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Contents

Original Papers

Review

Original Paper

Using Information Technology to Assess Patient Risk Factors in Primary Care Clinics: Pragmatic Evaluation

Leanne Kosowan[1*], MSc; Alan Katz[1,2*], MBChB, MSc; Gayle Halas[1*], PhD; Lisa LaBine[1*], MSc; Alexander Singer[1*], MB BAO Bch

[1]Rady Faculty of Health Sciences, University of Manitoba, Winnipeg, MB, Canada

[2]Manitoba Centre for Health Policy, Winnipeg, MB, Canada

[*]all authors contributed equally

Corresponding Author:
Alan Katz, MBChB, MSc
Rady Faculty of Health Sciences
University of Manitoba
408-727 McDermot Ave
Winnipeg, MB, R3E 3P5
Canada
Phone: 1 204 789 3442
Email: Alan.katz@umanitoba.ca

Abstract

Background: Tobacco use, physical inactivity, and poor diet are associated with morbidity and premature death. Health promotion and primary prevention counseling, advice, and support by a primary care provider lead to behavior change attempts among patients. However, although physicians consider preventative health important, there is often a larger focus on symptom presentation, acute care, and medication review.

Objective: This study evaluated the feasibility, adoption, and integration of the tablet-based Risk Factor Identification Tool (RFIT) that uses algorithmic information technology to support obtainment of patient risk factor information in primary care clinics.

Methods: This is a pragmatic developmental evaluation. Each clinic developed a site-specific implementation plan adapted to their workflow. The RFIT was implemented in 2 primary care clinics located in Manitoba. Perceptions of 10 clinic staff and 8 primary care clinicians informed this evaluation.

Results: Clinicians reported a smooth and fast transfer of RFIT responses to an electronic medical record encounter note. The RFIT was used by 207 patients, with a completion rate of 86%. Clinic staff reported that approximately 3%-5% of patients declined the use of the RFIT or required assistance to use the tablet. Among the 207 patients that used the RFIT, 22 (12.1%) smoked, 39 (21.2%) felt their diet could be improved, 20 (12.0%) reported high alcohol consumption, 103 (56.9%) reported less than 150 minutes of physical activity a week, and 6 (8.2%) patients lived in poverty. Clinicians suggested that although a wide variety of patients were able to use the tablet-based RFIT, implemented surveys should be tailored to patient subgroups.

Conclusions: Clinicians and clinic staff positively reviewed the use of information technology in primary care. Algorithmic information technology can collect, organize, and synthesize individual health information to inform and tailor primary care counseling to the patients' context and readiness to change. The RFIT is a user-friendly tool that provides an effective method for obtaining risk factor information from patients. It is particularly useful for subsets of patients lacking continuity in the care they receive. When implemented within a context that can support practical interventions to address identified risk factors, the RFIT can inform brief interventions within primary care.

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KEYWORDS

risk factors; information technology; primary health care; primary prevention

Introduction

Tobacco use, physical inactivity, and poor diet increase an individual's risk of morbidity and premature death [1-7]. The World Health Organization estimates that 80% of cardiovascular diseases and 30% of cancer can be avoided with the implementation of health promotion and primary prevention strategies targeting smoking, diet, physical activity, and alcohol use [5,8]. The impact of these risk factors is increased by their relationship with mental illness [9] and the social determinants of health such as poverty [10].

Primary care is usually an individual's initial point of contact with the health care system. Team-based primary care has gained support with the acceptance of models such as the Patient Centered Medical Home in the United States and Patient Medical Home in Canada [11,12]. These models include nurses and other providers who complement the care of a physician by providing a variety of services such as an initial assessment and follow-up with the patient (eg, test results, education resources) [10]. The role of the nurse and other providers may vary depending on the needs identified by the clinic as well as characteristics of the patient or appointment type. While providers consider preventative health important, they often fail to address primary prevention due to a focus on current symptoms, acute care, and medication concerns [10,13-16]. Primary care provides an important opportunity to identify risk behaviors and introduce primary prevention strategies [13,14,17-19]. Counseling, advice, and support from primary care clinicians increase awareness of potential behavior changes and are associated with patient's attempting to change their behavior [13-24].

Algorithmic information technology can collect, organize, and synthesize individual health information to inform and tailor primary care counseling, positively impacting health outcomes and patient health behavior change [16,20-22,25-33]. It is also an efficient and useful means for assessing sensitive and stigmatizing information [24,32].

We developed an interactive computer-based application called the Risk Factor Identification Tool (RFIT) to support primary care clinics in obtaining risk factor information. In a previous study, we demonstrated that RFIT is a practical prevention tool in family practice [20]; however, it relied on computer-generated, printed patient responses that presented challenges during implementation [20]. Feedback received suggested the need for improved integration into the electronic medical record (EMR) to expedite availability of RFIT responses, provide a permanent and comprehensive record of risk behaviors, and enable personalized approaches to behavior change [20]. In this study, we aimed to evaluate the use of tablet-based technology with the immediate transfer of RFIT responses to the EMR. This pragmatic developmental evaluation describes the integration of the tablet-based RFIT into one rural Manitoba primary care clinic and one urban Manitoba primary care clinic.

Methods

The RFIT

The RFIT is a patient-centered assessment tool that applies motivational interