicated that one of the most important features of a parenting app would be goal setting and tracking capabilities. Interviews illustrated the ways in which Latinx parents wanted to improve their parenting by learning about the developmental stages their children were experiencing, how to discuss sensitive subjects, and ways to better monitor their adolescents. The interviews also demonstrated how Latinx parents used technology in their everyday lives; parents discussed several apps they use daily, but few parents had tried a wearable device or an app focused on relaxation. Interviews with stakeholders further identified the values of community stakeholders, which were translated into requirements for the development of the app.

In the following paragraphs, we discuss the benefits of a CBPR approach to the formative evaluation and application of results to the design of the PIJP app in the first 3 phases of the CeHRes Roadmap. We also discuss future directions for this effort in the last 2 phases, encompassing operationalization through piloting and the implementation and evaluation of the mobile app with community partners.

Contextual Inquiry

The first phase of the CeHRes Roadmap, contextual inquiry, informed the initial planning of the app by soliciting multiple viewpoints and exploring the needs and strengths of the community. A contextual approach links to a key principle of CBPR, the commitment to understanding social, structural, and economic factors that may contribute to inequalities [16]. Working with community as full partners facilitated recruitment for the parent survey and interviews, which is a valuable contribution given the difficulty of engaging busy parents [29,30]. Other studies have demonstrated that commitment to include community stakeholders and members increases trust, in part, because potential end users of eHealth technology have familiarity with and input into product development [13].

Stakeholders had already identified the dissemination of the PIJP program as a high priority and agreed that building an app was an innovative and sustainable means to deliver the program to parents. In another PIJP study, researchers found that fathers were less likely to attend meetings face to face compared with mothers; program delivery via technology was identified as a means of increasing fathers' participation [31]. Other research has also emphasized the importance of a CBPR approach for engaging stakeholders and community partners in eHealth development to improve the sustainability of product use over time [32]. In this study, surveys, the first set of parent interviews, and stakeholder interviews informed the expansion of user requirements with the following additional features: inclusion of goal tracking and reminders for goals. Guided by the parents' feedback during the second set of parenting interviews, we decided to focus most on foundational parenting information and goals in the first release.

Value Specification

During the second phase of the CeHRes Roadmap, 3 values were identified by stakeholders and parents: familism, adolescent health, and sustainability through economic value. Consistent with formative research conducted for the face-to-face version of PIJP, the value of familism was identified as a social value [22]. Familism refers to the strong sense of importance and connectedness in family relationships and obligations among Latinx people [33]. Parents reported that improving parenting knowledge and supporting their children's education were key priorities, reflecting the value of familism. Furthermore, parents identified tracking of parenting goals as the most important features of a parenting app, as they responded to a ranking task about important features of the app.

Stakeholders also identified the value of improving adolescent health. They requested future modules on adolescent health topics, such as youth substance use, nutrition, and sexual health. On the basis of the stakeholder interviews, the site map of the proposed mobile app demonstrated the features of the app that we planned to design and showed the priority of each feature for each release. In the first release, we focused on basic parenting modules and goal setting capacity, and in subsequent releases, we plan to focus on wearable integration, social connection, and future topical modules on adolescent health. These decisions were also informed by the parent survey and interviews. In line with the CBPR principles of shared power,

the monthly meeting to obtain stakeholder feedback and refine the site map facilitated the integration of community knowledge into the CeHRes Roadmap process [10,16].

The PIJP community-academic group also discussed the potential for economic value, with a focus on sustainability of the PIJP mission and outreach, rather than profit. Stakeholders highlighted the importance of community access as a key value, and we discussed this further in monthly meetings. The possibility of a no-cost or low-cost app was appealing, especially in comparison with some costly programs. When we first discussed integrating a wearable device into the app, cost was a major concern. Some research-intensive wearables have multiple monitors and a focus on measurement [34,35], but Latinx parents in the community were unlikely to buy these or wear them on a regular basis. Furthermore, research-intensive wearables did not have the user-friendly interface that would allow parents to monitor their own stress data. We decided to do feasibility testing with the Spire stone, a commercially available, user-friendly wearable device that tracks breath rate [36]. Our focus in choosing this product was on accessibility, ease of community use, and feasibility from users' perspective [37]. However, although the wearable device complements the PIJP app, it is not necessary for parents to use the wearable device and engage in relaxation exercises to benefit from the app. The decision to create an accessible product rather than a research-intensive product and to make the wearable device an optional feature would not have been considered without the CBPR approach, which demonstrates that the insights of local stakeholders make valuable contributions to eHealth mobile app development.

Design

In the CeHRes Roadmap, design is defined as "building prototypes that fit with the [identified] values and user requirements [13]." The CBPR process provides a structure to identify values and requirements that meet the needs of marginalized communities. Through close collaboration with the community, the PIJP team was uniquely positioned to design a mobile app based on human-centered design principles. These design principles include a minimalist aesthetic and design, clear navigation, structural consistency, and heavy dependence on understanding and being responsive to users' needs and skills [38,39]. Inherent in the CeHRes Roadmap is the recognition of persuasive design as a key principle of eHealth development [13]. Working from the CBPR principle of leveraging community assets, we chose to apply a structured model of Persuasive Systems Design, which presents a process of designing eHealth products to "reinforce, change, or shape attitudes or behaviors or both without using coercion or deception" [25]. Collectively, these design principles supported a focus on creating a user-friendly app, identifying salient PIJP content, and making decisions that promoted the feasibility of parents using the app.

The CBPR process leveraged the deep knowledge and experience of Latinx community facilitators, stakeholders, and parents in shaping the delivery of content for the app. Community facilitators of the PIJP program became cocreators of content that would be selected for the mobile app version of the program. These facilitators were previously trained in and had presented the face-to-face PIJP program in the community [11,19]. Stakeholders and community facilitators of the face-to-face program recommended delivering the content through short videos based on their knowledge of the community. The use of videos for the delivery of parenting information in prevention settings has been previously validated [40]. In addition, videos have been recommended for delivering information to Latinx participants in eHealth contexts [5]. We then validated the idea of videos by asking parents to identify the most important and least important potential features of the parenting app. Although parents did not like the idea of long videos (25-30 min in length), they were open to the idea of short videos (3-5 min in length). To address parents' potential inability to stream content, we also plan to include the written script to each video in Spanish. Parents' and stakeholders' feedback on the prototype of the app will be incorporated into the final product, including emphasis on goal setting, shorter videos, and some minor changes to labeling of different app sections. Consistent with a CBPR approach, we engaged stakeholders, facilitators, and parents to ensure community members were cocreators in this process [16]. When communities are invested in the process, acceptability of the end product is more likely [13].

Operationalization

Dovetailing with the CBPR commitment to sustainability, the operationalization phase of the CeHRes Roadmap focuses on both pilot testing and business modeling. This dual process is important to establish viable and sustainable means of implementation, a critical process gap between the development of health care innovations and implementation in health care settings [41]. The operationalization phase and evaluation phase (below) represent future directions for the PIJP app. The pilot study will be conducted in close partnership with the Latinx community, and community members will be a part of the research process [11]. Simultaneously, the process of creating a business plan in a CBPR context requires negotiation and open discussions about partnership [10,11]. This process will help us identify how PIJP creates and delivers value. Furthermore, a business model will identify regulations, opinion leaders in the community, incentives that work with local parents, and opportunities to collaborate with insurance plans [13]. This process includes identifying key partners, resources, activities, and the cost associated with implementation as well as potential customers and distribution channels that may provide revenue. Having a business model before the implementation is critical to successful integration into health systems [18].

Summative Evaluation

The tensions between evidence-based practice, community priorities, and business models need to be weighed carefully in the evaluation phase. For a summative or outcome-focused evaluation, the gold standard for evidence-based practice is a randomized controlled trial (RCT). However, although an RCT may meet research needs, this design lacks the flexibility to meet community needs for those who are in the control group [11]. Therefore, we plan to conduct an optimization trial before

considering an RCT. In the context of this project, optimization refers to the process of identifying which components of the app and support systems (such as SMS reminders, weekly check-ins with community health workers, and training on the app) provide the best outcomes at a reasonable cost [42]. To establish the effectiveness of the mobile app and the impact on outcomes, after the design phase, summative evaluation is necessary [13]. To this end, we will conduct an RCT after the optimization trial. However, the idea that an evidence-based product should not change after positive results of an RCT is based on an assumption that the context of participants is not changing. Especially in a rapidly changing technological landscape, evidence-based practice should be coupled with a business model dedicated to ongoing evaluation and assessment of the impact of eHealth technologies on client behaviors, clinical practice, and health outcomes [13]. In the case of PIJP, ongoing collaboration with community stakeholders using CBPR supports long-term sustainability of a product and the commitment for the development and summative evaluation of future planned iterations of the product.

Limitations

This study follows a carefully designed formative evaluation of community needs and adheres to a well-respected process of building eHealth designs, the CeHRes Roadmap [13]. However, limitations must be acknowledged. Not all stakeholders we contacted were available for interviews, and we instead gathered feedback from some stakeholders at monthly meetings. We used word of mouth and community agencies to recruit participants, resulting in a convenience sample. As a result, the sample may be positively biased toward technology compared with those who did not participate in the formative study. In addition, we were not able to statistically analyze parent's rankings of best/worst choices of the app features after the interviews. To conduct a best/worst scaling analysis, future studies should be conducted with larger numbers of participants in a survey format [43]. Designing at the community level may meet the needs of local communities but may not be transferable to a greater audience; a balance between meeting community needs and being able to impact population-level health must be reached. It should be noted that the effectiveness of an app may be diminished if participants are unaware of its full functionality. We believe that CBPR is an approach that maximizes the effectiveness of programs, communication with participants, and adaptability of programs at the community level while adhering to evidence-based principles.

Conclusions

The integration of CBPR in developing eHealth technology for the Latinx community has enabled a critical feedback loop of community input into the design process. More specifically, the CBPR approach supported recruitment of parents in the community; built trust through the endorsement of community stakeholders; and leveraged the knowledge of stakeholders, prevention program facilitators, and parents in the process of app development. The PIJP commitment to a CBPR approach added a critical analysis of cultural needs and addressed power sharing in design decisions and business plans, which has the potential to effectively promote health equity [10,16]. By applying CBPR to eHealth technology development and business modeling, technology can be built in such a way to have a wider benefit and expand access for community members. A CBPR framework has the potential to add value to the CeHRes Roadmap and the process of eHealth adaptation of other family-based interventions for Latinx families.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Persuasive Systems Design model applied to the Padres Informados/Jovenes Preparados app.
[DOCX File , 19 KB - formative_v4i1e12618_app1.docx]

Multimedia Appendix 2
Example questions of qualitative interviews.
[DOCX File , 16 KB - formative_v4i1e12618_app2.docx]

Multimedia Appendix 3
Proposed site map of the Padres Informados/Jovenes Preparados app.
[PNG File , 37 KB - formative_v4i1e12618_app3.png]

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Abbreviations

CBPR: community-based participatory research
CeHRes: Center for eHealth Research and Disease Management
eHealth: electronic health
OR: odds ratio

PIJP: Padres Informados/Jovenes Preparados
RCT: randomized controlled trial

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Original Paper

A Co-Designed Social Media Intervention to Satisfy Information Needs and Improve Outcomes of Patients With Chronic Kidney Disease: Longitudinal Study

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Abstract

Background: The number of people living with a long-term condition is increasing worldwide. Social media offers opportunities for patients to exchange information and experiences with others with the same condition, potentially leading to better self-management and improved patient outcomes, at minimal costs to health service providers.

Objective: This paper describes how an online network with a range of social media platforms was created, with the help of a group of patients with chronic kidney disease and specialist professionals. The project considered whether information needs and health-related and social outcomes were met.

Methods: We performed a longitudinal in-depth evaluation of the creation of the moderated network, observation of the use of the platforms, self-efficacy surveys (at baseline and 6 months), and semistructured interviews (at baseline and 6 months).

Results: A total of 15 patients and professionals participated in the co-design of the network (hub), which was initially launched with 50 patients. Several platforms were needed to engage patients at different levels and encourage generation of information, with the support of moderators. In addition, 14 separate patients participated in the evaluation. Satisfaction of information needs through social engagement improved self-efficacy (n=13) with better self-care and management of illness. Social outcomes included seeking employment and an increase in social capital.

Conclusions: An online network (hub) with several social media platforms helped patients with chronic kidney disease manage their condition. Careful co-designing with users resulted in a sustainable network with wider applicability across health and social care.

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KEYWORDS

social media; patients outcomes; long term condition; chronic kidney disease; self-efficacy; patients information needs; co-design

Introduction

The increase in long-term conditions is seen as the greatest challenge faced by health systems globally [1], with one in three adults affected by multiple chronic conditions [2]. In England alone, the number of long-term conditions is estimated to reach 2.9 million in 2018, accounting for 70% of total health and social care spending [3]. From international to local levels, there is an increased focus on innovation and patient-centered and preventative care [3-7] including patient engagement with electronic health systems [8,9].

Information provision for patients often occurs as a result of a problem or symptom as well as dependence on the specific needs of the patients. “Information need is a recognition that your knowledge is inadequate to satisfy a goal that you have, within the context/situation that you find yourself at a specific point in the time” [10]. Information behavior is the totality of human behavior concerned with channels of information that

involves information seeking and use [11]. Patients engage in information behavior activities at different stages of their illness [12,13].

Research acknowledges that effective provision of information is a determinant in helping people self-manage their own illness [12], which then has the potential to improve self-care, health behavior, and quality of life [13,14]. Yet, satisfying the information needs of patients remains a challenge [10,15]. Patients with chronic kidney disease may not recognize that they need information [10], or the information they need to alleviate the uncertainty of the condition is not available [16]. Nevertheless, they are interested in talking to each other to gain knowledge about the condition and access peer support [10,16] and while on dialysis, they develop new relationships with clinical staff and the dialysis patient community [16]. Recent systematic reviews of online peer-to-peer communities suggest that they provide a supportive space for daily self-care related to chronic illness and a valued space to strengthen social ties and exchange knowledge that extends beyond the illness and medical care [17,18].

Social media provides opportunities for user-generated peer content, which embraces knowledge transfer (eg, advice, information, and resources) and support (eg, companionship) to address patient engagement, access to information, and positive outcomes. This model of information generation moves away from clinician-led information provision to patient-generated information in order to support patients' needs and positively influence patient self-management [19]. Social media allows access to information and support at a time and context that suits the patient. However, the inconsistency and quality of information shared via social media networks poses significant challenges [20], and the variety of social media platforms (eg, Facebook, Twitter, blogs, and forums) and their different audiences adds an additional challenge to those conducting research in terms of deciding which platforms to choose.

Research suggests that social media can be used in long-term conditions to exchange information and trigger positive outcomes [21]. However, an understanding of how kidney patients actually engage with these platforms and the resulting information generation and outcomes are lacking. This is important to effectively exploit the potential of social media for meeting the information and supporting the needs of patients with long-term conditions.

This study therefore aimed to use a variety of linked social media (a hub) to encourage patients with chronic kidney disease in one area of the United Kingdom to generate (post) information and respond to the contributions of others. A social media hub was co-designed with patients and then evaluated to determine whether it met patients' information needs and improved health and social outcomes.

Methods

Approach

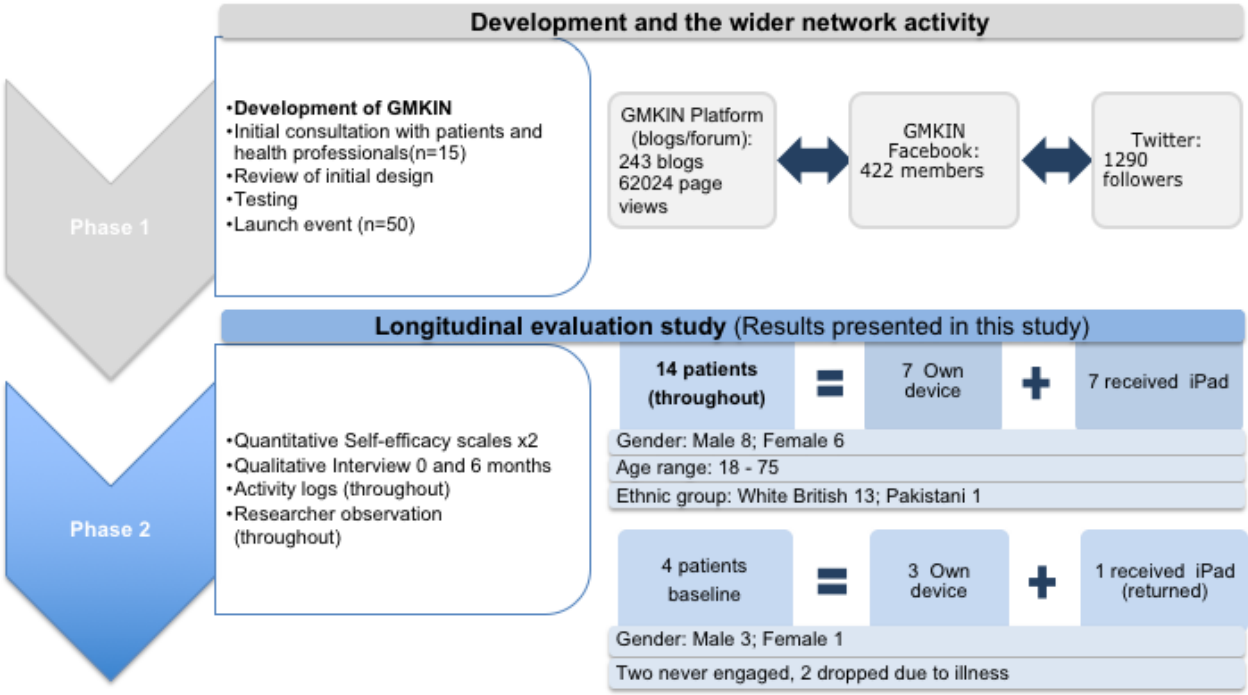
The project used a realist [22], longitudinal, mixed methods approach over two phases: (1) design and training, and (2) longitudinal evaluation.

Ethics approval was obtained from the University of Salford, who hosted the study and the system used within the UK Health service (NHS Research Ethics) prior to recruiting patients in the longitudinal study. All participants involved in the longitudinal evaluation study provided written consent.

Setting and Sample

The study took place in the North West of England, following meetings with the local Kidney Patient Association, patients, and carers recruited via local health care professionals from a large teaching hospital. A total of 15 users (patients, carers, health practitioners, and researchers) engaged in the co-design of the social media hub (online network). A launch event was held with 50 patients to provide training, and the majority signed up to join the hub and Facebook group. For the longitudinal evaluation, 17 separate patients with chronic kidney disease and 1 carer were recruited via the local Kidney Patients Association, Facebook, and word of mouth. Patients were eligible for inclusion if they were aged over 18 years, had chronic kidney disease (predialysis, hemodialysis, peritoneal dialysis, or transplant), were recommended by a health care professional, could provide written informed consent, and could read and write English. A theoretical sampling approach was used to ensure a mix of ages, gender, and stages of kidney disease and to ensure that this sample group did not overlap with those involved in the design. The carer was included because he used the Greater Manchester Kidney Information Network (GMKIN) on behalf of his non–English-speaking mother. To maximize inclusion, patients with no access to technology (n=7) received an iPad and additional training to facilitate participation. Four patients dropped out (two did not engage at all and two could not take part in the final interview due to illness). Over the period of the evaluation, health professionals and patients were free to join and use the hub, contributing to hub activity, in general. It is not possible to calculate the number of users of the hub over the evaluation period, but activity in the hub in this time frame is presented in Figure 1.

Figure 1. Overview of the sample. GMKIN: Greater Manchester Kidney Information Network.



Phase One: Design and Training

Hub Design

Meetings with the Kidney Patient Association, patients, and carers identified a clear need to find innovative ways to enable patient access to health information and support. Findings from previous research [23] were combined with the user engagement and information needs theory [10,24,25] to inform a user-centered design (UCD) process [26], led by the lead researcher (CV) and involving a three-stage iteration [27]:

1. Initial consultation with patients and health professionals, reviewing social media platforms, and a potential hub to support patient-centered care and self-management
2. Presentation of hub and discussion on color scheme, usability, and accessibility (create accounts, write and share posts, add comments) and integration with social other social media platforms
3. Platform testing and virtual meeting (using Facebook) to refine the hub before releasing it to the public

The hub was named GMKIN and incorporated social media platforms with active users (Facebook), advocacy (Twitter), blogging, and a forum (Multimedia Appendix 1). The Facebook group was initially open (setting for anybody to see group members and their posts) to attract new membership and then closed (setting for only members of the group) to protect the confidentiality of the information posted. A launch event provided training and registration.

Moderation

In line with most existing Web platforms that moderate posts and comments before publishing [25], the GMKIN was moderated by a manager (CV) and a patient (P1) as follows:

- GMKIN Platform: Blogs (patients' stories) were screened prior to publication on the hub. Those with potential health risks were referred to a multidisciplinary group of health care professionals who signposted patients to a relevant service. Comments posted relating to blogs were approved by either the moderators or the author of the blog.
- GMKIN Facebook: Moderators screened each post following update notifications.

The manager actively encouraged and motivated members to take an active role in the GMKIN to influence community growth and foster underlying psychological bonds. Community commitment and relationship building were facilitated by using the principles of social capital (bonding, bridging, and linking) [28,29], which involved creating an identity based on local interest (North West), shared values, interests, and goals, reaching broader audiences with an informal tone and humor.

Phase Two: Longitudinal Evaluation

Phase two aimed to explore patients' engagement with the hub, information generation, and health and social outcomes.

Data Collection

Quantitative and qualitative data collection tools (Table 1) were used to obtain multiple perspectives, capture user experience. Interviews were conducted at a location convenient for the participant (hospital, home, or university setting), lasted 1-2 hours, and were audiorecorded.

This created an in-depth rich triangulated data set from which to draw the conclusions.

Table 1. Data collection methods.

Data collection method	Tool	Purpose
Quantitative Self-efficacy scales (two scales; at 0 and 6 months)	• General Perceived Self-Efficacy Scale [30] • Self-Efficacy for Managing Chronic Disease 6-Item Scale [31]	Used as a barometer to identify the difference in self-efficacy after becoming involved in the GMKIN
Activity data/researcher observation (throughout)	Complement weekly logs by collecting activity data (eg, inbuilt analytics within the website software [WordPress plugin]) and monitoring engagement via manual monitoring of Facebook and twitter	Create individual profile of monthly activity and interactions and identify platform usage
Qualitative interview at 0 and 6 months	Semi-structured interview	Understand the context of each patient entering the study and gain in-depth knowledge on key themes explored: levels of engagement, role of each platform, information needs, and outcomes
Patient logs/blogs (throughout)	Blogs posted on the platforms (using WordPress). Self-reported weekly activity logs, using Google docs, of GMKIN activity to capture rich descriptions of *"real life"* [32]: 11 across space and time	Understand levels of engagement, what works, and why

Data Analysis and Synthesis

The data were collected, analyzed, and synthesized by the GMKIN Manager and lead researcher (CV). Methods to reduce bias included multiple methods of data collection (eg, checking interview statements against patient activity) and checking coding of interview transcripts with other members of research team.

Quantitative Data

The quantitative data from the self-efficacy scales were analyzed to determine the mean score of the six items by using descriptive statistics in Microsoft Excel (Microsoft Corporation, Redmond, Washington). The higher the score, the higher the indication of self-efficacy. A *t* test was performed to determine if the results were statistically significant between baseline and follow-up. As the small sample size was unsuitable for any further statistical test, the Self-Efficacy for Managing Chronic Disease 6-Item Scale (CSE) and General Perceived Self-Efficacy Scale (GSE) scores were used to as a barometer to inform the discussion within the context of patient interviews, rather than demonstrate effectiveness.

Activity Data/Patient Logs/Blogs

Activity data were collected using a WordPress plug-in for patient blogs and manual observation of Facebook posts and Twitter feeds.

Interviews

Baseline and 6-month data were analyzed using a case and thematic analysis to describe and map conceptual findings [32] in relation to context mechanisms and outcomes [22]. Baseline data were used to create a framework, which created a starting point for analysis of the 6-month data.

Data Synthesis

A framework (matrix) approach was used to synthesize cross-sectional descriptive qualitative data using the following steps:

- Matrix development from themes identified from a literature review [33]
- Theming and mapping the interviews against the framework. The matrix was expanded to include the new themes.
- Data were compared and contrasted across individual cases to explore contextual factors and patient outcomes.
- Activity data were used to create individual case engagement logs.

Results

Sample

Figure 1 provides an overview of the participants and network activity throughout phases 1 and 2. A total of 15 patients and health professionals were involved in the hub design; 50 patients attended the launch event (phase 1), and 14 separate participants are reported in the longitudinal evaluation (phase 2). Participants in the evaluation phase spanned a range of ages, with a comparable number of male and female participants, and included people at different stages of chronic kidney disease, receiving different treatments, and a carer.

Quantitative Results for Self-Efficacy

Table 2 shows that 13 of 14 patients indicated an increase in self-efficacy at least for one of the instruments from baseline to 6 months, with one reporting a decrease in self-efficacy. It is worth noting that patients who reported that they were had depression before or at the point of joining the GMKIN (P1, P5, and P12) increased their self-efficacy across all domains within the first 6 months.

Activity data revealed three engagement roles: influencers, conversationalists, and browsers [25]. There was one *influencer* who described engagement as a facilitator of meaningful relationships among users through light discussions, sociability, and support of prospective leaders. Four *conversationalists* were crucial to sustaining conversations and contributed to content creation and provision of feedback, while nine *browsers* read and collected information and preferred to engage in this way,

because they perceived that they did not have enough knowledge or experience to share. An important finding is that patients from all different roles of engagement (influencers, conversationalists, and browsers) benefited equally in terms of self-efficacy. This was further reinforced by the qualitative findings (see below).

Table 2. Self-efficacy trend for Self-Efficacy for Managing Chronic Disease 6-Item Scale and General Perceived Self-Efficacy Scale.

Patient	GMKIN[a] role	iPad access	Age group	Modality	Gender	CSE[b]		GSE[c]	
						Change in self-efficacy	*P* value	Change in self-efficacy	*P* value
P1	Influencer	No	51-60	Transplant	Male	+[d]	0	+	.1
P2	Browser	Yes	51-60	Dialysis	Male	+	.46	+	.05
P4	Browser	No	<30	Carer	Male	+	.7	+	.1
P5	Browser	Yes	41-50	Dialysis	Male	+	.03	+	<.001
P12	Browser	Yes	<30	Predialysis	Female	+	.03	+	.002
P8	Browser	No	>61	Transplant	Male	+	.03	No change	Not applicable
P6	Browser	No	<30	Transplant	Male	+	.36	–[e]	.1
P14	Browser	Yes	31-40	Dialysis	Female	–	.14	+	.03
P13	Browser	Yes	51-60	Dialysis	Female	+	.08	–	.61
P7	Browser	No	>61	Predialysis	Female	–	.08	+	0
P3	Conversationalist	No	>61	Predialysis	Male	–	.47	+	.6
P11	Conversationalist	Yes	41-50	Dialysis	Male	–	.01	+	.06
P9	Conversationalist	Yes	31-40	Predialysis	Female	+	.79	–	.002
P10	Conversationalist	No	<30	Predialysis	Female	–	.04	–	.008

[a]GMKIN: Greater Manchester Kidney Information Network.

[b]CSE: Self-Efficacy for Managing Chronic Disease 6-Item Scale.

[c]GSE: General Perceived Self-Efficacy Scale.

[d]+: increase in self-efficacy.

[e]–: decrease in self-efficacy.

Qualitative Findings (Information Needs and Outcomes)

Regardless of engagement role, patients' information needs were satisfied and outcomes were improved as described below.

Information Provision to Satisfy Information Need

Patients reported in interviews that the patient-generated content shared in the form of blogs, posts, and tweets provided them with valuable information. Most respondents identified that through the GMKIN, they gained an understanding of the condition and its living implications:

> *I think it's kind of triggered me to go and look at other things, and go and find out things, and I've learnt things that I didn't know; like now, I know that there is, you can do home dialysis, which I never thought of.* [P12]

They learned about the different treatment options such as hemodialysis (HD), peritoneal dialysis (PD), home dialysis, and monitoring the progression of the disease:

> *To be quite honest with you I did not know the difference between HD and PD, I do now, but even before dialysis, that was it, I did not realise that were different forms of dialysis and this is something I picked up – just an example there are many things I picked up.* [P3]

Accessing information such as new clinical developments and people's positive stories provided patients with the mechanisms to cope with the condition and give them hope for the future:

> *I have learnt this from a lot of people listening to their story that in relative terms my journey has not been easy but it's been absolutely a piece of cake compared to what other people gone through and that's made me realise perhaps my quality of life is better than what I was perceiving it beforehand.* [P1]

Patients explained how other people's stories and updates helped them identify their own symptoms and develop management strategies:

> *The long-term effect of kidney disease is one of those things you don't really know about...I read yesterday a link to her [patient] own blog, about anti-inflammatories, which I found quite interesting because I suffer a lot with sinus problems and I take anti-inflammatories which are bad for kidney...but they never tell you why, so I found out... I thought - I*

> *have been fine I have used them before so to take them again will not be too bad - but reading the post its best not to.* [P10]

The interviews demonstrated that patients were unaware of their information deficits. Some indicated that they had been told that the illness had progressed, but they only realized the implications after seeing other people's symptoms on GMKIN:

> *I didn't realise that the pains in my legs was due to my kidneys until somebody was writing it on.* [P7]

Importantly, engaging via the GMKIN gave patients confidence and a purpose, believing it could help others:

> *It has given me purpose… it has given me more focus. I have not allowed things like fatigue or lack of concentration to stop me. It has given me a motivation that was missing before that motivation is primarily to help others. I am feeling like genuinely helping other people, I think that is the essence of what we are like human beings this gives us the opportunity, GMKIN gives the opportunity to do it.* [P1]

Some patients, especially those new to chronic kidney disease, found the information overwhelming, but synthesized information pertinent to them to manage their condition better:

> *I'll stop reading, then I try to put what they have said into my own mind to stop me doing certain things that I should not do to help to keep my kidney function.* [P7]

> *Discussing things like drugs or having discussions about the problems with getting supplies delivered…I really, really struggled and I've got to the part where I was talking to my partner and I was considering phoning you up and saying: No, I don't want it.* [P12]

Health-Related Outcomes (Self-Efficacy, Self-Management, and Psychological Benefits)

The study revealed a positive impact on patient's self-efficacy and self-management, which can be seen as a means toward achieving more quantifiable health outcomes such as improved kidney function. These are reported below, and in more detail, using patients' stories in Multimedia Appendix 2.

Shared (vicarious) experiences and social persuasion contributed to an increase in self-efficacy, a key feature in the management of long-term conditions:

> *I think it helped me that he is going through so much and has dealt with the condition for such a long time and lived a positive normal life.* [P9]

Furthermore, patients who engaged with GMKIN reported better ability to self-manage the condition:

> *Watching and listening to what others are saying has helped me to sort my life out by managing my diet.* [P7]

Patients reported other psychological benefits including increased confidence and feeling generally better about themselves.

> *It's almost been like a snowball effect, because once I've got over the kind of the shock and I dealt with things I recognised how the community on GMKIN was actually really helpful…and because I'd dealt with my issues I felt comfortable in getting involved in other things and that has increased my confidence.* [P12]

> *I don't think I would have engaged with her before GMKIN I would not have felt confident enough in myself to be able to hold my own in a conversation with someone who clearly knows a lot about not just programme management but also renal problems and that is given me enormous satisfaction but again added to the boost in self-confidence.* [P1]

Accessing peer stories (although overwhelming for some) encouraged participants to make changes in their self-management to preserve their kidney function:

> *The condition and anything I can do to maintain a healthy lifestyle: eating the right food, drinking the right things, where to get travel insurance from, just general day to day things which is helps.* [P8]

Social Outcomes

In addition to health, GMKIN engagement demonstrated an impact in a range of social areas. A number of patients reported that they were now considering employment:

> *Entertaining the idea of getting some proper employment again and that would be an achievement. I never thought I do certainly giving the past 10 years in my life already didn't think I could get to that point again.* [P1]

> *'I applied for two jobs one with the kidney association, one of them I had to write things down, like an email.* [P2]

Patients who received an iPad acknowledged that it was enormously beneficial. One patient indicated that the iPad is his lifeline, which enabled him to be socially connected:

> *This is my lifeline [iPad]...this [iPad] is everything in one and then if you don't want to watch anything at least you can look at someone else's feelings read their things on GMKIN and if you want to know medical things, diet things everything is in one place, just look you don't have to get bored.* [P5]

Another indicated that it enabled him to gain an interest in drawing:

> *I had never drawn so much then I had these past. Well I suppose since I've got the iPad, really. It's influenced me a lot and my life and it's helped me to sort of put away the troubles and stuff and just concentrate on the drawings.* [P13]

The affiliation with the community through bonding, bridging, and linking mechanisms such as light and friendly conversations (welcoming messages), social support, and the human touch (personal photos) suggested that GMKIN enabled trust, social camaraderie, friendship, and affection (or social capital) to be developed:

I just think it is amazing that people had the time to kind of develop something good for the condition, it is really nice that people are going on there and helping each other through, in this day and age when you read all this horrible stories and there isn't much of social camaraderie really that people are taking the time and effort to support complete strangers through the condition. [P9]

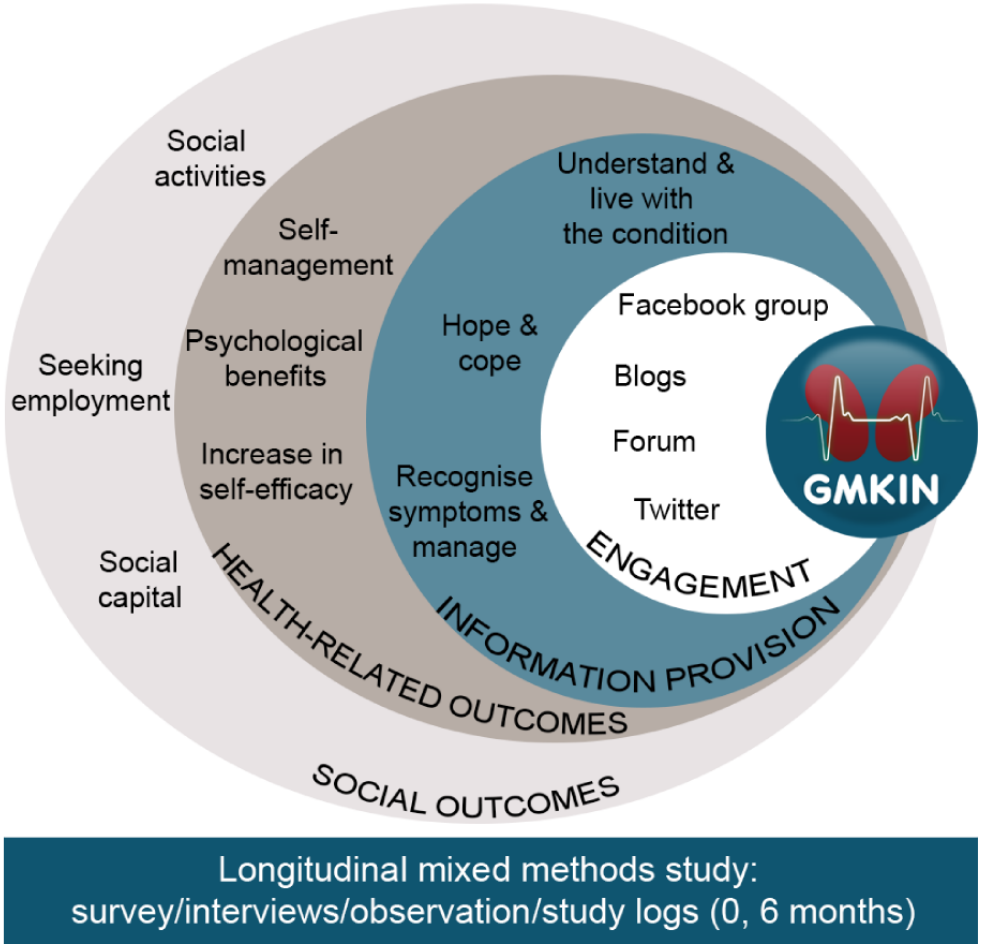
...bond in the sense, you know all this people, a bit of empathy and a bit of you know obviously banter and that it is good. [P3]

Discussion

Principal Findings

This study used longitudinal data sets with a variety of quantitative and qualitative methods to enhance validity and rigor (Figure 1). It demonstrated that patient-generated information shared via social media contributes to satisfaction of information need and triggers positive health-related and social outcomes (Figure 2). These outcomes were achieved regardless of the way or extent to which patients engaged with the hub. This has wide-ranging and potential value in establishing similar hubs or online networks for others with long-term conditions and in contributing to national and international policy initiatives of promoting self-management [4-6].

Figure 2. Overview of the findings. GMKIN: Greater Manchester Kidney Information Network.



The findings are in line with previous research in that social media contributes to an increase in self-efficacy [21]. Individuals draw on four different types of sources to discern self-efficacy: enactive mastery experience, vicarious experience, social persuasion, and physiological and emotional state [34]. Enactive mastery experience was linked to experiences in contributing to GMKIN and receiving positive feedback, which increased patient confidence in their ability to help other patients. Patients who engage in conversations with fellow community members are benefiting from accessing experiential information from peer stories [35]. Patients indicated that seeing other people's stories had given them a new outlook on life, reducing negative perceptions of being different. The positive feedback posted by conversationalists on the GMKIN Platform and GMKIN Facebook encouraged patients to engage in posting and increased their self of worth and thus self-efficacy. Three patients with self-reported depression reported a statistically significant increase in at least one domain of self-efficacy of the GSE [30] or CSE [31]. This confirms previous research acknowledging the benefit of social media in increasing self-efficacy of patients with depression [36]. Bessière and colleagues [36] identified that using the Web for health information alone could increase depression, but using it to connect with friends will have a positive effect [36]. It is

believed that the dual purpose of Facebook (friends and health) and the social capital developed through the network contributed to the positive effect [25]. In addition to the health-related outcomes, three patients intended to seek employment as a result of their involvement in GMKIN. This finding is unique to this study and is described as a social outcome of social media.

Although previous research highlighted that Facebook and blogs contribute to information generation [37-39], this study demonstrates that this information generation meets the previously identified information needs of kidney patients [10] such as living with the condition, symptoms, and expectations and self-management. These information needs are in line with information needs for other long-term conditions [12,40,41], suggesting wider potential application of the model.

This study also exposed that patients had unknown information deficits; for example, a participant indicated that he had not known about the different forms of treatment available until he read it on the network. Others measured themselves against patient stories and realized that they were not as ill as they had previously believed. By being part of the community and disclosing information, patients learned about their illness and how to self-manage it.

The GMKIN did not appear to work for everyone: Two patients dropped out because it was not fulfilling their needs and one remained in the sample but suggested in the interview that it did not work for him personally.

Limitations

Although the study appeared to facilitate better health outcomes as a result of self-management, it is not clear whether this is directly linked to an increase in self-efficacy, as the quantitative findings are too small to be generalizable. However, the self-efficacy scores were used as a barometer to discuss self-efficacy further with patients and these qualitative data from interviews and direct observations of patients were in line with the quantitative scores.

Wider Impact

Although not measured in the evaluation, one of the most significant outcomes of the project is a patient-led expansion to other UK regions. Patient-generated evidence of impact (Multimedia Appendix 2) is used to encourage other Kidney Patient Associations to join the GMKIN while retaining local autonomy. This has already been taken up in two other regions (Multimedia Appendix 3). Furthermore, responsibility for the network has been transferred to the patients, while the manager retains a supportive role and focuses on developing a new national model of patient-generated social media kidney disease support. More widely, knowledge generated through the GMKIN has contributed to the development of national guidance on the use of social media for patient and public engagement [42], and the theoretical learning regarding social media and engagement has influenced other initiatives linking patients/users and professionals via social media including antenatal care [43], rheumatic and musculoskeletal conditions (Multimedia Appendix 4), and prevention of the exploitation of young people [44].

Conclusions

This mixed methods longitudinal study successfully co-designed and implemented a social media hub with patients and practitioners on the basis of the theory on engagement [24] and patient information needs for chronic kidney disease [10,23]. Patients within the online network used the hub to generate information about their long-term condition, which satisfied their information needs (including those they were unaware of), increased self-efficacy, and facilitated overall better health management and health and social outcomes. The positive outcomes achieved from this model has led to the development of a new national model of patient-generated information provision for those with kidney conditions via social media and influenced the theoretical development of other patient-focused social media initiatives and policies.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Gmkin link.
[DOCX File , 25 KB - formative_v4i1e13207_app1.docx]

Multimedia Appendix 2
Patient voices.
[DOCX File , 27 KB - formative_v4i1e13207_app2.docx]

Multimedia Appendix 3
Uptake of gmkin.
[DOCX File , 25 KB - formative_v4i1e13207_app3.docx]

Multimedia Appendix 4
Uptake rheumatic and musculoskeletal conditions.
[DOCX File , 26 KB - formative_v4i1e13207_app4.docx]

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Abbreviations

CSE: Self-Efficacy for Managing Chronic Disease 6-Item Scale
GMKIN: Greater Manchester Kidney Information Network

GSE: General Perceived Self-Efficacy Scale
HD: hemodialysis
PD: peritoneal dialysis

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Original Paper

Development of a Mobile Phone App to Promote Safe Sex Practice Among Youth in Stockholm, Sweden: Qualitative Study

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Abstract

Background: Mobile health (mHealth) has been shown to be effective in increasing knowledge of sexual health among youth. To date, evaluations mostly refer to interventions delivered via computer, email, and text messages. The possibility of downloading apps on mobile devices has opened up opportunities to develop engaging interventions on safe sexual health promotion. To attract young users and have them engage with a sexual health app, it is important to involve youth in intervention development.

Objective: This study aimed to obtain input from youth on the content of a mobile phone app intended to promote safe sex and increase condom use among youth in Stockholm.

Methods: This study was conducted at the Youth Health Clinics (YHC) in Stockholm County, Sweden. A total of 15 individual in-depth interviews and 2 focus group discussions (with youth aged 18-23 years) were conducted at the YHC in Stockholm. Areas explored were: (1) youth perceptions of condom use (advantages and obstacles), (2) perceptions of mHealth to promote safe sexual practices, and (3) content development for a mobile phone app to promote safe sex.

Results: The smartphone app was developed based on the categories that emerged from the data. With regard to content, youth requested sex education, including information on sexually transmitted infections. In addition, condom-specific information, including practical usage technique, advice on how to have the condom talk, and how to decrease shame related to condom use, was requested. Youth suggested different modes to deliver the content, including text messages, movie clips, and push notifications. It was suggested that the tone of the messages delivered should be fun, entertaining, and supportive. The inputs from youth influenced the development of the following sections of the app: *Condom Obstacles and Solutions*; *Quiz*; *Games*; *Self-Refection*; *Challenges*; *Stories by Peers* (stories from peers and information from a doctor); *Condom Tips, Pep Talk, and Boosting*; and *Random Facts*.

Conclusions: It is important to use input from youth when developing a smartphone intervention since the success of the intervention largely depends on the level of engagement and usage by youth. Furthermore, if proven efficient in increasing condom use, it is important that the development, including content and mode, is thoroughly described so that the intervention can be replicated. Likewise, if proven inefficient, it is important to learn from mistakes to improve and adjust the intervention. The effect of this smartphone app on safe sexual practices among youth is being evaluated in a pragmatic randomized controlled trial in Stockholm (ISRCTN13212899) and will be reported separately.

(JMIR Form Res 2020;4(1):e12917) doi:10.2196/12917

KEYWORDS

mHealth; youth; sexual health; condoms; Sweden

Introduction

Background

Sexual risk taking, including multiple sexual partners, sex outside stable relationships, and sex without a condom, has increased among Swedish youth over the past years [1-3]. In addition, *Chlamydia trachomatis* infections have steadily increased since the mid-90s, and young people aged 15 to 29 years account for 85% of all infections in the country [4]. These reports indicate that efforts, such as sex education in schools, accessibility to youth friendly clinics, and widespread testing for sexually transmitted infections (STIs), need to be complemented with new innovative interventions to reduce the burden of these infections among youth.

Mobile health (mHealth), that is, using mobile devices to address health priorities, has been shown to be effective in promoting elements of sexual health, such as increased broad knowledge regarding sexual health, increased testing for STIs, and condom use, among youth [5,6]. To date, evaluations mostly refer to interventions delivered via computer, email, and text messages [5,6]. The possibility of downloading apps on mobile devices has opened new opportunities to develop and distribute engaging health promotion interventions [7]. Health promotion via apps is suitable for youth who are a tech-savvy population that spends a significant amount of time on their mobile phones. It has been reported that this population checks their smartphones as often as 300 times per day [8]. In addition, the coverage of mobile phone ownership is high; 98% of the Swedish population owns a mobile phone, and 92% of these are smartphones [8]. To attract young users and get youth to engage with an app on sexual health, it is important to involve the target group in the development of the intervention [9-11].

We developed a mobile phone app to increase sexual health and condom use among youth. We used 2 different models of behavioral change. The transtheoretical model (TTM) is a model that conceptualizes the process of intentional behavior change and includes the following different stages of change [12]: *precontemplation*—not ready for a change, *contemplation*—getting ready for a change, *preparation*—intends to take action within the foreseeable future and has taken some behavioral steps in this direction, *action*—changed behavior, and *maintenance*—adheres to the new behavior. In a subsequent randomized controlled trial (RCT), youth with high-risk sexual behavior will be included. We, therefore, assumed users of the app to be at the *precontemplation* stage when entering the intervention study. The app was designed to help participants move through the different stages of change toward a new behavior. The second integrated behavioral model (IBM) contains 5 components affecting behavior [13]: *behavioral intention*, which is determined by attitudes, perceived norms, and personal agency; *knowledge and skills* to carry out the behavior; *importance to the individual*, *environmental constraints* that make behavioral performance difficult; and *habit* (experience performing the behavior and the behavior will become habitual). The IBM was taken into account while developing different self-reflecting exercises in the app.

Objectives

The objective of this study was to describe exploratory work with youth from Stockholm County to obtain their input on the content of a mobile phone app to promote condom use. Feedback from participants are to be incorporated subsequently into the app, which will then be tested at the Youth Health Clinics (YHC) in Stockholm County.

Methods

Setting

This study was conducted at the YHC in Stockholm County, Sweden. There are 250 clinics in the whole country and 33 in Stockholm County [14,15].

Participant Selection

A total of 15 individual in-depth interviews with youth at the YHC and 2 focus group discussions (FGDs) were conducted. Interviewed participants were selected purposefully using heterogeneous sampling [16] so that youth from different socioeconomic areas were represented. For the FGDs, youth who were clients of the YHC were invited to participate. Sociodemographic characteristics of the participants are presented in Table 1.

Table 1. Sociodemographic characteristics of participants in individual interviews and focus group discussions.

Population characteristics	Individual interviews (n=15)	Focus group discussions (n=10)	Total (N=25)
Sex, n			
Male	7	4	11
Female	8	6	14
Age (years), range	18-22	18-23	18-23
Origin, n			
Swedish	10	9	19
Non-Swedish	5	1	6
Socioeconomic, n			
High	3	5	8
Middle	6	3	9
Low	6	2	8

Data Collection

Interviews with youth aged 18 to 23 years were performed from April 2015 to August 2016 (7 males and 8 females). Interviews with youth were performed by the first author (AN) in Swedish. They were recorded and transcribed verbatim. The FGDs were held in October 2016 and November 2016. The first FGD had 4 female participants, whereas the second FGD had 2 females and 4 males. The FGDs, supported by 3 members of the research team, were recorded; notes were taken; and a summary of notes and the recordings were made. Individual interviews were conducted to enable exploration of the sensitive subject of sexual health, and FGDs were held to allow for inspiring exchanges and development of new ideas. All participants stated heterosexual preferences.

Areas Explored

The questions posed in the interviews and FGDs originated from preknowledge regarding low condom use among youth in Sweden and the current primary and secondary prevention strategies for STIs. The areas explored were as follows:

- Why do you think condom use is low among Swedish youth?
- What is positive with condom use?
- What do you think about mobile phones to reach young people with health messages?
- Could a smartphone app work to mediate safe sexual practices?
- What would such an app contain?
- How could the app be made attractive to youth?
- Mode and timing of push notifications (message/reminders to engage in activities) in the app.

Data Analysis

The recordings and transcripts were listened to and read through on several occasions. Data were divided into 3 different categories, which were directly related to the areas explored and the suggestions from youth regarding what the app should contain, how the content should be delivered, and what tone should be used. Subcategories that emerged from the data were organized under each of these main categories as a result of parallel analysis and mutual in-depth discussions between researchers.

Planned Duration of the Intervention

The intervention duration was intended to be 180 days. This duration was chosen based on previous research that had shown a positive effect on condom use for an mHealth intervention lasting less than 6 months, with decreasing effect over longer follow-up periods [5].

Ethical Considerations

Written informed consent was obtained from each participant. The study was approved by the Stockholm Regional Ethical Board (reference number 2013/1399-31/2, with amendment 2015/739-32).

Results

The team that developed the app had varied backgrounds, including YHC staff working with youth (eg, midwife) and in public health, medicine, information technology (IT), and behavioral science. The smartphone app (subsequently named *Skyddslaget* or *Protection Team*) was developed based on the main categories and subcategories that emerged from the data from interviews and FGDs. The main categories were app content, app mode, and app tone. Suggestions for the content, mode, and tone and the subcategories are presented in Textbox 1.

Discussions regarding low condom use among the youth in Sweden and obstacles to condom use (eg, embarrassing to mention and loss of sensation) as well as positive aspects of using protection generated subcategories under app content. For example, youth requested sex education, including STI information, and, additionally, condom-specific information, including practical usage technique. Youth also requested advice on how to have *the condom talk* and decrease shame related to condom use.

While discussing how the app should be made attractive to youth, study participants suggested different modes to deliver the content, including text messages, movie clips, and push

notifications. To retain the interest in the app, new information should be added into the app. Youth suggested that the tone of the messages delivered should be fun, entertaining, and supportive. In addition, youth requested that content from peers should be added.

During the subsequent process, the inputs from youth (Textbox 1) influenced the development of the following different sections of the app: *Condom Obstacles and Solutions*; *Quiz*; *Games*; *Self-Refection*; *Challenges*; *Stories by Peers* (stories from peers and information from a doctor); *Condom Tips, Pep Talk, and Boosting;* and *Random Facts.* The different sections of the app were related to the content, mode, and tone requested by participants. For example, in the *Condom Obstacles and Solutions* section, information on condom technique and exercises on how to suggest a condom to your partner were included. The names of the sections and the material presented in the different sections were developed by the research team. As described, the TTM was chosen as the theoretical framework for intervention development. In the modified TTM, each stage lasted for 30 days and aimed to help youth move from one stage to the next and thereby achieve behavioral change.

At the beginning of the intervention, the precontemplation phase, the messages included general educative information regarding the benefits of safe sexual practices, taking into account that the participants were not yet ready for a change. As the intervention evolved, the content became more oriented toward behavioral change by asking participants to reflect upon individual reasons behind sexual risk taking and benefits of a new behavior. Toward the end, the messages aimed to support the new behavior.

Textbox 1. Requests from youth regarding the content, mode, and tone of the app.

Content

- Information regarding sexually transmitted infection
- Sex education
- Condom information
- Increase self-confidence related to condom use
- Condom technique
- Preparation for the condom talk
- Decrease shame and stigma related to condom use
- Alcohol and unsafe sex
- Questioning norms (sex with condom is not good)
- Normalizing condoms

Mode

- Games
- Weekend condom reminders
- Movie clip
- Imagery (emojis)
- Text (not heavy)
- Quiz
- Push notifications
- Adding new information to retain interest
- Interactive

Tone

- Fun and entertaining
- Supportive
- Containing pep talk
- Allowing
- Scaring (the “light version”)
- Identifying with peers
- Encouraging

The self-reflecting and pedagogical tasks in the app were based on the IBM. These tasks addressed feelings, thoughts, experiences, attitudes, and perceived self-control in relation to condom use and unprotected sex and were mainly found under the *Condom Obstacles and Solutions* and *Self-Reflection* categories. Self-reflection was introduced during the preparation and action phases. Identification with peers was strongly suggested by youth and was included in the *Stories by Peers* category (peers tell their story), and this aimed to create a sense of identification and thereby eliminate possible feelings of shame related to a behavior. On each day of the intervention, at least one condom tip was posted (under the category *condom tip*). The aim was to inform about different condom types and sizes and to normalize condoms by daily exposure. In addition, push notifications were used to inform users that new content had been added into the app. Every Friday evening, a condom reminder push notification was sent out to participants. Figures 1 and 2 show details of the app (screenshots). Table 2 presents the different sections of the app with the TTM stages of change.

Content was added to the app on a daily basis for 180 days. The function and content of the app were initially piloted among 10 users. The pilot users requested more attention to be drawn to the app during the first weeks of usage; this resulted in an increase in the number of push notifications sent to the participants during the first and second week of the intervention. In addition, there were a number of minor technical support issues from the app development side that needed attention. For example, when opening the push notifications, the user was not redirected to the app, and all weekend reminders (N=26) were posted on the first Friday of the intervention.

Figure 1. Screenshot of the intervention.

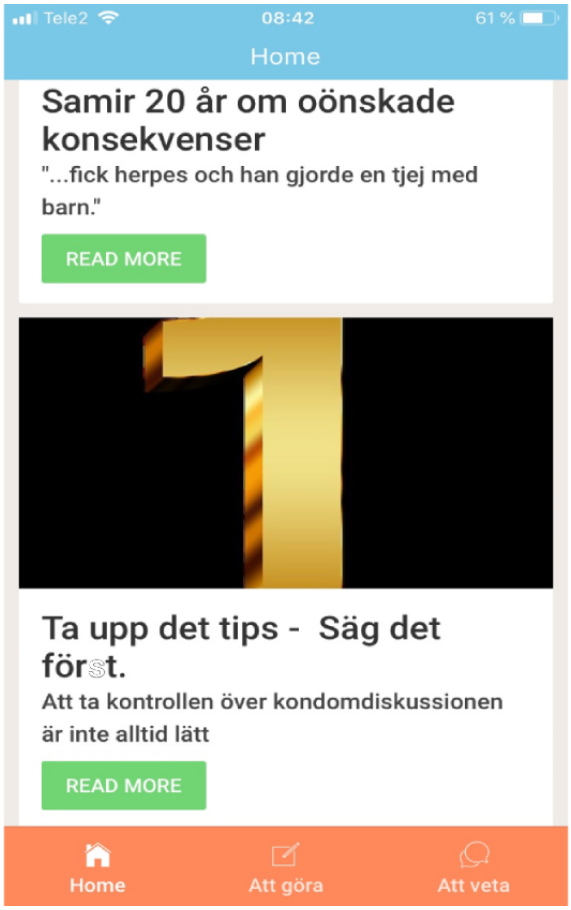

Figure 2. Screenshot of the intervention.

Table 2. App sections with examples of content in the different stages of change according to the transtheoretical model.

App sections	Precontemplation (no intention to take action)	Contemplation (intends to take action)	Preparation (ready to act toward safer behavior)	Action/decision (changed behavior)	Action/normalize (normalizing new behavior)	Maintenance (maintaining new behavior)
Condom Obstacles and Solutions	Practice makes perfect—use a condom during self-sex	Examples of comebacks if someone refuses a condom	Finding the best fit in relation to size and shape	Let go of negative attitudes toward condoms	—[a]	Advanced comebacks related to noncondom users
Quiz	Professional condom user or beginner? Do the test here.	Would you have sex with someone who…?	Will you stick with your condom decision when drunk?	Which lubricant to which condom?	About different STIs[b]	Make condoms sexy
Games	—	—	Icebreaker: discuss condom use with friends	Discuss condoms in an intimate way with a partner	—	—
Self-Reflection	How would you feel if someone suggested a condom?	Are you affected by others' opinions about condoms?	Are you letting your feelings take over your decision?	Holding on to your decision	Are you letting others decide what/who/when/how?	Looking back: summarizing new knowledge and behavior…
Challenges	—	—	—	Bring a condom with you for the coming 10 days	Talk about condoms, mention condoms	Pick your own challenge for the future
Stories by Peers	Doctor provides information on different STIs	Eric, 22 years: "I sometimes think about what can happen if I don't use a condom."	Philippe, 21 years: "She kept the baby and moved abroad."	Kim, 20 years, on getting herpes, "It is so not worth it."	Ellen, 18 years, on alcohol and unsafe sex	Adina, 21 years: "I took the decision early on to always use a condom."
Condom tip	Condom of the day	Condom of the day	Condom of the day	Condom of the day	Condom of the day	Condom of the day
Pep talk	Increase the chance of using a condom by bringing one	Expose yourself to condoms	Love yourself—you do not have to agree to have sex without a condom	Do not forget to practice your new skills	Forget the feelings of embarrassment, just say it	You have all the knowledge now
Random facts	The World Health Organization's definition of sexual health	Did you know circumference is the most important aspect of condom fit?	Which lubricant for which condom	Information about femindom	History of the condom	Anecdotes

[a]Not applicable.

[b]STI: sexually transmitted infection.

Discussion

We used the data from FGDs and individual interviews with youth belonging to the target group to develop the content, mode, and tone of a mobile phone app to promote safe sex. Heterogeneous sampling was used, which allowed for input from youth of different backgrounds to be explored. It is important to use input from youth as the success of the intervention largely depends on their level of engagement and usage. The content and the mode of delivery were directly obtained from discussions with youth, which could possibly increase the level of interest among the target group. Input from youth were embedded into existing frameworks that were previously proven to be successful (TTM and IBM) [17].

A program delivered via a mobile phone app is unique as most previously evaluated mHealth interventions for sexual health were delivered via text messages and websites [5]. In addition, the intervention time of 180 days is longer than what was previously reported. Previous evaluations of the effects of technology-based programs indicate that, specifically for condom use, stronger effects were found in short-term interventions (ie, 1- to 5-month follow-up) compared with studies that evaluated intervention effects for a duration of 6 months or more [5,6]. The lack of long-term sustainability is a problem with the short-duration interventions previously reported. There is no report on the sustainability of effect with long-term (≥6 months) interventions.

This study presents a number of valuable lessons for future app developers. Based on the strengths and limitations of the process

we used to develop our app, the following should be taken into consideration:

- Organize more FGDs so that a variety of views, some possibly divergent, can be obtained. Discussions among the project team members on divergent views better inform intervention development.
- Be present during interactions with youth to raise the right questions and address limitations of the technology. Health professionals should also be present.
- Run past iterative versions of the intervention as it is in the process of development with users, so that there are multiple opportunities to test and change. This requires an investment of time over a reasonably long period, which was a constraint during the development of the intervention in this study.
- Once the intervention has been developed, pilot test for a month with a small closed group to ensure any persisting bugs are removed.

mHealth interventions are particularly suitable for youth and sexual health promotion as the intervention is delivered in a familiar and discrete way to at-risk population [18]. Analysis of the *MObile phone for SEXual health in Youth* trial where the *Skyddslaget* app was subsequently evaluated in a pragmatic RCT will be reported separately [19].

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Conflicts of Interest

None declared.

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Abbreviations

FGD: focus group discussion
IBM: integrated behavioral model
IT: information technology
mHealth: mobile health
RCT: randomized controlled trial
STI: sexually transmitted infection
TTM: transtheoretical model
YHC: Youth Health Clinics

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Short Paper

Challenges and Lessons Learned From a Mobile Health, Web-Based Human Papillomavirus Intervention for Female Korean American College Students: Feasibility Experimental Study

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Abstract

Background: Mobile health (mHealth) and Web-based research methods are becoming more commonplace for researchers. However, there is a lack of mHealth and Web-based human papillomavirus (HPV) prevention experimental studies that discuss potential issues that may arise.

Objective: This study aimed to assess the feasibility of research procedures and discuss the challenges and lessons learned from an mHealth and Web-based HPV prevention experimental study targeting female Korean American college students in the United States.

Methods: A pilot randomized controlled trial (RCT) was conducted in an mHealth and Web-based platform with 104 female Korean American college students aged 18-26 years between September 2016 and December 2016. Participants were randomized to either the experimental group (a storytelling video intervention) or the comparison group (a nonnarrative, information-based intervention). Outcomes included the feasibility of research procedures (recruitment, eligibility, randomization, and retention).

Results: From September 2016 to October 2016, we recorded 225 entries in our initial eligibility survey. The eligibility rate was 54.2% (122/225). This study demonstrated a high recruitment rate (95.6%, 111/122) and retention rate (83.7%, 87/104) at the 2-month follow-up.

Conclusions: Findings from this study demonstrated sufficient feasibility in terms of research procedures to justify a full-scale RCT. Given the increased possibility of invalid or misrepresentative entries in mHealth and Web-based studies, strategies for detection and prevention are critical.

Trial Registration: ISRCTN Registry ISRCTN12175285; http://www.isrctn.com/ISRCTN12175285

(JMIR Form Res 2020;4(1):e14111) doi:10.2196/14111

KEYWORDS

mHealth; Web-based intervention; fraud; experimental design

Introduction

Background

Korean American women (11.9 per 100,000) are disproportionately affected by cervical cancer compared with the overall population of women in the United States (7.2 per 100,000) [1]. Korean American women have been consistently identified as the least likely subgroup to receive cervical cancer screenings [2,3]. Despite growing evidence showing the benefits of human papillomavirus (HPV) vaccines in preventing cervical cancers, there are few population-based data on HPV vaccination behavior and intervention studies to promote HPV vaccination behavior for young Korean Americans [4,5].

Mobile health (mHealth) and Web-based research methods are increasingly common as a tool for research and research settings [6]. In particular, online outreach is the most effective recruitment method for young, bilingual Korean Americans [7]. Despite this significant potential, there are minimal HPV intervention studies that discuss issues specific to mHealth and Web-based studies of particular populations.

Objective

To fill this gap, this study aimed to (1) assess the feasibility of research procedures (recruitment, eligibility, randomization, and retention) to inform a future randomized controlled trial (RCT) of an mHealth and Web-based HPV prevention program targeting young Korean Americans and (2) discuss the challenges and lessons learned from an mHealth and Web-based study.

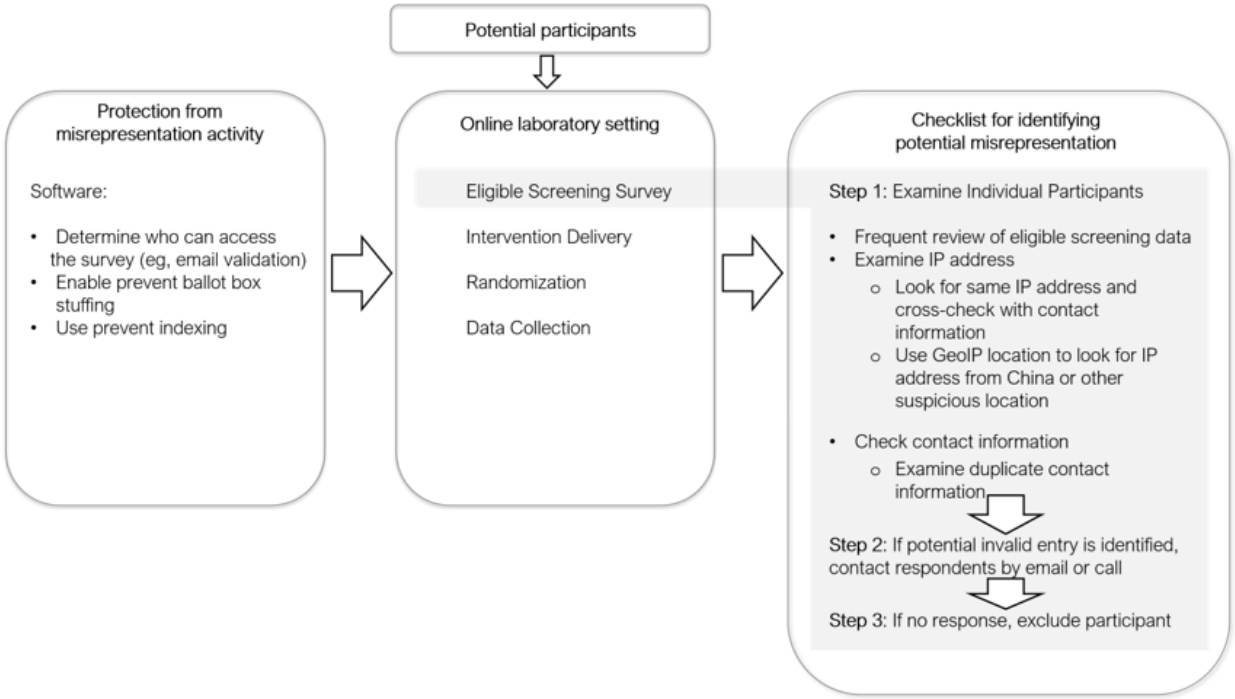
Methods

Study Design

This was a pilot RCT that consisted of multiple stages: (1) a qualitative study [8] including an HPV storytelling intervention [9], (2) assessment of the acceptability of the intervention [9], (3) assessment of the feasibility of mHealth and Web-based research procedures, and (4) evaluation of the preliminary effectiveness of the intervention [4]. This study reports on the feasibility of research procedures in light of a 2-month follow-up.

The study protocol was designed to maintain data and research integrity (Figure 1). We used personally identifiable information (eg, name, email address, phone number, and internet protocol [IP] address) to detect multiple attempts or duplication in the online survey. The protocol was explained in the consent form provided. The institutional review board at the University of Massachusetts Boston approved the research procedures of this study.

Figure 1. The process of preventing and detecting misrepresentation entries. IP: internet protocol.



Recruitment Process

From September 2016 to October 2016, we recruited participants via social networking sites (eg, Facebook and KakaoTalk), Korean community websites, and word-of-mouth sources, including Korean church communities and Korean student associations in the northeast. Recruitment materials focused on the following theme: "I Want to Know More about the HPV Vaccine." Potential subjects were instructed to visit the study website.

Eligibility Criteria

We anticipated that some respondents would be ineligible for the study. Therefore, we used a 4-question online survey to ensure that respondents were female Korean American college students (aged 18-26 years) from the northeastern United States who had not yet been vaccinated against HPV. Eligible participants received a link to our mHealth and Web-based study platform where we collected data, disseminated the intervention, performed randomization, and accommodated mobile devices and Web services.

Participant Randomization

At the end of the baseline survey, participants were randomly assigned to either the experimental group (a storytelling video intervention) or the comparison group (a nonnarrative, written statement about HPV and HPV vaccine) using the randomizer tool in Qualtrics survey software that offers the mobile and Web-based platform, until each group contained 60 participants.

Study Retention

Furthermore, 2 months after the intervention, participants received a follow-up survey via email with a passcode. In total, two reminders about the follow-up survey were sent via email. Each individual received a US $20 electronic gift (e-gift) card at the end of the postintervention survey and was entered into a drawing for an e-gift card at the end of the follow-up survey.

Feasibility Outcome

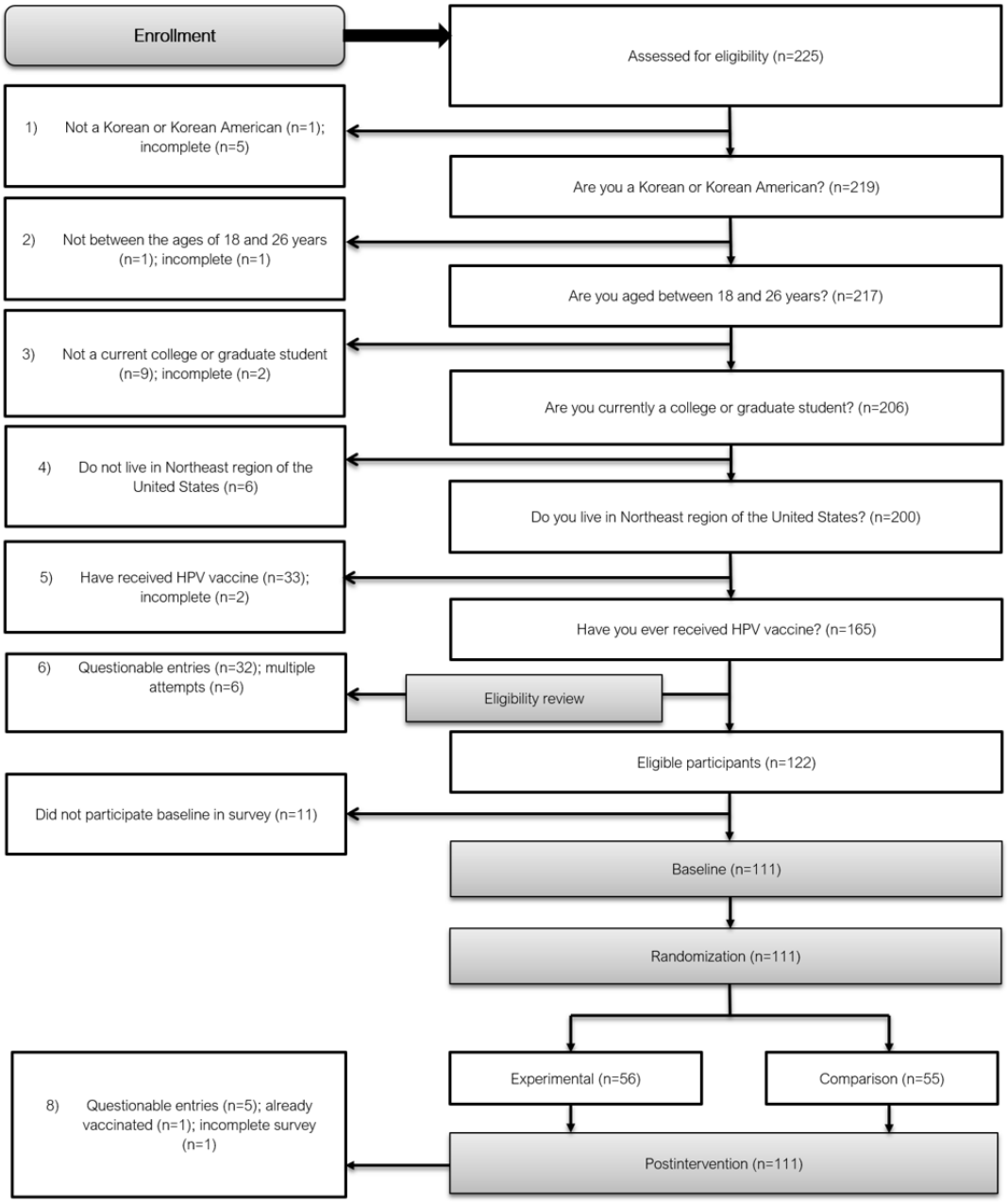
The feasibility and validity of mHealth and Web-based research procedures were measured as follows: (1) recruitment rate was measured for the percentage of participants who signed the informed consent forms out of the total number of eligible participants, (2) eligibility rate was measured by dividing the number of total entries in the eligibility screening survey by the number of individuals who met the inclusion criteria, (3) randomization was measured by whether we were able to randomize eligible participants evenly, and (4) retention rate was measured by the 2-month follow-up participation. In addition, we identified the recruitment source by asking how participants had heard of the study.

Results

Participant Selection

Figure 2 shows the flow of participants throughout the pilot RCT.

Figure 2. Flow chart. HPV: human papillomavirus.



Recruitment Rate

Between September 2016 and October 2016, the recruitment target of 60 participants in each group was achieved. Out of 225 potentially eligible participants, 204 individuals responded to how they heard about the study. The most commonly reported recruitment methods were through friends 46.1% (94/204) and social media 33.8% (68/204). The recruitment rate was 95.6% (111/122).

Eligibility Rate

The eligibility rate was 54.2% (122/225) after excluding ineligible participants (n=60), multiple attempts at entries (n=6), and questionable entries (n=37; Figure 2).

Randomization

Randomization between groups was effectively demonstrated through the Qualtrics software. However, after ineligible and incomplete cases were excluded, an uneven number of participants remained in each group: 56 in the experimental group and 55 in the comparison group.

Retention Rate

In total, 83.7% (87/104) of participants participated in the 2-month follow-up study: 45 in the intervention group and 42 in the comparison group.

Discussion

Principal Findings

This study assessed the feasibility of using an mHealth and Web-based HPV intervention experimental study with young Korean Americans to inform a future RCT. Overall, these findings demonstrate that the mHealth and Web-based experimental study is feasible if software protection and a systemic approach to eligibility screening are used. This study demonstrated a high recruitment rate (95.6%, 111/122) and a moderate eligibility rate (54.2%, 122/225). Although our eligibility rate was moderate because of restrictive inclusion criteria, we believe that our recruitment strategies filled the gaps of previous studies' concerns in recruiting Korean Americans [10,11] by achieving the target sample size in 2 months of recruitment activities. Our approach suggests a way to overcome this challenge. Randomization was evenly distributed between the groups, although ineligible and incomplete cases led to an uneven number of participants in each group in the dataset. In this study, the retention rate was high (83.7%, 87/104) at the 2-month follow-up. In future RCT research, encouraging reminders are recommended as a method to improve HPV vaccine participation and compliance and increase engagement, minimize attrition, and maximize retention.

Challenges and Lessons Learned From the Data Validation Process

Several challenges in the process provide important lessons for future mHealth and Web-based experimental studies. One challenge was the prevention and detection of multiple attempts at entries and potential misrepresentation, which could threaten the validity of the study. We addressed this challenge with software protection, such as *Prevent Indexing* and *Prevent Ballot Box Stuffing* (which prevents participants from taking a survey multiple times by using browser cookies), as well as a systemic approach for eligibility screening to prevent and detect multiple attempts at entries and identify potential misrepresentation.

Despite these precautions, we found a considerable number of invalid entries. These entries had similar or identical IP addresses, and contact information and IP addresses were from outside the northeastern United States. These activities may be explained by our use of monetary incentives, which can not only enhance recruitment and retention in mHealth and Web-based studies [12] but also encourage ineligible applicants and multiple attempts by eligible individuals. Studies using electronic health have discussed similar challenges [13,14] and suggested that a systematic approach for eligibility screening may help obtain valid data [13-15]. In addition, we believe it is critical to cross-check the respondent's information (eg, email address, phone number, and demographic information) with the information collected during the eligibility screening and after the data collection. We found 6 cases of multiple attempts during the eligibility screening and additional 5 cases of multiple attempts via the screening of IP addresses and contact information after the postintervention survey when we reviewed their contact information to send incentives.

Ultimately, it may be necessary to use an email validation feature to ensure that respondents are entering a valid email address. For example, researchers can set a condition to include *edu* in the first email field and a logic condition to require that verification email to be equal to the first email. In this way, researchers may decrease invalid or multiple entries and confirm the verification of respondents' student status regardless of recruitment methods. Moreover, researchers can block questionable IP addresses or contact information using a survey software.

To protect the integrity of mHealth and Web-based research data, researchers and institutional review boards must be mindful about possible misrepresentation activities and how or what to take action on when these activities are suspected or detected. In future research studies, we suggest researchers develop a data and safety monitoring plan regarding how to maintain research integrity if an invalid activity is suspected or detected.

To our knowledge, this is the first study to examine the feasibility of an mHealth and Web-based experimental study to promote HPV vaccination among young Korean Americans who are at a high risk for HPV infections and HPV-attributable cancers. These findings may not be generalizable to other populations.

Conclusions

An mHealth and Web-based HPV prevention experimental study is an efficient and flexible way to perform research with female Korean American college students. However, given the increased possibility of invalid and multiple entries in mHealth and Web-based studies, strategies for detection and prevention are critical. Findings from this study demonstrated sufficient feasibility in terms of research procedures—including recruitment, data collection, randomization, and retention—to justify a full-scale RCT. The lessons learned from this study

provide key insights into other future mHealth and Web-based experimental studies.

Conflicts of Interest

None declared.

Multimedia Appendix 1
CONSORT‐EHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 1561 KB - formative_v4i1e14111_app1.pdf]

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Abbreviations

e-gift: electronic gift
HPV: human papillomavirus
IP: internet protocol
mHealth: mobile health

RCT: randomized controlled trial

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Original Paper

“Positive Peers”: Function and Content Development of a Mobile App for Engaging and Retaining Young Adults in HIV Care

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Abstract

Background: Although treatment for HIV infection is widely available and well tolerated, less than 30% of adolescents and young adults living with HIV infection achieve stable viral suppression. Mobile technology affords increased opportunities for young people living with HIV to engage with information, health management tools, and social connections that can support adherence to treatment recommendations and medication. Although mobile apps are increasingly prevalent, few are informed by the target population.

Objective: The objective of this study was to describe the “Positive Peers” app, a mobile app currently being evaluated in a public hospital in the Midwestern United States. Formative development, key development strategies, user recruitment, and lessons learned are discussed in this paper.

Methods: “Positive Peers” was developed in collaboration with a community advisory board (CAB) comprising in-care young adults living with HIV and a multidisciplinary project team. Mobile app functions and features were developed over iterative collaborative sessions that were tailored to the CAB members. In turn, the CAB built rapport with the project team and revealed unique information that was used in app development.

Results: The study was funded on September 1, 2015; approved by the MetroHealth Institutional Review Board on August 31, 2016; and implemented from October 11, 2016, to May 31, 2019. The “Positive Peers” mobile app study has enrolled 128 users who reflect priority disparity population subgroups. The app administrator had frequent contact with users across app administration and study-related activities. Key lessons learned from the study include changing privacy concerns, data tracking reliability, and user barriers. Intermediate and outcome variable evaluation is expected in October 2019.

Conclusions: Successful development of the “Positive Peers” mobile app was supported by multidisciplinary expertise, an enthusiastic CAB, and a multifaceted, proactive administrator.

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KEYWORDS

HIV; young adults; mobile applications; self-management

Introduction

Background

By the end of 2016, over 254,000 young people aged between 13 and 34 years were living with HIV in the United States [1,2]. Although young adults had similar care patterns as older patients living with HIV, they were less likely to have or adhere to antiretroviral therapy and achieve viral suppression [3-5]. Among those newly diagnosed, the most affected subpopulations are young, black, or Hispanic men who have sex with men [6]. Once engaged in HIV care, young adults also face social and economic barriers that jeopardize viral suppression. For example, younger adults are more likely to live in low-income households, to have been recently homeless or incarcerated, and to be uninsured or have only Ryan White Program–funded health care [7-10]. Not surprisingly, gay and bisexual teens and young adults report feelings of isolation and lack of support [3,11-13].

Young adults' high behavioral risk profile is compounded by the stigma associated with HIV and generally low HIV literacy among this group [11,14]. Along these lines, a Kaiser Family Foundation survey showed that 51% of young adults aged between 18 and 30 years said that they would be uncomfortable having a roommate with HIV and 58% said that they would be uncomfortable having their food prepared by someone with HIV [15]. More than half of this sample agreed with the false belief that HIV can be transmitted by spitting or kissing. Perceived stigma and misperceptions about HIV may prevent young adults from disclosing their HIV status to others or seeking HIV care [16,17]. Given these challenges, there is a need to develop interventions that offer safe entry to long-term, continuous, and coordinated HIV care and address the varied socioeconomic and psychosocial needs of young people living with HIV (YPLWH) [18-22].

HIV research reflects a legacy of innovation and commitment to engaging patients in the care cascade. For example, boosting resilience, seek and test strategies, single-tablet treatment regimens, and same-day antiretroviral therapy availability have all been shown to attract hard-to-reach patients to treatment [23-26]. This spirit of innovation has recently been applied to newer modes of technology and communication that reach many more patients, particularly young people.

A growing number of mobile apps have been introduced, that offer users a range of functionality [27-31]. Mobile apps afford users with increased accessibility to clinicians, tools for self-management, and connect geographically dispersed members of a disease- or illness-defined group [30,32,33]. Over time, these networks can serve as a significant source of emotional support, a known protective factor during chronic illness [34-36].

Although mobile apps that support YPLWH are being implemented with greater frequency [31,37-42], most focus on medication adherence [43]. In addition, there are few available mobile apps offering a broad complement of functionality that includes both group- and interpersonal-level peer connections. Peer influence regarding engaging in risk behavior and decision making is strongest among adolescents and younger adults [44]. Within the context of social media networks, peer approval and peer feedback has been associated with improved self-esteem [45], learning [46], and perceived social support [47].

"Positive Peers" is a Web-based, mobile app that serves as a tool for young adults diagnosed with HIV to manage their health, establish connections with local resources, and engage in a supportive peer community (See Multimedia Appendix 1). Although this app is currently being evaluated in the field, increasing demand to create digital tools for key populations motivated us to share our formative approach and lessons learned [17,27]. This effort is part of the Health Resources and Services Administration (HRSA), HIV/AIDS Bureau's (HAB's) Special Projects of National Significance (SPNS) Program initiative, *Use of Social Media to Improve Engagement, Retention, and Health Outcomes along the HIV Care Continuum*. This is the first report of an ongoing study created to design, implement, and evaluate "Positive Peers."

Theoretical Foundation

"Positive Peers" is informed by media affordances theory, which specifies that communication qualities of technologies provide opportunities to act in a specific way relative to a user's needs [48-51]. Although the features of a technology can influence a user's perceptions of an app's utility, these features do not determine user affordances alone. For example, a chat feature on a social media platform may be desirable to a potential user, but availability alone will not determine if or how often that user will actually use the feature. Affordance is not established until the user has a chance to explore and use the chat feature. Users' perceptions of affordances emerge from interaction with the technology rather than from the technology itself [48,52].

The "Positive Peers" app is a social and technological behavioral *process* that affords the user opportunities to meet perceived needs, such as HIV-relevant information or supportive companionship. App functions reflect known affordances (eg, accessibility and social presence) and are intended to reflect qualities of social (ie, communication) transactions [48]. As we expect users' needs to change across users and over time, the app is designed to provide a range of information and support services.

Methods

Formative Development Phase

"Positive Peers" was prompted by positive experiences with a clinic-sponsored private Facebook page shared by several young adults retained in HIV care. This group comprised 63 in-care patients who consistently attended support groups at the clinic. The age of this group ranged from 13 to 55 years, and 65% (41/63) of them were aged under 35 years. The group included 16 females and 47 males, and 75% (47/63) of them were people of color. As Facebook users thought that a mobile app would be far preferable, the HIV social worker who ran this group met with the users to identify desirable characteristics and potential functions of a HIV-centric mobile app. These specifically included chat, reminder, and resource functions. Consequently, the social worker explored the idea of a locally based mobile

app (now named "Positive Peers") with a hospital physician specializing in HIV.

Multidisciplinary Project Team

The key members of the "Positive Peers" project team include the clinicians described above; a social scientist with a PhD and training in health communication theory and intervention development for evaluation; and a trained biostatistician to manage, link, and evaluate app data. A local design firm with health care marketing experience was invited to manage the creative activities of the project. The chief executive officer (CEO), a trained graphic designer and creative writer, is the creative director of the project and oversees the development of visual and written material. Finally, a local digital development firm, with significant experience building and maintaining health-related websites and apps, was brought onto the project to create the app architecture from the ground up. The director of app development and the senior developer are both trained in computer science, programming, and coding. They are also responsible for creating tracking tools to reliably record all app activity while it is in the field. The project administrator, selected post funding award, is a community HIV activist trained in public health administration. All activities that followed were conducted under the auspices of the MetroHealth Hospital's Institutional Review Board.

Community Advisory Board

The formative work for "Positive Peers" continued with the creation of a community advisory board (CAB). As user collaboration is key to the development of population-specific health technology [53-56], we asked this group to generate ideas that defined the tone, look, and functionality of the "Positive Peers" mobile app. The group meets with the development and implementation team on an ad hoc basis to address app-related concerns. They are compensated for their time and provided a catered meal. The CAB group demographics are 78% (29/37) male, 9% (3/37) transwomen, 81% (30/37) black or African American, 86% (32/37) aged less than 30 years, and 84% (31/37) who identify as Lesbian, Gay, Bisexual, Trans, or Queer (LGBTQ. Although the CAB group is large (n=37), not all members are present for every meeting, which tends to include 12 to 15 members.

To maintain a lively and productive atmosphere, a number of structured techniques were used to collect feedback in the CAB meetings, including card sorting, brainstorming, dyadic and small group idea generation, and traditional focus group methods. The CAB members are sometimes presented with booklets containing illustrated options or screenshots for app functions and features. The CAB first met with team members to view and vote on color schemes and avatar styles and discuss what functions might be most important to them in an HIV-centric app. Their primary concern at this meeting was privacy. They did not want anyone looking over their shoulder to see *HIV* in the name or function titles and preferred cartoon avatars and made up usernames to selfies and actual names. They also collaboratively imagined app features, including personal stories, a community forum, a resource page, medication, and appointment reminders.

"Positive Peers" Prototype

Following the translation of the CAB's initial ideas by graphic design and digital team members, a prototype (ie, alpha) of the "Positive Peers" app was presented at a joint CAB and project staff meeting. The digital engineers helped the CAB members download and navigate the prototype functions, whereas the design and marketing organization gauged the reaction to the app's appearance, titling, content, and other design elements. This first meeting provided an opportunity for the nonclinical staff to get to know the CAB members and consider ways to further refine messaging and design. The project staff observed the reactions of the CAB members and noted questions and comments. In general, the CAB members expressed enthusiasm seeing their ideas come to life, which created increased anticipation for a beta version of the app. Subsequent team debriefing concluded that users found the app easy to download and that the app functions were intuitive and potentially useful. Although the CAB recommended against easily identifiable usernames, there were some concerns about users requiring frequent username and password reset.

A second CAB event was held a few months later to gain insight on the preferred messaging and content strategies. To attract as many CAB members as possible, this interactive CAB event took on a carnival theme that featured incentivized games designed to collect the CAB members' needs, perceptions, and concerns about living with HIV as well as inform the tone and appearance of the app. For example, in exchange for a chance to play a game (eg, ping pong ball toss and Plinko), participants needed to offer a blog topic suggestion, a stigma-inducing or stigma-reducing suggestion, or name a function (eg, *Tales of Triumph*), depending on the purpose of that station. In a more private setting, personal stories of living with HIV were recorded by an interviewer, whereas a professional photographer took artistic portraits of the storyteller. Audio and photo consent were collected before this activity. Participants were also given the option to have a photograph that hid their facial features if they wished to maintain anonymity. The team designed colorful game booths and provided inexpensive carnival-type prizes, cotton candy, soda pop, and hot dogs to match the theme.

These early CAB meetings informed the primary app functions and directed the design team toward topics, issues, and images desired by potential users. As illustrated in Table 1, the social media affordances scale was used to map the desired functions to empirically derived affordances of various social media. We aimed to ensure broad coverage of these affordances to maximize usability among our population. Future evaluation will assess perceived affordances and investigate their association with study outcomes.

Table 1. "Positive Peers" functions mapped to social media affordances.

App function	Affordance	Affordance definition
Reminders, blogs, daily inspiration, forum, chat, and entire app	Accessibility	Convenient to use, easy to message anytime, and few structural barriers or gatekeepers
Blogs, daily inspiration, forum, and chat	Bandwidth	Richness of information one can convey (eg, nonverbal cues and expressed emotion)
Forum, chat, daily inspiration, and tales of triumph	Social presence	Perceived interpersonal closeness or immediacy of others on the channel
Chat	Privacy	Only the user can see the communication or messaging with another
Forum	Network association	Multiple users can participate in an interaction and other users can see who is communicating with whom
Reminders, forum, and chat	Personalization	Freedom to tailor messages and direct communication to select people
Blogs, tales of triumph, forum, and resources	Persistence	Permanence of messaging, permanence of content, and a record of activity
Reminders, forum, and chat	Editability	Ability to delete or edit messaging and ability to edit before posting
Forum and chat	Conversation control	Freedom to enter or end conversations
Forum, chat, and entire app	Anonymity	Channel blinds the user's identity or allows the user to create an identity

At this stage of development, the development team needed to carefully consider the app size. Although we had the plan and expertise to include a wide range of features, we could not deliver an app that was so big that it was quickly deleted by users with budget smartphones. A review of existing popular apps suggested that "Positive Peers" must not exceed 150 MB. For example, popular apps such as *Facebook* and *Snapchat* can range from 400 MB to 650 MB, whereas *Instagram* (200 MB), *Yelp* (150 MB), *Twitter* (110 MB), and some weather apps (120 MB) are much smaller. We aimed to deliver an app comparable in size with those on the lower end. Currently, *"Positive Peers"* app requires 117 MB of smartphone memory to use. Our next step was to translate our CAB recommendations into a testable digital app with targeted content.

"Positive Peers" Content Development

"Positive Peers" serves as both an information hub for newly diagnosed participants and a recruiting tool for eligible out-of-care community members. Therefore, a broad scope of content is available within the app and via a network of "Positive Peers" branded social media platforms, including *Facebook*, *Instagram*, and *Twitter*. Select "Positive Peers" content is also available on the project website [57], although most features are limited to authorized users on the mobile app. The purpose of related social media content is to disseminate accurate HIV education to young people, while also creating positive brand perceptions of "Positive Peers" within the larger HIV community.

"Positive Peers" blog content is researched, written, and presented by the design team. Before content development, a social media posting protocol was developed by the project team in collaboration with MetroHealth. "Positive Peers" text and imagery (eg, blog or social media posts and inspirational stories) are designed to maintain a consistent voice that is proactive, energetic, affirming, contemporary, and accurate. The CAB members asked for information to be realistic and open about the challenges of sex, dating, gender orientation, and LGBTQ issues. Messaging aims toward projecting inclusivity and tolerance while also maintaining a sense of humor and care for people who may follow our messaging. As recommended by the US Department of Health and Human Services, all content is designed not to exceed a seventh-grade reading requirement [58] and is vetted by both the project team and the CAB members. CAB meetings revealed that our population prefers edgier content that includes sexually graphic images, photos of real people, and humorous approaches. They requested diversity of gender, race, and fashion style in all photographic and illustrated artwork.

The app development was time and labor intensive. Progress was affected by several unpredictable factors, including CAB availability, organizational constraints (eg, legal negotiations), and funder requirements. The app development process benefited from allowing time for key team members to become familiar with each other's work process, vocabulary, and personalities. The project manager implemented project organization (eg, meeting agenda and action plans), monitored frequent in-person meetings, and utilized project management tools for electronic to-do lists, group discussion, and document archives. "Positive Peers"' development phase took 1 year to develop the prototype and an additional 4 months to deliver a beta version.

The "Positive Peers" App

The "Positive Peers" app comprises 3 general functions: (1) health management, (2) resources, and (3) social networking. The app affords several features that support these functions.

App Function 1: Health Management

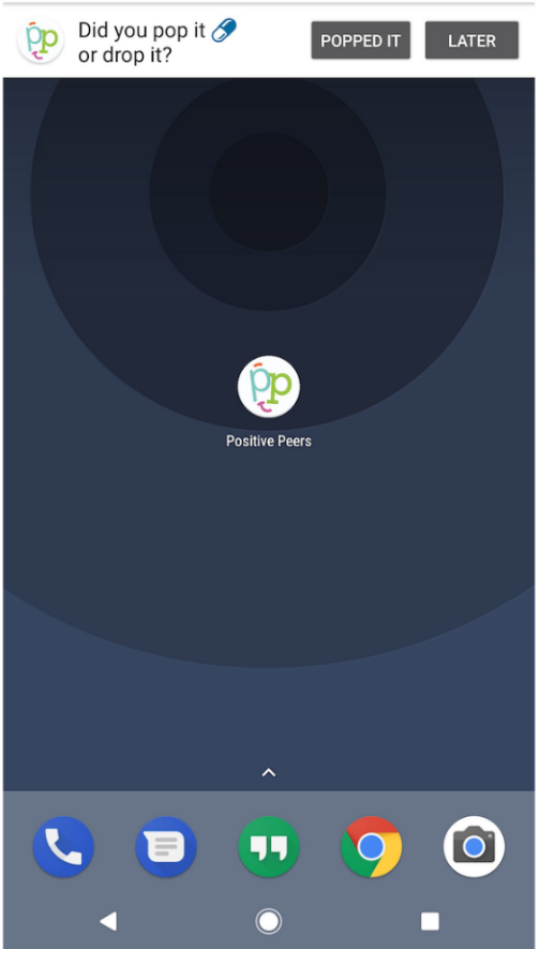
The "Positive Peers" app offers 3 tools for managing HIV-related health needs. These include a reminder tool, lab tracker, and daily inspirational support. Each of these health management tools are described briefly below.

Reminders

This feature allows users to create an appointment or medication reminder that is received directly via push notification on their mobile device. Upon receipt, the user can confirm, snooze, or

ignore the reminder directly from the received push notification (Figure 1). As push notifications can appear suddenly on a locked home screen, the language is brief, informal, and does not mention HIV specifically (eg, "Did you pop it or drop it?"). This is to protect the user's privacy, while also making the notification easy for the user to recognize and understand. The reminder function also offers users an opportunity for tailoring this function by selecting to opt out of various push notifications.

Figure 1. Screenshot of the interactive medication reminder.



Lab Tracking

CD4 counts and viral load values are the primary indicators of HIV disease progression and response to therapy. "Positive Peers" users have the ability to manually input their CD4 count and viral load values after they receive a lab report. This function is also optional so that the users can choose whether or not to store protected health information in the app.

Daily Inspiration

As a means of supporting emotional well-being, the app uses push notifications to deliver daily inspirational messages from the project administrator. These simple, affirming messages (eg, "If it feels like nothing is going right, go left.") are sent to all registered app users. Brief inspirational messages are drafted by the design team, vetted by the clinical staff, and released on weekdays. These are aimed to (1) normalize fears and uncertainties; (2) create a humorous, positive, and action-oriented tone; and (3) reinforce reaching out for support.

App Function 2: Resources

The *Resources* tab on the "Positive Peers" app offers 3 features: (1) *Tales of Triumph*, a collection of CAB-created personal stories; (2) *The Blog*, a blog feed of culturally affirming content; and (3) *Local Resources*, a curated list of local organizations and services that may be of interest to young adults living with HIV.

Tales of Triumph is a collection of brief, first-person narratives of personal challenges written by several community members of "Positive Peers" (Figure 2). These voluntarily provided stories are intended to be an inspirational and motivating opportunity for new users to identify with the community. Stories often reflect personal journeys through diagnosis, status disclosure, and other stigma-related challenges, emphasizing solutions and lessons learned. The Blog is a dynamic stream of informative, HIV-centric topics that appear on the Resources tab of the app as well as on the publicly available "Positive Peers" website and social media posts. Many entries reflect HIV health and wellness education, various community resources, and lifestyle features (Figure 3). Topics are categorized in an index for searchability. Past topics include "I'm worried I was exposed to HIV," "What happens if I don't seek treatment for HIV?," and "Reasons you may feel tired." The Blog also provides a recurring video blog with the project administrator (Hey Josh!) and the HIV social worker on the project (What's up Jen?).

These posts feature people known and liked by the "Positive Peers" community and typically generate several user comments.

The *Resources* tab provides a selection of current local community resources such as housing assistance, support groups, food and clothing sources, and substance abuse programs. There is also a directory of the hospital HIV clinical staff using which a patient can call or email their contact information with the tap of their finger.

Figure 2. Screenshot of the Tales of Triumph homescreen.

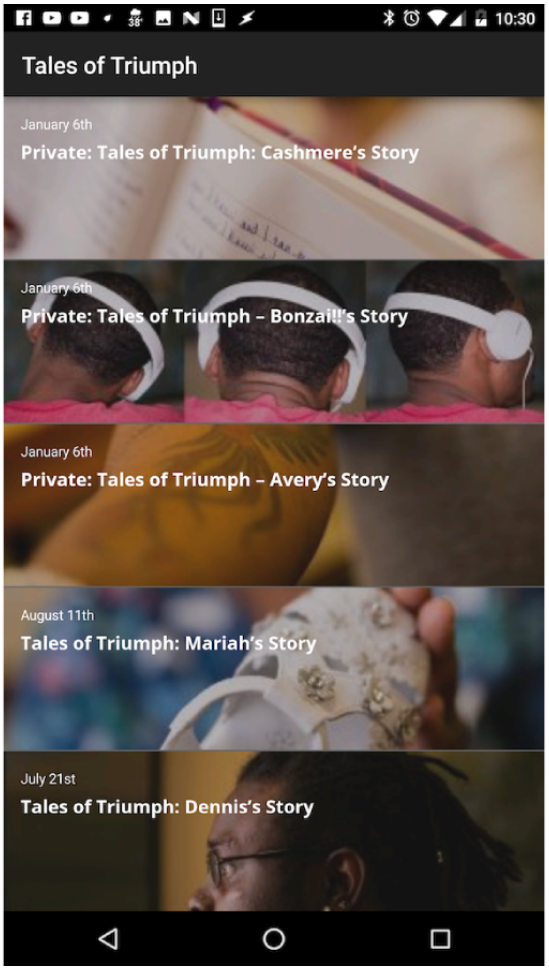
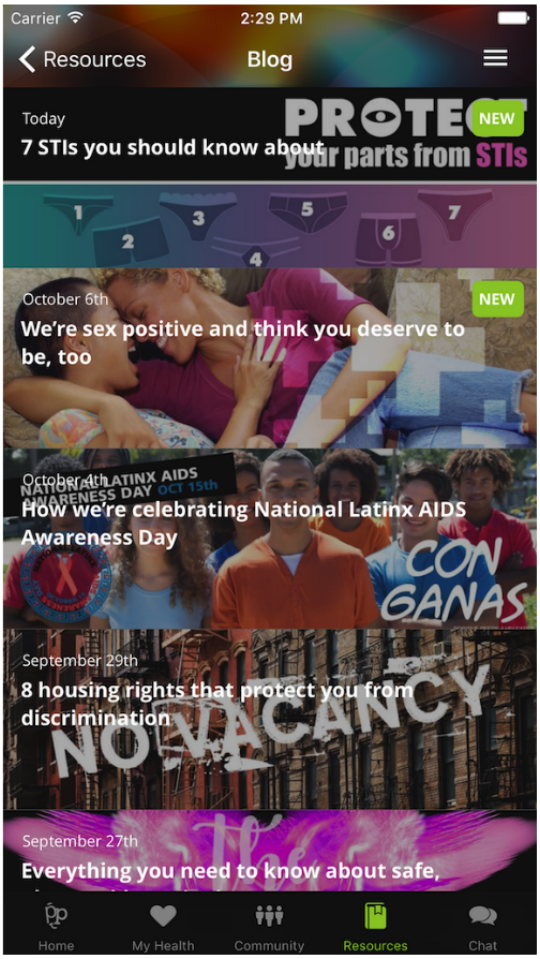


Figure 3. Screenshot of The Blog.



App Function 3: Peer Networking

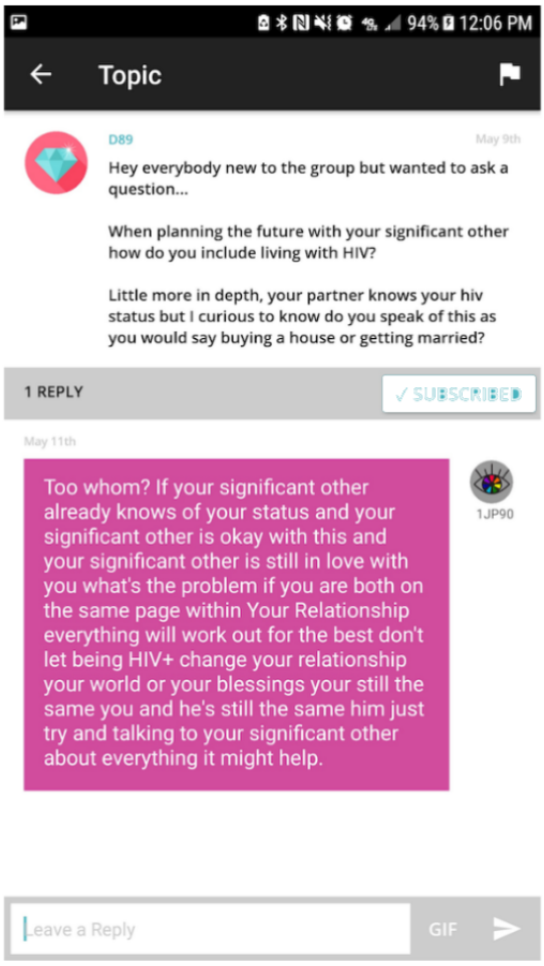
An HIV diagnosis is a life-changing, stressful experience compounded by social stigma and loss of support. However, social connection is a vital resource known to predict physical and mental health and promote resilience in HIV care [35,59]. "Positive Peers" was designed to increase social connectedness for YPLWH via the following 2 functions: community forum and chat.

Community Forum

"Positive Peers" offers 2 distinct social networking functions. The first is a virtual community for registered users moderated by the project administrator. This app feature is intended to help users overcome feelings of isolation and to facilitate supportive and informational conversations (Figure 4).

Users are able to post their own discussion threads or respond to those posted by other users. Before gaining access to the app, all users received a copy of rules regarding civility and barring sexual provocation. Users are then required to sign a form indicating formal acknowledgment of the rules and agreement to abide by the protocol. As the CAB expressed a strong need for safety in the community forum, this feature offers a flag, which when clicked will allow a user to report any misbehavior directly to the administrator.

Figure 4. Screenshot of the Community Forum.



Chat

The chat feature allows users to message another user or the administrator privately. Chat affords users the ability to connect with one another and share personal information (eg, phone number and real name) at their discretion. Chat also provides the project administrator a quick and reliable way to communicate directly with any app user. Importantly, the chat function is stratified by age group. Minor users (<18 years) are segregated from adults to protect them from inappropriate posts or solicitations. The administrator retains the ability to communicate with everyone.

Project Administrator

The project administrator is a central figure to the "Positive Peers" network and important to the daily functioning of the app. The person in this role manages recruiting, referrals, and onboarding procedures; monitors app-based interaction; responds to users' questions and password reset requests; coordinates evaluation activities; and generally, serves as the human face of "Positive Peers" in the clinic and the community. This role requires significant flexibility, problem-solving ability, and social skill. Our "Positive Peers" population is generally highly transient and cautious of others. Our administrator is perceived as a group insider and advocate.

Updates and bug fixes are a natural part of sustaining a mobile app in the marketplace. Although the app is closely monitored, bugs have been reported by users to the administrator, who works closely with the app design specialist to pinpoint and address the issue. Both planned and unplanned updates are part of regular operating conditions. Planned updates typically reflect expansion, new features, or platform updates. Unplanned updates tend to address bugs, unanticipated platform updates, and other issues that threaten normal operations.

Results

Participants

"Positive Peers" is designed for use by YPLWH. The design and content of the mobile app are created to be relevant to young people of low socioeconomic status and of racial/minority backgrounds. Although "Positive Peers" was developed for adolescents and young adults, the app could be modified to target any particular user group. The eligibility requirements for "Positive Peers" included (1) being aged between 13 and 34 years, (2) ability to speak English, (3) having a clinical diagnosis of HIV, (4) having either a new diagnosis (within the past year) or being out-of-care for 6 or more months (within the last 2 years) or not virally suppressed (>200 viral load), and (5) willingness to receive care at the MetroHealth HIV clinic.

Table 2 illustrates the participant characteristics to date. Only 2 adolescent (<18 years) participants are enrolled in the app, and the majority of users (100/128, 78.1%) reported their ages as between 18 and 30 years. Additional descriptors showed that

this user sample was primarily non-Latinx (113/128, 88.3%) and African American (87/128, 68.0%). People who reported LGBQ+ orientation comprised 75.8% (97/128) of the group, and a small set of users identified their gender identity as something other than cisgender (7/128, 5.5%). Although almost 20.3% (26/128) of users did not graduate high school (or attain a General Education Diploma), most have experienced some college (59/128, 46.1%). One-third of the users were diagnosed within 1 year of enrollment. Generally, these users were aged under 30 years and were LGBTQ people of color, who had been living with HIV for 5 years or less.

Table 2. "Positive Peers" users' demographic characteristics (n=128).

Characteristics	Value, n (%)
Age (years)	
13-17	2 (1.6)
18-24	42 (32.8)
25-29	58 (45.3)
30+	26 (20.3)
Race	
White	25 (19.5)
African American	87 (68.0)
Multiracial or other	16 (12.5)
Latinx	
No	113 (88.3)
Yes	15 (11.7)
Sexual orientation	
Heterosexual	31 (24.2)
Lesbian or gay	60 (46.9)
Bisexual	27 (21.1)
Queer	3 (2.3)
Other	7 (5.5)
Gender identity	
Cisgender male	101 (78.9)
Cisgender female	20 (15.6)
Trans/transgender man	1 (0.8)
Trans/transgender woman	4 (3.1)
Genderqueer or gender nonconforming	1 (0.8)
Other	1 (0.8)
Education	
Not a high school graduate	25 (19.5)
High school graduate and no college	44 (34.4)
Some college	59 (46.1)
Employment status	
Full-time employment	37 (28.9)
Part-time employment	28 (21.9)
Unemployed	51 (39.8)
Student	6 (4.7)
Disabled	6 (4.7)
Incarceration	
Never	63 (49.2)
1-2 times	34 (26.6)
3-5 times	23 (18.0)
>5 times	8 (6.3)
Born with HIV	
No	116 (90.6)

Characteristics	Value, n (%)
Yes	12 (9.4)
First diagnosed with HIV	
Within the past 12 months	42 (32.8)
More than 12 months ago	86 (67.2)
Living with HIV	
1 year or less	47 (36.7)
2-5 years	38 (29.7)
6-10 years	23 (18.0)
>10 years	20 (15.6)

Recruitment and Retention

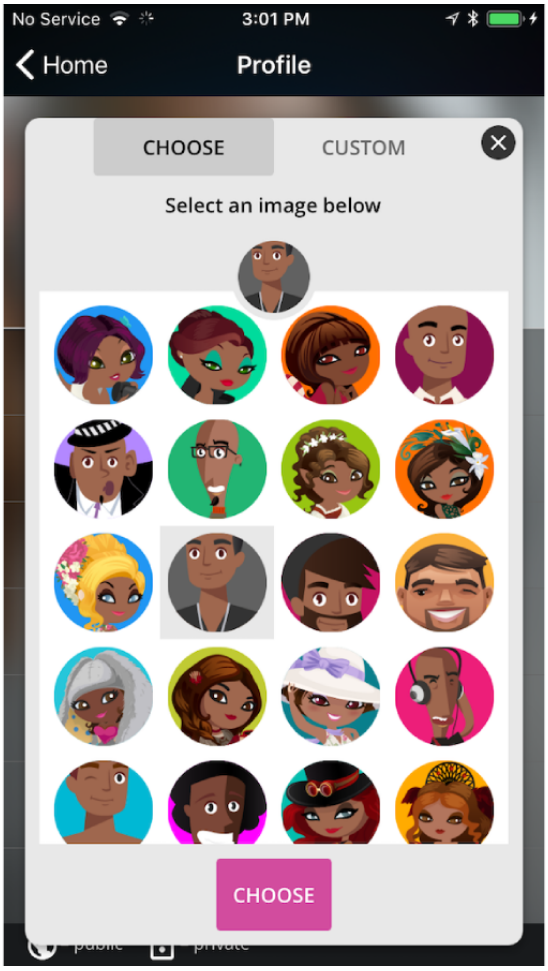
Recruitment

The most effective form of recruitment for "Positive Peers" was in-person interactions between clinic staff or a current "Positive Peers" app user and an eligible patient. Although "Positive Peers" made use of geographically targeted and carefully targeted social media (ie, *Facebook*, *Instagram*, and *Twitter*) to support recruitment, these methods recruited few eligible users, primarily because of the restriction on where individuals received HIV care. Alternatively, clinic posters, clinician referrals, users' word of mouth, and team attendance at local events, such as Cleveland's Pride parade, produced the majority of enrolled participants. The rate of accrual was 6.4 new users a month over a 20-month enrollment period.

Potential participants contacted the app administrator directly to request eligibility confirmation via medical record review. Once eligibility was established, the administrator met with the potential participants to review the study evaluation procedures, secure informed consent, and review the app usage policies (see Multimedia Appendix 2). Posting policy clearly prohibits solicitation of sex or other inappropriate, discriminatory, hateful, or stigmatizing content on the *Community Forum*. All user communications are monitored by the administrator. To date, there have been no issues with inappropriate content.

The "Positive Peers" app is designed to function on both Apple (iPhone Operating System [OS]) and Android platforms. Each enrolled user downloads the app on their own mobile device from the respective app provider for their OS, either Google Play or iTunes. A user's virtual presence on the app is signified by a colorful contemporary cartoon visage that the user can choose from a large collection created by the design team (Figure 5). The style of these avatars, chosen by the CAB at the first meeting, reflects the demographic characteristics (eg, race and gender) and tastes (eg, fashion and attitude) of our young users.

Figure 5. Screenshot of the "Positive Peers" avatar collection.

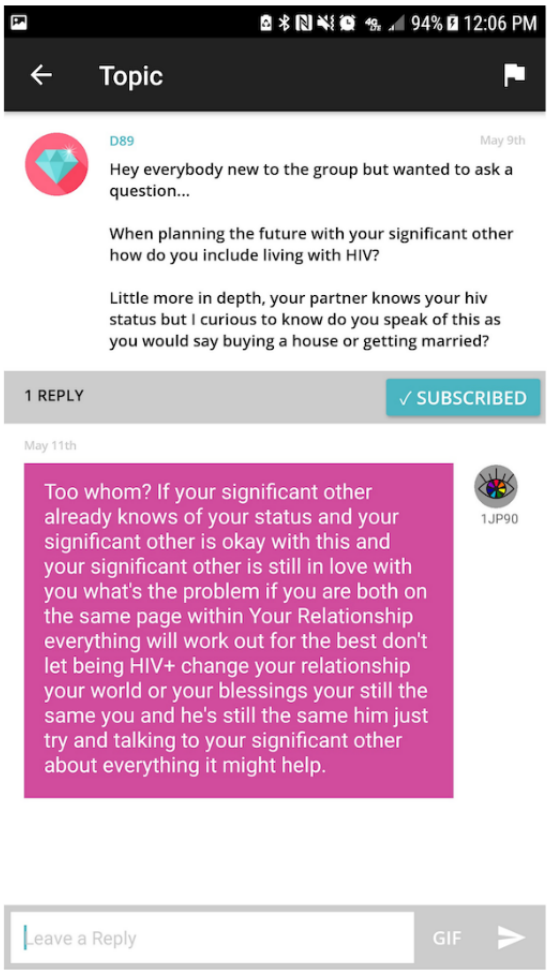


The app administrator logs in at least daily for 5 days per week and monitors conversation posts on the community forum. If the participants feel that they are experiencing a mental health crisis, there are in-app directions to text 741741, a national suicide text line. A referral protocol was designed to aid the administrator in addressing or referring users' concerns. All administrator communications are documented in a secure database and reviewed regularly at team meetings.

Retention

The administrator engages in several activities to retain users and support app use. Following enrollment, the administrator remains available to the user by office phone, email, or chat to troubleshoot problems or reset forgotten passwords or usernames. In addition to sending *Daily Inspiration* push notifications, the administrator may start or respond to conversation threads on the community forum (eg, "Topic Tuesday;" Figure 6). The administrator maintains a visible presence in the user community and regularly attends clinic HIV support groups, community social and educational events for people living with HIV, and all "Positive Peers"–related functions. Importantly, the administrator makes an effort to check in with users not heard from over the previous month. This surveillance activity is intended to remind users of their involvement with the project and spur activity.

Figure 6. Screenshot of a community forum post from the admin.



Compensation

Participants are compensated for the time they spend in each project evaluation activity, including prospective evaluation, qualitative interviews, and CAB activity. Participants were not compensated for using the app. Compensation is provided in the form of a US $25 gift card to either Target or Walmart. In addition, participant parking for meetings or data collection is validated, and local transportation vouchers are provided to commuters.

Discussion

Lessons Learned

Several important lessons have been revealed since “Positive Peers” began field testing in December 2016. These include cross-disciplinary challenges, hosting logistics associated with the medical center server, and participant barriers to use.

Cross-Disciplinary Collaboration

The members of our “Positive Peers” project team are professionally diverse and accustomed to different working styles and jargon. It was important to take time to learn these differences and adopt shared, team-defined methods for problem solving, tracking progress, and communicating needs. Inclusive meetings and messaging, detailed meeting notes from multiple participants, group decision making, Web-based electronic archives, and weekly contact help maintain an open, egalitarian group process that emphasizes nonsummative collaboration over siloed work. This approach is a significant resource toward the development of shared vision and consistent voice for “Positive Peers” activities, content, and evaluation.

Hosting Challenges

At implementation, all app metadata were hosted on a secure hospital server and tracked by *Google Analytics* (GA). After 5 months of weekly monitoring, metadata indicated that several user cases showed no log-in activity at all. This scenario triggered questioning as the user’s enrollment log-in should have been represented as user activity. In response, the digital design specialist and app administrator conducted tests with the archived, raw GA data and discovered that app log-ins that occurred on the hospital campus, or other free Wi-Fi services, were blocked from tracking by GA, our then primary source of user app activity data. Furthermore, GA tended to record additional session time as it did not *end* a session until the user logged out. GA counted app switching (eg, switch from “Positive Peers” to the phone to answer a call) and smartphone time-outs (without a log out) as time spent in “Positive Peers.” In response, a custom analytic system was created with the *Parse* open-source platform to collect app activity directly from the “Positive Peers” server.

User Barriers

App deletion by the user is a significant and unexpected barrier to using "Positive Peers." Although users deleting the app to save device space is not unusual, the team was surprised at the regularity of this occurrence. This discovery was first observed during the early examination of the app metadata, which showed a large number of inactive cases. Upon exploration with the CAB and individual users, we discovered that our population not only deleted the app to make room for other apps but also lost, broke, and changed phones often; frequently forgot log-ins; and otherwise just forgot about the app. In response, the administrator monitored weekly activity and contacted those users to troubleshoot problems. Generally, the project team plans updates every 6 months to maintain interest, keep current with the OS changes, and address bugs.

Anonymity management was sometimes a barrier to app use for several users. Initially, the CAB requested the use of avatars to provide a layer of anonymity to all users. However, as the number of users grew, so did the demand to provide an option for uploading a profile picture and reveal additional demographic details in users' profiles. Several users stated that they resisted in-app communications with each other as they were unsure of the identities of potential chat partners or community forum posters. Interpersonal communication theory suggests that this is a typical relational response [60,61]. Interpersonal relationship development is a behavioral process grounded in self-disclosure and incremental trust development. Social relationship development on social media can follow a similar pattern of intimate disclosure but may also include positive or entertaining disclosures as predictors of connection and closeness [62,63]. Although internet-based communication has been critiqued for disconnections between privacy values and disclosure behaviors, disclosure on social media has been shown to be a function of multiple privacy constructs, particularly privacy value and concern [64,65]. Given the ongoing stigma associated with HIV, we expected that our users would retain significant privacy concerns when communicating in-app. This challenge was addressed by organizing periodic in-person meetups, where our user community could learn more about each other. In addition, the app was changed to offer a choice to upload a selfie photo rather than cartoon avatar. Choosing when and how to share true identities affords our users additional control that they value.

Another challenge was jump-starting communication in the community forum. This is a primary app function, but at the outset, users were unsure who was using the app. Consequently, many users lurked instead of risking being the first to send a message. In an effort to increase interpersonal communication on the app, the administrator posted topics several times a week. Although this was successful at generating replies for a short period, the CAB ultimately provided feedback to stop the special posts as they were perceived as "the only posts (users) would ever see when logging in," thus restricting the open dialog function of the community forum. The CAB further noted that there was a balance needed between the administrator-led conversations and the user-led conversations. After that, the administrator strived to do more replying than posting and limited posting to 1 to 3 posts a month.

Next Steps

The immediate next step for "Positive Peers" dissemination and evaluation is the development of a virtual onboarding process that will allow "Positive Peers" to be available throughout the United States. This shift will reduce the responsibility of the app administrator (eg, user registration) but enable manageable growth with existing resources. Given the important cohesion that the app administrator generates, we are considering a tiered approach to administration that preserves a local contact but offloads some responsibilities to a central coordinator. Although bimonthly project team meetings continue, CAB meetings now occur on an ad hoc basis when a sufficiently developed agenda emerges from the ongoing activity. We expect that as the density of users increases, the CAB will be invigorated and will assume a more regular schedule. We will be testing long-distance conferencing technology to accomplish this aim.

At this writing, the final data collection for this first field experience with "Positive Peers" was near completion. Our evaluation of specific hypotheses and research questions are forthcoming, but given the burgeoning interests in locally designed and implemented health apps, we wished to provide others an overview of our development process and challenges.

Conclusions

The "Positive Peers" mobile app aims to provide a secure virtual community tailored to those HIV subgroups most in need of attention and support. The development of "Positive Peers" was strongly collaborative, iterative, and time intensive. Continued development is bolstered by the interpersonal trust and cohesion created between the CAB and development team. The community of "Positive Peers" users made the request for this mobile app, informed its design, and continue to refine its function. Our cross-disciplinary approach provided specific expertise to create, implement, and evaluate this targeted technology.

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Conflicts of Interest

JB is the CEO and owner of Blue Star Design, the marketing and design firm responsible for the technical creation of the app. Digital work was done in partnership with BlackBird Digital.

Multimedia Appendix 1
"Positive Peers" demonstration video.
[MP4 File (MP4 Video), 111064 KB - formative_v4i1e13495_app1.mp4]

Multimedia Appendix 2
"Positive Peers" Dos and Don'ts for user posting.
[DOCX File , 41 KB - formative_v4i1e13495_app2.docx]

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Abbreviations

CAB: community advisory board
CEO: chief executive officer
GA: Google Analytics
HAB: HIV/AIDS Bureau
HRSA: Health Resources and Services Administration
LGBTQ: Lesbian, Gay, Bisexual, Trans, or Queer
OS: operating system
SPNS: Special Projects of National Significance
YPLWH: young people living with HIV

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Original Paper

A Telehealth-Delivered Pulmonary Rehabilitation Intervention in Underserved Hispanic and African American Patients With Chronic Obstructive Pulmonary Disease: A Community-Based Participatory Research Approach

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Abstract

Background: Although home telemonitoring (TM) is a promising approach for patients managing their chronic disease, rehabilitation using home TM has not been tested for use with individuals living with chronic obstructive pulmonary disease (COPD) residing in underserved communities.

Objective: This study aimed to analyze qualitative data from focus groups with key stakeholders to ensure the acceptability and usability of the TM COPD intervention.

Methods: We utilized a community-based participatory research (CBPR) approach to adapt a home TM COPD intervention to facilitate acceptability and feasibility in low-income African American and Hispanic patients. The study engaged community stakeholders in the process of modifying the intervention in the context of 2 community advisory board meetings. Discussions were audio recorded and professionally transcribed and lasted approximately 2 hours each. Structural coding was used to mark responses to topical questions in interview guides.

Results: We describe herein the formative process of a CBPR study aimed at optimizing telehealth utilization among African American and Latino patients with COPD from underserved communities. A total of 5 major themes emerged from qualitative analyses of community discussions: equipment changes, recruitment process, study logistics, self-efficacy, and access. The identification of themes was instrumental in understanding the concerns of patients and other stakeholders in adapting the pulmonary rehabilitation (PR) home intervention for acceptability for patients with COPD from underserved communities.

Conclusions: These findings identify important adaptation recommendations from the stakeholder perspective that should be considered when implementing in-home PR via TM for underserved COPD patients.

Trial Registration: ClinicalTrials.gov NCT03007485; https://clinicaltrials.gov/ct2/show/NCT03007485

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KEYWORDS

COPD; pulmonary rehabilitation; telehealth; CPBR; disparities; telemonitoring

Introduction

Background

Chronic obstructive pulmonary disease (COPD) is the leading cause of hospitalization for older adults in the United States. According to the World Health Organization, COPD will become the third leading cause of death worldwide by 2020 [1,2]. Disparity populations unquestionably bear a more significant burden of suffering, with death rates rising faster than that in whites [1,2]. African Americans and Hispanics are disproportionately affected by social and economic inequalities that impact access to care, including language, acculturation, and immigration status [3]. Both groups bear a high burden of illness and death due to COPD and asthma and are twice as likely to visit the emergency room for COPD-associated conditions as compared with non-Hispanic whites [4,5]. Higher rates of smoking, reduced health access (especially to pulmonary rehabilitation [PR]), and lower socioeconomic status (SES) all contribute to this high disease burden [6,7]. Lower SES and ethnic minority COPD patients are also at increased risk for readmission. COPD patients admitted for COPD exacerbation have a 23% and 50% risk of 30-day and 12-month readmission [8], respectively, and African American and Hispanic race or ethnicity is associated with an almost twofold increase in hospitalization risk [9]. Patients and their caregivers suffer from discontinuity of care and decreased quality of life with each of these transitions into and out of the hospital. This phenomenon has been adopted as a marker of quality care and is tied to penalties and incentives imposed by large payers, including the Centers for Medicare and Medicaid described in more detail below.

Fortunately, early PR after admission has been shown to improve patient quality of life, satisfaction, and adherence; decrease hospitalization; and improve functional capacity, as measured by the COPD Assessment Test; body mass index, airflow obstruction, dyspnea, and exercise capacity index; 2-min step test; and 6-min walk test [10,11]. Unfortunately, referral and uptake rates are poor, particularly for African American and Hispanic patients, with only a small proportion of the intended target population receiving PR [10,12,13].

Previous research suggests that interventions that have been culturally tailored may result in improved patient outcomes. To improve generalizability across racial, ethnic, and income groups, COPD interventions should be tailored for acceptability and relevance for at-risk, underserved populations [14-16]. The community-based participatory research (CBPR) approach is one such approach to cultural tailoring. CBPR, a collaborative approach between researchers and stakeholders (including patients, caregivers, community-based organizations, and providers), has been applied in studies to assist in developing programs that address the needs of underserved communities in multiple areas [14]. These areas include heart failure [17], mental health [18], cancer [19], sexually transmitted infections [20-22], and smoking [23]. Similar to a science practitioner model, the purpose of the CBPR process is to address gaps between theoretical and *real-world* implementation using joint decision making. These decisions can include defining the research question, collecting and analyzing the data, interpreting the findings, and disseminating the results [14].

Objectives

There is a dearth of literature regarding telehealth adaptation in COPD patients from underserved communities. The qualitative process reported herein describes the method used to identify factors perceived by community members to be crucial in successfully testing a home telemonitoring (TM) program in communities with poor access to care. We used a CBPR approach via a community advisory board (CAB) that included African American and Hispanic COPD patients and caregivers, community advocates, and disparity experts in the New York metropolitan area. This paper presents community and stakeholder feedback on iterative adaptations to a research study testing telehealth-delivered PR. Involving the community in outcome selection, intervention adaption, and interpretation of results is key in enabling overall intervention effectiveness, as one that is not acceptable in a particular community is not be likely to be replicated [16].

This study aimed to explore the perspectives of community stakeholders through the conduct of 2 focus groups of members of a CAB established to ensure patient centeredness at every phase of a mixed methods, comparative effectiveness research study of in-home telepulmonary rehabilitation.

Methods

Study Design

Data shown herein were collected during the first 2 of the 5 CAB meetings that occurred during the first 2 years of the 3-year study period. These initial 2 CAB meetings were conducted before the randomized controlled trial (RCT) to culturally tailor the intervention to the needs of the community. Different moderator guides were developed for each of the CAB meetings (see Multimedia Appendix 1) [24].

Participants

Approximately 20 CAB members were invited to each meeting, with about one-third representing patients and caregivers, one-third representing providers (pulmonologists, researchers, and primary care physicians), and another one-third representing the other stakeholders (such as community-based organizations). Meetings were held in a private room of a public library in Queens, New York, to facilitate attendance by community members. The vast majority of CAB members attended both meetings (CAB meeting 1=10 and CAB meeting 2=18). CAB members were reimbursed (US $50) for their time and transportation for participation in each discussion.

CAB members included stakeholders, including African American and Hispanic COPD patients; nonprofessional caregivers; experts in health and social disparities; clinicians (geriatrician, pulmonary expert, and a respiratory therapist); and patient advocates. The role of the CAB was to advise the study team on all aspects of study design, implementation, evaluation, and dissemination over time. More specifically, the CAB was responsible for identifying factors expected to impact acceptance and feasibility among this population. Although

feedback from all CAB members was incorporated, the study team gave particular weight to patient stakeholder feedback. Discussions lasted around 2 hours each and were audio recorded and then professionally transcribed.

Data Analysis

Content analysis was used to analyze transcript data. After each session, the recordings were professionally transcribed, and a facilitator developed a codebook that allowed for categorization of the data. Moreover, 2 qualitative researchers initially worked independently on the coding of each transcript. After completion of the coding, the researchers met to discuss and revise the codes. A process of discussion and reflection was used to settle any disagreements on the codes. Thereby, researchers were able to identify themes and relationships found in the data [25,26]. The main themes that emerged identified specific recommendations and perceptions of barriers and facilitators for intervention implementation.

Ethics, Consent, and Permissions

All study activities were approved by the institutional review board (#16-663; Feinstein Institute for Medical Research's Institutional Review Board). All participants consented to study participation and audio recording.

Interventions

The standard pulmonary rehabilitation (SPR) arm receives a referral to SPR, which occurs in a rehabilitation center and meets twice a week for 8 weeks. The SPR arm also receives an automatic linkage to a social worker to navigate health care resource access and manage social work–related concerns. Patients in the telerehabilitation arm receive a referral to comprehensive pulmonary disease management program (CPDMP) for 8 weeks. CPDMP is identical to the SPR comparator except for the delivery of PR being via telehealth in either the patients' home or community center (depending on their preference). Blood pressure, oxygen saturation rate, and pulse or heart rate are measured before, during, and after sessions and transmitted in real time to the respiratory therapist conducting the sessions.

During the first CAB meeting, a general discussion of community needs was followed by a dialog regarding specific factors about both intervention equipment and study design. CAB members were presented with the intervention (in English and Spanish), and a demonstration of core components and vital adjustable characteristics of the intervention was provided. A qualitative consultant led the community discussions, with content guided by predetermined topics outlined in an interview guide, including instructions to prioritize patient stakeholders' contributions above medical and professional stakeholders' contributions [27]. The first meeting (held before the start of the RCT) focused on adapting the intervention and included a discussion of (1) ease of intervention use, (2) intervention usefulness, (3) barriers to intervention implementation, and (4) adjustment recommendations. A second meeting was held with the CAB (also, pre-RCT) to present and confirm adaptations made to the intervention based on the CAB's recommendations. All meetings were conducted in both English and Spanish with a professional translator in attendance.

Results

General Themes and Subthemes

The results described below show the general themes and subthemes that arose from the 2 focus groups of the CAB stakeholder meetings. The discussion centered around the adaptation of the PR TM program, from both consumer and provider perspectives. Consumer perspectives mainly focused on cultural tailoring, whereas provider perspectives focused on equipment functionality (eg, Can a frail, older patient sit on the bike?).

The first meeting began with a general discussion of the needs of COPD underserved patients; multiple challenges were identified, including factors that affect access to PR. These factors included insurance payment for PR, repeated hospitalization, medication management, and comorbidities.

After the general needs assessment discussion, the principal investigators presented a demonstration of the initial version of the rehabilitation equipment (a bicycle). The equipment demonstration illustrated that the equipment initially overwhelms some patient stakeholders; although the hands-on aspect of the demonstration helped them feel more at ease, the CAB felt that important adaptations were needed to ensure safety and improve the usability of the intervention.

Theme 1: Equipment Changes

Subtheme 1: Safety and Comfort

One theme that emerged quickly was bike ergonomics: the need for a bike that was safe and comfortable for patients with relatively limited mobility. Specifically, 1 participant noted that the bike would need to be stable with a seat that patients can get in and out of easily. One patient noted:

> *You don't have to struggle... with all the equipment, everything is set up just right for the patient to access everything.*

Specifically, the upright nature of the bike was perceived as dangerous, as patients could more easily fall because of the unstable nature of the design; a recumbent bicycle was strongly encouraged by the CAB. A patient noted:

> *The bike is not difficult, but the bike was breaking down. The arm wasn't good...*

Another provider participant noted that the tablet attached to the bike was too high and needed to be at eye level. The arm, which holds the tablet, should have the ability to *swivel* to facilitate getting in and out of the bike and to accommodate for varying patient heights. A stable arm or surface was deemed necessary to help with transfer; choosing the voice that speaks to the patient, in the accent that is most familiar; considering the gender of the patient and their wardrobe (wearing dresses); and a wider seat with more cushioning than a typical bike to accommodate an older, larger body.

Subtheme 2: Ability to See Vital Signs

One patient participant discussed that he would want the ability to see his vital signs while exercising on the bike. Having access to feedback—the ability to look at vital signs—is a good

teaching opportunity for participants. If patients make adjustments during exercise and see an improvement in their vitals, this feedback reinforces what they are being taught by the respiratory therapist.

Theme 2: Recruitment Changes

Subtheme 1: Recruitment Brochure

CAB patient participants recommended multiple updates to a recruitment brochure that was developed by staff. These changes included increasing the font size, testing the grade level it is written in, and checking that information is accurately translated for multiple dialects. For example, several patient members of the CAB suggested not just using the term *COPD* but also using the term *Enfermedad pulmonar obstructiva crónica* (*EPOC*).

Subtheme 2: Culturally Tailoring the Recruitment Process

A second theme that emerged from the discussion was the need to culturally tailor the enrollment process for a population that does not often receive PR or frequently participates in research. At the third CAB meeting, the staff presented a recruitment video and a recruitment brochure in response to previous CAB recommendations to develop a recruitment video. The video used an untrained actor posing as a patient. One patient suggested including multiple patients exercising together in the video. This would show communication and support among patients. Another patient suggested having real patients in the recruitment video (as opposed to untrained actors) to make the experience look more realistic:

> *...the video was very good, but I think it will be much better when they get more people involved...they're communicating together at the same time, it's like...supporting each other, you know...*
>
> *It didn't impress me much. I liked the part that you played, I thought you did a very good job there. But he doesn't really look the part...*
>
> *I think you want to think about incorporating the caregiver, because...it's not just the patient... it's the spouse (Mrs Lopez)(*names changed to protect patient privacy) who's been watching... been part of the story of Mr. Lopez, just as much as he's been a part. Different role, but together. [Mrs. Lopez] was very clear and very eloquent talking about this. And... [Mrs Lopez] said that now you can't get him off the bike... It's an inspiration to see Mr. Lopez, but also to hear Mrs. Lopez...So I would just suggest you think about the caregiver.*

Study enrollment was discussed at the second CAB meeting; both patients and providers suggested using a recruitment brochure and a video for enrollment that shows a patient with COPD that looks like them (Hispanic and African American patients) successfully participating in PR.

Theme 3: Study Logistics

Subtheme 1: Lateness Protocol

The respiratory therapist asked the CAB what to do when a patient arrives late to the multiuser session. Both patients and providers suggested having a protocol in place for when this happens, including putting a time limit on how late they can arrive, stating that they will not receive extra time if they are late, or providing phone call reminders before the start of class:

> *When you're on a multi-person call... if people start showing up late, everything gets disrupted, so now you've got a dosage issue because your one-hour session just became 45 minutes because Person 1 was there on time, Person 2 was ten minutes late...and you've got to redo your greetings, and you—it disrupts everything.*

Subtheme 2: Gradual Exercise

The CAB discussed the patient educational process in using the bike for exercise. Specifically, providers recommended that the exercise be presented as graded tasks (ie, starting simple with 1 or 2 instructions and adding on over time). Given that the COPD bike is different from an ordinary bike, requiring an extended, longer, and more gradual learning period, it is essential for patients to be comfortable with what they are doing and understand what is going on:

> *Exactly, you cannot just throw it at one time, you gotta educate them, like from A to B,... you gotta teach them step by step.*

Theme 4: Self-Efficacy

Subtheme 1: Communication

The committee discussed the importance of being able to communicate effectively during exercise. This communication between both the respiratory therapist and patient is to foster learning and understanding of the program and how patients are reacting to the movements. Our patient partner shared:

> *Yes, absolutely. I am able to hear him loud and clearly, we're able to interact and switch between bike and exercises and warm-up, and I ask him to (put on his?) blood pressure cuff and his pulse oximeter, everything is—we are able to do pretty much everything.*

Subtheme 2: Motivation

One participant discussed how motivating it is for them to see others succeeding on the bike, particularly patients who are similar in terms of age, condition, ability, etc. He noted that seeing others succeed gives him the confidence that he too can successfully participate in the program. Another patient commented on how they were personally motivated to do more things because of the program:

> *The way [Mr. Lopez] here was doing the bike, when we see the video, we get motivated seeing him doing it...the way he's breathing is excellent according to what I saw there.*
>
> *It got me out of my room with my anxiety and my depression—it motivated me to do other things that I didn't do before.*

Subtheme 3: Health Control

There was additional CAB discussion about regaining control of one's health resulting from perceived improvements in health status as a result of exercise. The discussion reflected that patients have a *better understanding* of what to do to improve their health. Patients who completed the program commented that they were able to see improvements from the exercise and use what they have learned outside of the program:

> *I liked them a lot, I wanted to see if this worked for me. It wasn't easy at first because I wasn't used to it, but now I can even do them on my own.*
>
> *It was hard in the beginning. Because when you don't exercise for a long time and then you start—it is stressful but then gets easier. I was always allowed to rest during the sessions. I felt an 80% improvement. My chest isn't that tight and I can breathe through my nose when I do the breathing exercises that I learned in the program.*

Subtheme 4: Importance of Coaching and Presence in the Home

The final subtheme that emerged from the CAB meetings came from our patient advocate, who indicated that, given the importance of culturally congruent social interaction within the Hispanic community, having a combination of in-person interaction in addition to Web-based interaction (via technology)—rather than exclusively online—is more meaningful and preferable to patients.

Theme 5: Access

On multiple occasions, the CAB discussed the benefit of having access to PR right in one's home. Given that for this patient population, it is not always feasible to travel to therapy, having this access allows patients to continually participate in exercise—an important part of maintaining quality of life. One patient also noted that they felt more comfortable being at home with this program than going out to a gym:

> *The other thing I think it's great, because in the home...winter time, it's snowing, raining, sleet, and all that stuff... sometimes it's not feasible to get there. So, if you got [the respiratory therapist] on the screen, you can still do what you got to do.*

Discussion

Principal Findings

Although previous meta-analyses have documented the clinical efficacy of remote monitoring of patients with chronic illness [28,29] and discussed the importance of adapting interventions to facilitate cultural relevance [17,18], this is the first study to describe the formative process of a CBPR study aimed at optimizing home TM utilization among African American and Latino COPD patients from underserved communities. As noted above in detail, 5 major themes emerged from qualitative analyses of the CAB meetings. Interestingly, although some of the tailoring was *cultural* in nature (eg, developing recruitment brochures and videos of persons who *look like us*), much of the tailoring had to do with intervention comfort and logistics. For example, progressive teaching to self-efficacy was an important theme that transcends culture and language.

Intervention Changes

Several significant changes to the equipment were made in response to CAB recommendations. Specifically, the CAB recommended lowering the height setting on the bike to accommodate patients who may be unsteady *climbing up* onto the seat. To ensure patient safety in getting on and off the equipment and to ensure the patient's competency in using the equipment, the CAB recommended that the patient be accompanied by a staff person for at least the first session.

Another intervention adaptation involved welding the arm that holds the pulse oximeter to the back of the bike to remove restriction of movement because of the wire from the pulse oximeter. Similarly, a second arm was welded onto the bike that allowed the patient to move the tablet to the best possible position for viewing.

Other intervention adaptations to facilitate safety included the replacement of the pulse oximeter by a Nonin watch, whereby sensors are kept on throughout the whole session and sensor values are directly sent to the respiratory therapist for immediate monitoring. Tablets were also adapted for icon use to facilitate easier access to different aspects of the app (*point and click*), regardless of patient primary language.

Protocols for handling patients who signed on to the session late (thereby interrupting others) were also set by the CAB. Similarly, the CAB also suggested the importance of graded tasks, or mastery experiences, as an important component of self-efficacy: in this case, having the respiratory therapist gradually introduce exercises to patients over time to facilitate task confidence.

Recruitment Changes

CAB changes to the recruitment process included the use of a recruitment brochure and a video that presents real patients *that look like us* (vicarious modeling) rather than actors. Brochures were developed to inform prospective patients about the study and leave detailed information with the patient to share with caregivers and family. The CAB also strongly suggested utilizing a common language rather than medical jargon. For example, using the term *EPOC* was recommended to accompany the term *COPD*, which is often unfamiliar to Hispanic patients without medical backgrounds and can be especially daunting to those patients with lower health literacy and for whom English is a second language. The CAB also suggested that the recruitment team work with inpatient respiratory therapists to help create *buy in* from hospital staff to recruit for the study.

In addition, as a result of CAB recommendations, recruitment staff were trained in motivational interviewing techniques. Finally, in response to recruitment challenges, the CAB suggested that we expand recruitment efforts from inpatient to outpatient clinic recruitment as long as the patients met the criterion of no more than 3 weeks from hospital discharge.

Study Limitations

This qualitative study limited data collection to a CAB with membership from the New York metropolitan area. Thus, findings from the study may not be generalizable to other settings and should be interpreted with caution. Other study limitations include the small number and mixed nature of the groups, potentially limiting the likelihood that full theme saturation was reached.

The strength of this qualitative study is the utilization of a CBPR approach. The role of the CAB was to provide the study team with stakeholder perspectives and guidance in the development, implementation, and evaluation of home TM COPD rehabilitation intervention tailored to underserved African American and Hispanic patient populations. The CAB led discussions on adaptation, usability, and program satisfaction and ensured that the conduct of the research remained patient-oriented. Each member of the CAB provided a unique perspective. All members had different expertise, skills, and experience, which contributed to the success of the adaptation of the intervention. As evidenced by our themes, the CAB was critical in identifying and resolving issues that surfaced during the project. A CBPR process was necessary to ensure that relevant cultural and patient-centered factors were addressed in optimizing our intervention as feasible and acceptable to African American and Hispanic underserved patients.

CAB meetings were held in English and in Spanish simultaneously through the use of a live interpreter. Although the translation resulted in a slower session, it facilitated the inclusion of stakeholder perspectives from both English- and Spanish-speaking participants.

Conclusions

There has been a dearth of literature regarding telehealth adaptation in COPD patients from underserved communities. This qualitative study allowed us to gauge community stakeholder perspectives about intervention adaptations for PR at home. Identifying adaptations that are important to key stakeholders through the CBPR-based method is a necessary process to ensure that a complex intervention is generalizable for patients from underserved communities.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Moderator guide.
[PDF File (Adobe PDF File), 198 KB - formative_v4i1e13197_app1.pdf]

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Abbreviations

CAB: community advisory board
CBPR: community-based participatory research
COPD: chronic obstructive pulmonary disease
CPDMP: comprehensive pulmonary disease management program
EPOC: Enfermedad pulmonar obstructiva crónica
PCORI: Patient-Centered Outcomes Research Institute
PR: pulmonary rehabilitation
RCT: randomized controlled trial
SES: socioeconomic status
SPR: standard pulmonary rehabilitation
TM: telemonitoring

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Original Paper

Development of a National Caregiver Health Survey for Hematopoietic Stem Cell Transplant: Qualitative Study of Cognitive Interviews and Verbal Probing

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Abstract

Background: Roadmap 1.0 is a mobile health app that was previously developed for caregivers of patients who have undergone hematopoietic stem cell transplantation (HSCT). Formative research targeted toward its end users (caregivers) can help inform app design and development, allowing additional components to be incorporated into the app, which can then be tested in a future randomized controlled trial.

Objective: This study aimed to create a methodologically rigorous national survey that would help inform the development of Roadmap 2.0.

Methods: We conducted a prospective, qualitative research study that took place between November 18, 2018, and February 7, 2019, in a blood and marrow transplant unit within a large academic medical institution in the midwestern part of the United States. Cognitive interviews, including think-aloud and verbal probing techniques, were conducted in 10 adult caregivers (≥18 years) of patients who had undergone HSCT.

Results: Most participants were female (9/10, 90%), white (9/10, 90%), married (9/10, 90%), employed at least part time (6/10, 60%), caregivers of adult patients (7/10, 70%), and had some college education (9/10, 90%) and an annual household income of $60,000 or higher (6/10, 60%). All but one interview was audio-recorded, with permission. Overall, participants were engaged in the cognitive interview process of the draft survey, which included 7 topics. The interviews highlighted areas wherein survey items could be further refined, such as offering more response choices (eg, “NA”) or clarifying the type of transplant (eg, autologous or allogeneic) or context of transplant care (eg, pre-HSCT, during HSCT, post-HSCT, inpatient, and outpatient). Apart from these findings, the items in demographics, caregiving experiences, technology, positive activities, and mood were generally interpreted as intended. On the basis of the transcript data and field notes by the interviewer, items within self-efficacy (Caregiver Self-Efficacy Scale) and coping (Brief Coping Orientation to Problems Experienced inventory) questionnaires generated more confusion among interviewer and participants, reflecting difficulties in interpreting the meaning of some survey items.

Conclusions: This study incorporated the four cognitive aspects of survey methodology that describe the question-answering process—(1) comprehension, (2) information retrieval, (3) judgment and decision making, and (4) responding—by using the

think-aloud and probing techniques in cognitive interviews. We conclude that this methodologically rigorous process informed revisions and improved our final questionnaire design.

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KEYWORDS

hematopoietic stem cell transplantation; caregivers; mobile applications; qualitative research

Introduction

Background

Millions of individuals depend on family caregivers to manage their care [1]. Although family caregivers are a central part of health care [2], they often are invisible in our health care system, so much so that they are sometimes referred to as "hidden patients" [3]. The economic value of unpaid hours of care by family caregivers was estimated at US $470 billion in 2013, and their contributions continue to intensify [4]. Indeed, with the aging population in the United States and the rising need for caregivers, efforts to foster caregiver health and well-being are essential for sustaining long-term care [5]. Caregivers assist patients with a wide range of activities, including managing complex medical tasks, organizing care plans, and advocating on their behalf [3]. These demands are of a time- and labor-intensive nature, and they place caregivers at high risk for injury and adverse events [3,6-8]. Addressing the needs of at-risk caregivers is an urgent public health priority [1].

Caregiver burden is defined as the "negative reaction to the impact of providing care on the caregiver's social, occupational, and personal roles" [9]. Much focus has been placed on the wide range of negative implications associated with caregiving [10] (eg, depression and anxiety) [11]. Despite this, most caregivers have recognized the benefits of caregiving [12,13]. The imbalance of focusing primarily on negative aspects may limit our ability to develop new assessment and intervention methods [14]. Thus, a "corrective focus" is needed in caregiving research to expand our knowledge on the positive aspects of caregiving [15,16]. Research on self-management suggests that self-efficacy, a positive aspect, can promote caregiver health, well-being, and positive health behaviors (ie, improved sleep and physical activity) [17,18].

The positive aspects of caregiving may explain how caregivers can positively engage patients in self-care activities [19]. Caregivers with better self-efficacy and well-being (ie, health-related quality of life) may positively affect patients' health outcomes [20-22]. Simple strategies aimed at enhancing positive thoughts, emotions, and behaviors have been shown to be effective and highly scalable [23-25]. Positive activity interventions, such as daily positive reflection, using gratitude journals, and conducting acts of kindness, have been used in the management of heart disease, cancer, diabetes, and chronic pain [26-29].

Blood and marrow transplant (BMT), commonly referred to as hematopoietic stem cell transplant (HSCT), is an intense but potentially curative therapy for a number of life-threatening blood diseases [30]. Given the high risk associated with BMT, a dedicated caregiver is necessary and expected for at least the first 100 days after the transplant [31]. However, HSCT caregivers are often unprepared for this role; it is not surprising that HSCT caregivers experience significant levels of anxiety and distress, especially during the peritransplant period [32,33]. Psychoeducational, skills training, and therapeutic counseling interventions have been shown to benefit caregiver health and well-being [34]. However, major barriers in translating successful interventions to clinical practice have included (1) limited understanding of the mechanism of action of an intervention and the (2) need for expert trainers, intensive training, and monitoring [3]. Interventions that are mechanism focused, low cost, and sustainable are needed [35].

We recently developed BMT Roadmap (Roadmap 1.0) as a mobile health (mHealth) app to provide patient-specific information, education, and skill-building exercises for caregivers to use during their inpatient stay. The modular components included patient-specific disease characteristics (eg, infectious disease markers, blood type, donor characteristics, and conditioning chemotherapy regimen), laboratory studies (ie, results shown in real time), medications (ie, lists of medications grouped according to indication, eg, antibiotic or antiemetic), clinical trials (ie, easy-to-read description of clinical trials and copies of informed consents), and a health care provider directory (ie, photographs of nurses, physicians, social workers, pharmacists, and nutritionists) in a yearbook style. To date, more than 100 HSCT caregivers have enrolled in institutional review board–approved studies to assess the feasibility of implementing Roadmap 1.0. Major themes that emerged from qualitative interviews conducted with users of Roadmap 1.0 included the following: (1) Roadmap 1.0's usefulness, ease of use, and likeability; (2) positive aspects of caregiving (ie, benefits of providing care); and (3) desire to expand Roadmap 1.0 to the outpatient setting, specifically targeting "caregiver-specific resources" and "positive activities" components [36-40].

Objective

Thus, in addition to the qualitative research findings from our single institution, we sought to develop a national caregiver health survey that could be broadly distributed to a diverse sample of HSCT caregivers. The goal of the survey was to examine design considerations for an outpatient version of Roadmap 1.0 (will be referred to as Roadmap 2.0 henceforth). Specifically, our intention was to develop a useful and understandable survey aimed at HSCT caregivers as the target audience. Thus, the aim of this study was to create a methodologically rigorous, broadly national survey that would help further inform the development of the app, in addition to contributing to substantive empirical research on caregivers of

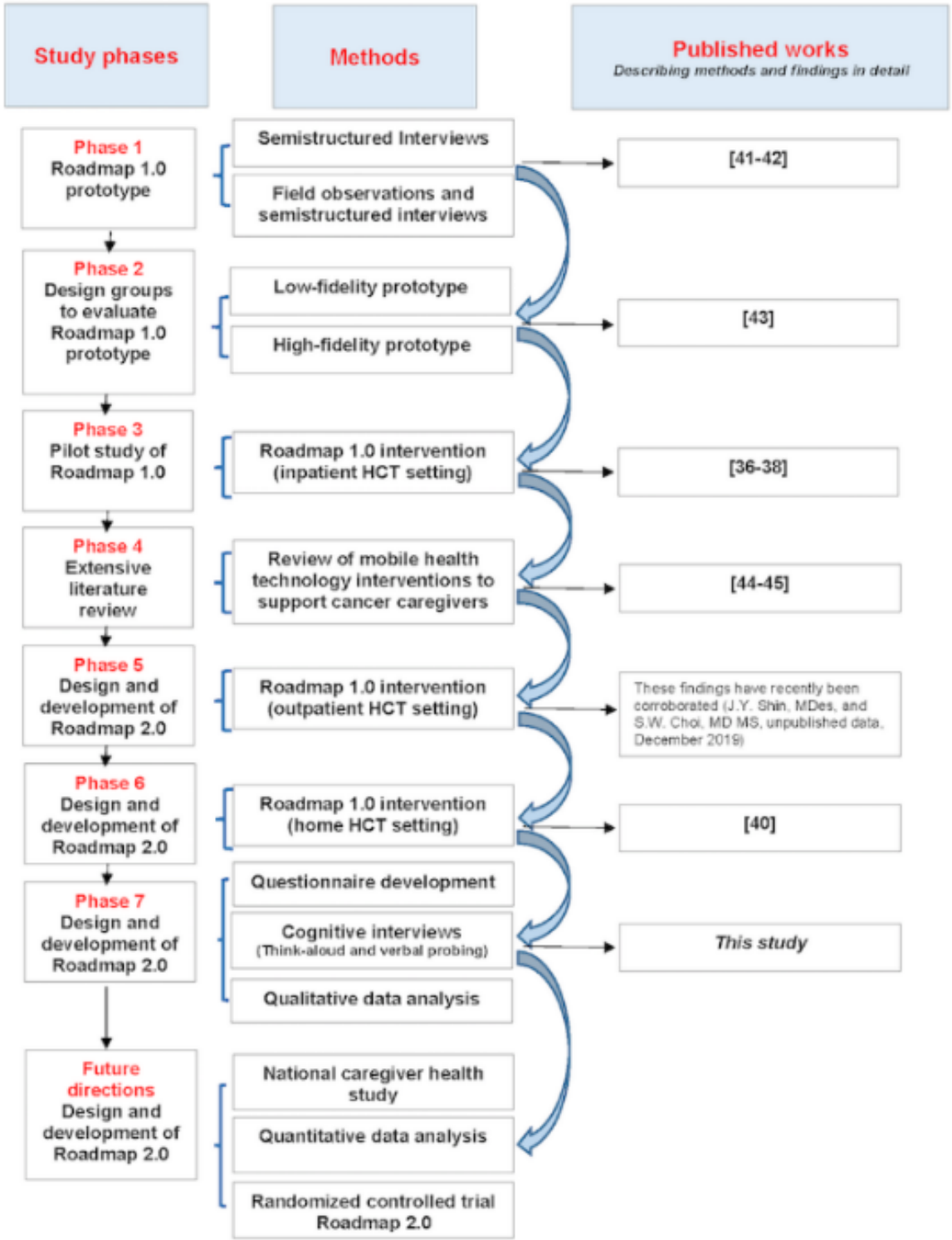
patients who have undergone HSCT. To do this, we conducted cognitive interviews to assess each survey item and adjusted, iterated, and rewrote the survey thereafter, which we report herein.

Methods

Survey Development Process

This work is part of a multiphase project (Figure 1) that will develop and test Roadmap 2.0 in a randomized controlled trial.

Figure 1. Study phases, methods, and references to published works. HCT: hematopoietic stem cell transplant.



Development of the Caregiver Health Survey was based on research derived from phases 1 to 6 [36-38,40-45]. The 6 sequential phases led to the development of a draft survey that included (1) demographics, (2) general caregiving duties and life experiences after transplant, (3) use of mobile technology (eg, mHealth apps and wearable sensors), (4) personal

enrichment through positive psychology–based activities, (5) mood, (6) confidence in providing care for a loved one (patient) and self-care (self-efficacy), and (7) ability to handle stress and use coping strategies. For items 5 to 7, we incorporated the Patient Health Questionnaire [46], Caregiver Self-Efficacy Scale (CaSES) [47], and Brief Coping Orientation to Problems Experienced (COPE) inventory [48], with permission. The psychometric properties of these instruments are provided in Multimedia Appendix 1.

To ensure that survey items were clearly worded and provided contextualized understanding relevant to HSCT caregiving experiences, we conducted cognitive interviews. In short, the cognitive interview is based on the conceptual frameworks and methods in cognitive and social psychology [49]. As it is an important method used in survey development, particularly under the cognitive aspects of survey methodology (CASM), this approach was used in our survey design to ensure the quality and interpretability of question items [50]. We evaluated interviews using the 4 CASM steps that describe the question-answering process: (1) comprehension, (2) information retrieval, (3) judgment and decision making, and (4) responding [51].

During cognitive interviews, the interviewer read aloud each item and asked the participant to express any questions or concerns regarding the item. The interviewer used both think-aloud interview and verbal probing techniques. Think-aloud interviewing provided an opportunity for open-ended answers without interviewer direction. Verbal probing was used after the participant answered the think-aloud interview to provide further insight into the response [49-51]. In addition, the interviewer recorded field notes or observations from each interview session and also documented handwritten notes after reading each item out loud to the participant.

Study Recruitment and Informed Consent

The study was approved by the institutional review board (HUM00115569). Cognitive interviews were conducted with family caregivers of patients of the BMT unit of a large academic medical center in the midwestern part of the United States. Eligibility conditions for study participation were that the subject should be (1) the primary family caregiver who had already experienced the transplant procedure with their loved one (patient) and was in the posttransplant phase of care, (2) aged ≥18 years, and (3) comfortable with reading and speaking English. Participants were recruited through referrals from the clinical team (eg, physician or advanced practitioner). The clinical team recruited caregivers who met eligibility criteria from the inpatient and outpatient settings. Only one caregiver declined participation; another caregiver signed the informed consent but was not available on the interview day. Thus, a total of 10 caregivers signed the informed consent and participated in the study.

The cognitive interviews took place between November 19, 2018, and February 7, 2019. Each interview session was approximately 30 to 50 mins in length and was audio-recorded, with permission, and subsequently professionally transcribed (Babbletype LLC). One caregiver participant refused audio-recording. Participants were compensated with a $10 gift card for their participation. A trained project manager with a background in survey methodology (Survey Research Operations, Survey Research Center, Institute of Social Research) moderated the cognitive interviews in a private hospital conference room. The interviewer was not affiliated with the BMT program. Recruitment ended once it was determined that no new data were being identified that informed the content of the survey items. Saturation was defined as a criterion for discontinuing data collection and/or analysis [52].

Data Analysis

The analysis approach included 3 steps. First, two experts in public health and survey methodology (Survey Research Operations, Survey Research Center, Institute of Social Research), neither affiliated with the BMT program, read the audio-recorded transcripts and the observation and summary notes of each survey item independently. They generated their own notes of each survey item, met together to compare notes, and provided suggested edits (ie, changes to survey items) to the research team. Second, the research team reviewed the results, validated the interpretations and conclusions in a peer-debriefing session, and developed a revised draft survey. Third, a survey methodologist at an external survey research organization (Center for Survey Research) reviewed all of the observation and summary notes and draft survey and provided additional edits of the draft survey. All changes to survey items that led to the final survey were made in collaboration with the lead study investigator.

Results

Participant Demographics

As shown in Table 1, the median age of the study participants was 57 years (range: 35-70 years). Most participants were recruited from the inpatient setting (7/10, 70%), female (9/10, 90%), white (9/10, 90%), married (9/10, 90%), caregivers of adult patients who had undergone HSCT (7/10, 70%), and employed at least part time (6/10, 60%) and had some college education (9/10, 90%) and an annual household income of $60,000 or higher (6/10, 60%). Detailed demographics are provided in Multimedia Appendix 2. Overall, participants were engaged in the cognitive interview process. The findings are described below per survey topic. A list of questionnaire items from which the quotes were derived is provided in Multimedia Appendix 3.

Table 1. Demographics of the study participants (N=10).

Demographics	Values
Age (years), median (SE); range	52.4 (13.99); 35-70
Sex, n (%)	
Male	2 (20)
Female	8 (80)
Race and ethnicity, n (%)	
Non-Hispanic white	9 (90)
Non-Hispanic black	0 (0)
Hispanic	1 (10)
Other or multiple	0 (0)
Marital status, n (%)	
Married or in domestic partnership	9 (90)
Divorced	1 (10)
Single	0 (0)
Highest level of schooling, n (%)	
High school graduate or general education diploma	1 (10)
Some college or 2-year college degree	3 (30)
4-year college graduate	1 (10)
More than 4-year college degree	5 (50)
Current employment status, n (%)	
Employed part time (up to 39 hours/week)	1 (10)
Employed full time (40 or more hours/week)	4 (40)
Self-employed or unable to work	1 (10)
Homemaker	0 (0)
Unemployed and not currently looking for work	0 (0)
Retired	4 (40)
Annual household income, n (%)	
$0-30,001	1 (10)
$30,001-60,000	2 (20)
$60,001-100,000	4 (40)
$100,001-200,000	2 (20)
Greater than $200,000	1 (10)
Prefer not to answer	0 (0)

Survey Topic

Demographics

Most caregiver participants were able to respond to demographic items in the survey with ease. A minor finding suggested to include additional response options:

> *Interviewer: Here's, "Other (please specify….)." I didn't see, but still, daughter, that seems like it should have an answer choice.*
>
> *Participant: Probably pretty common.* [Caregiver #06]

A survey item asked, "How long ago did the patient receive an allogeneic transplant?" However, caregivers expressed that type of transplant could include autologous (eg, self) or allogeneic (eg, another related donor or another unrelated donor):

> *Interviewer: Who donated the stem cells for the patient's transplant? Was it a related donor? An unrelated donor? Or do you know?*
>
> *Participant: The patient themselves (this refers to autologous transplant).* [Caregiver #07]

Caregiving Experiences

In this section, caregivers expressed that some of the items were not applicable to their caregiving experiences as they were caring for their loved ones (care recipients or patients) at different stages of the transplant. For example, questions about hours spent caregiving did not make sense for a caregiver whose patient was currently hospitalized, undergoing the transplant procedure (ie, care mostly provided by a nurse):

> *Participant: How long have I been providing care?*
>
> *Interviewer: Mm-hmm (agreement).*
>
> *Participant: Thirty-five years, but for this (transplant), a month. Almost, three weeks.*
>
> *Interviewer: How many hours of caregiving have you provided per week for the patient?*
>
> *Participant: I've probably been here (in the hospital) for 10 hours a day, so 70.* [Caregiver #08]

Technology

Items in this section were considered straightforward and easy to understand by participants. For example, most of the items were quantitative (ie, "How many apps do you use daily?"), and there were no major sources of confusion identified in this section. However, some of the items allowed for only a "Yes" or "No" response, but caregivers preferred a neutral response and suggested a "maybe," "not applicable (NA)," or "I am not sure" option:

> *Interviewer: That's okay, it's not an answer choice, but I can put that was your first response because that's not a choice. Which is closer, yes or no, to what you would do?*
>
> *Participant: I would use it sometimes, so yes.* [Caregiver #03]
>
> *Interviewer: If a caregiver app existed, would you want the app to connect with other caregivers undergoing similar experiences in the transplant experience?*
>
> *Participant: Sure...I wouldn't mind texting back and forth. The one-on-one face time I wouldn't necessarily want to do.*
>
> *Interviewer: Do you feel like maybe you would need a different answer choice like yes, no, or maybe? Participant: Maybe.* [Caregiver #10]

Personal Enrichment Through Positive Activity Exercises

In this section, participants were asked to rate positive psychology activities based on their usefulness and how likely they were to participate in them. Participants were asked to provide a rating for each activity by indicating a response on a scale from 1 (extremely unlikely) to 5 (extremely likely). All of the participants were able to clearly articulate a score. This section was considered straightforward:

> *Interviewer: Exercise one. I'll just read through the exercise, and you can tell me on a scale of one to five, how willing you would be able to do the exercise. In exercise one, you would be asked to spend a few minutes each day savoring at least two everyday experiences such as morning coffee, the warmth of the sunshine, a call from a friend. You are to be mindful, very aware of the moment while savoring the experience and using all of your senses, sight, hearing, taste, and touch to solidify the memory. Please rate this activity on a scale of one to five, one, extremely unlikely, two, moderately unlikely, three, neither unlikely or likely, four, moderately likely, five, extremely likely.*
>
> *Participant: Four.*
>
> *Interviewer: Four?*
>
> *Participant: Yes.* [Caregiver #03]
>
> *Interviewer: Exercise two. In this activity, every evening you would think about the things that made you happy that day. You would write down one of these moments on a piece of paper, fold up this piece of paper and drop it into a piggy bank. We would provide the piggy bank. At the end of 30 days, you would close your account, which means you would open the piggy bank and read and savor all of the deposited happy memories. On a scale of one to five, extremely unlikely, moderately unlikely?*
>
> *Participant: Probably one.*
>
> *Interviewer: Extremely unlikely.* [Caregiver #04]

Mood

This section included 4 items, which were previously developed in a US sample of 2149 patients from 15 primary care sites [46]. Overall, the items were considered straightforward and easy to follow. Participants seemed to have little to no difficulty following this section's directions, and they did not express significant concerns about the intent of the items. However, several participants commented that the 4 response options (eg, "not at all," "several days," "more than half the days," and "nearly every day") were not adequate (ie, a fifth option, such as "every day," should be included). A participant declined to provide a response because she did not feel comfortable answering some of the items in this section to the interviewer:

> *Participant: I'm pretty private. I know that seems weird because I'm doing this study.*
>
> *Interviewer: This is private.* [Caregiver #01]

Confidence in Providing Care to a Loved One (Patient) and Self-Care

The CaSES questionnaire has been previously studied in caregivers of patients with advanced cancer [47]. Participants commented that some of the items in this section were framed with assumptions about the caregivers' experiences (ie, caregiver of adult vs pediatric patient). Some of the experiences did not apply to all of the participants, depending on the transplant phase (eg, pre-HSCT, during HSCT, or post-HSCT). Most of the caregivers needed clarification on the response options and alluded to needing an "NA" response option:

Interviewer: That's helpful. Continue to provide care when you feel scared?

Participant: Yes, I can. It's more about willing and able and definitely will do it, but we haven't been. Interviewer: You haven't been scared yet?

Participant: Not yet. [Caregiver 06]

Interviewer: How about angry? Continue to provide care when you feel angry?

Participant: That hasn't happened. [Caregiver #06]

Ability to Handle Stress and Use Coping Strategies

Participants encountered the most difficulty in interpreting items in this section related to the Brief COPE questionnaire, which has been previously studied in family caregivers of women with advanced breast cancer [48]. Participants reported frustration in responding to questions, such as "I've been looking for something good in what is happening" or "I've been making fun of the situation," as they appeared to be insensitive to their journey.

Again, similar to the self-efficacy items, when responding to the coping-related items, acknowledging the caregivers' frame of reference was important (ie, defining whether the items refer to the pre-HSCT, during HSCT, or post-HSCT setting, or more generally, in the midst of a stressful event). Medical, personal (patient), and family goals also influenced how participants responded to certain items. For example, for some patients, the goal was to work toward more independence. For others, caregivers were instructed to provide as much help as possible to reduce patient suffering:

Interviewer: I've been taking action to try and make the situation better.

Participant: That's the same thing. To me, that question implies a parent could have done something to make it better. It feels like a crappy question. It makes me feel bad like I should have done something differently or I should have taken action to make this better. In reality, parents don't have control over this. [Caregiver #02]

Discussion

Principal Findings

In this study, we report the findings of cognitive interviews conducted in caregivers of patients who had undergone HSCT that assessed each survey item. Following the 4 CASM steps that describe the question-answering process—(1) comprehension, (2) information retrieval, (3) judgment and decision making, and (4) responding and using the think-aloud and probing techniques—we found that this methodologically rigorous process informed revisions and improved our final questionnaire design. Indeed, evidence-based data have shown that pilot testing a survey is typically insufficient to ensure the quality and accuracy of the questionnaire [49].

Some of the participants identified confusion within certain sections of the survey that may have been missed with pilot testing alone. Interestingly, the sections that prompted the most concerns were the CaSES and Brief COPE items. For example, the wording of some of items created confusion for our participants, which may have been because of the context of care that is unique to HSCT (eg, pre-HSCT, during HSCT, post-HSCT, inpatient, outpatient, caregiver of an adult patient, or caregiver of a pediatric patient). Thus, this led to the following changes: (1) inclusion of more succinct and clear instructions in the introduction or preamble to each section; (2) incorporation of anchoring terms, such as "at the time of transplant"; and (3) inclusion of questionnaire items tailored to the HSCT population (ie, to better align the items to HSCT, we deleted some items that repeatedly raised concerns in the participants).

Importantly, the interviews revealed that the original set of items was not exhausted and highlighted areas wherein survey items could be further refined by (1) offering more response choices (eg, "NA"), (2) removing some negatively worded items, (3) including more items to make our points clear, (4) moving the order of some items so that it flowed more clearly within each topic, and (5) collapsing redundant items (eg, collapsing income brackets/categories). Thus, we found that during the course of this study, we were able to examine item interpretation and readability and adjust, refine, and rewrite items that would be understood correctly by future survey respondents. We also redesigned the formatting of certain sections by (1) creating a grid or matrix question format with x-axis that listed the item and y-axis that listed the response options, (2) developing a single-response or "radio-question" format, and (3) auto-populating or piping in the patient's name from a previous response to further reduce the readability burden. Personal enrichment through positive activity exercises did not identify any potential problems that might lead to survey response error, and thus, no further changes were made to any of its items.

Comparison With Prior Work

Overall, we found that participants were willing to contribute to this type of project, specifically to help future caregivers who would undergo this process, which was consistent with our prior research [53]. Participants of this study were caregivers of both adult and pediatric patients who had undergone BMT. The cognitive interviews identified areas that helped us refine language to allow for interpretability regardless of caregiver type (eg, adult or pediatric). Prior HSCT survey reports have examined either adult or pediatric HSCT [54,55]. Thus, our findings offer a unique contribution to the literature.

Conducting cognitive interviews and using techniques such as think-aloud can help us to learn how participants interpret questionnaire items in their own words, thereby facilitating the development of an instrument that is discriminating, reliable, and valid. de Leeuw et al conducted 2 recent studies [56,57] using a rigorous methodological process that included cognitive interviews in the development of an instructional design evaluation survey. Our findings herein support the use of such rigorous processes in developing surveys that verify how participants are interpreting survey items and whether the survey format and response sets are understandable.

Strengths and Limitations

Major strengths of the study include the development of a refined survey through rigorous methodology that involved a trained interviewer, experts in qualitative data analysis through the lens of survey methodology (and not affiliated with the BMT study population), a research team with extensive knowledge in the BMT study population, and an external survey methodology research investigator (not affiliated with our institution). Not involving survey methodology experts in our study population helped remove biases in the interpretation of our findings.

On the basis of the review of the transcript data and field notes captured by the moderator, we found that the think-aloud technique was successful in capturing constructive feedback, particularly related to the self-efficacy and coping-related items. Participants freely shared that some items were not pertinent to them, insensitively phrased, or required more response options. Verbal probing revealed items that caused confusion (ie, the participant was stuck or paused for a long time, and the interviewer posed a clarifying question or comment to identify the confusion). Overall, the probes were not directive, and participants were able to verbalize their thoughts freely and openly. In the instances that participants refused to answer an item (ie, because of the insensitive nature of the survey item or privacy concerns), the moderator did not probe further. For example, a caregiver declined to answer the 4 psychological distress items because of privacy concerns. It is possible that survey quality will improve in the future with an anonymous, self-administered survey (ie, removing the interviewer).

Despite our extensive work to develop a survey that would be reliable and interpretable, we recognize the limitations of our work. First, participants who were engaged in this research participated in our research. All but one caregiver agreed to participate when approached by the clinical care team, which may reflect social desirability to please the health care providers. In addition, this could mean that our data were skewed by selective input of those engaged in research. Most participants were white, female, married, and highly educated. We recognize that caregiving experiences could be different based on race, gender, and other identities. Our study was also conducted in a single institution in a midwestern location in the United States. The location could change the needs of a community, and a single-institution study could have reflected the interpretation of individuals attending our center. Although cognitive interviews were conducted to improve questionnaire design and to inform revisions, it is likely that some individuals may still have difficulty interpreting some items as intended, which could lead to inaccurate responses or missing data, if left unanswered.

Nonetheless, findings from our cognitive interviews were invaluable in the refinement of our final Caregiver Health Survey. In general, interventions to support caregivers longitudinally across the trajectory of care are limited. Our larger research agenda aims to contribute to the intervention literature. We hope that the findings from our study, which highlight the importance of cognitive interviews, will be useful for research investigators designing surveys with caregivers in mind, especially surveys in support of developing health interventions. Furthermore, in-depth explorations of survey items by asking caregivers about their perceptions provided them with an important opportunity to include them as active partners in the care of their loved ones (patients). Sharing these data about caregivers' views of survey items and what their thought processes are when responding to items may also facilitate future caregiving work.

Future Research

The main goal of this study was to create a survey that will inform the development of our future Roadmap 2.0 app and continue research on mHealth interventions. Data collected herein informed our national caregiver health survey, which was deployed nationally from May to June 2019 (data analyses are forthcoming). Although this investigator-initiated survey queried respondents on health behavior and use of mHealth apps generally to inform our Roadmap 2.0 app, once developed and tested, we anticipate using one of the many recent well-developed and well-validated surveys, such as the Health Information Technology Usability Evaluation Scale [58], mHealth App Usability Questionnaire [59], and/or the Mobile App Rating Scale [60], to assess the app's usability.

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Authors' Contributions

JK, SK, DC, RV, GC, JS, and DH contributed to data curation, data analysis, and reviewing and editing of manuscript drafts. AM contributed to patient recruitment, data curation, and reviewing and editing of manuscript drafts. MO contributed to data collection, data curation, data analysis, data interpretation, visualization, and reviewing and editing of manuscript drafts. LY contributed to data analysis, data interpretation, visualization, and reviewing and editing of manuscript drafts. SC contributed to data curation, investigation, methodology, data analysis, resources, supervision, visualization, writing original draft, and reviewing and editing of manuscript drafts.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Psychometric properties of the Patient Health Questionnaire-4, Caregiver Self-Efficacy Scale, and Brief Coping Orientation to Problems Experienced inventory.
[DOCX File , 23 KB - formative_v4i1e17077_app1.docx]

Multimedia Appendix 2
Detailed demographics of study participants.
[DOCX File , 14 KB - formative_v4i1e17077_app2.docx]

Multimedia Appendix 3
List of questionnaire items from which the quotes were derived.
[DOCX File , 16 KB - formative_v4i1e17077_app3.docx]

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Abbreviations

BMT: blood and marrow transplant
CaSES: Caregiver Self-Efficacy Scale
COPE: Coping Orientation to Problems Experienced
HSCT: hematopoietic stem cell transplant
mHealth: mobile health

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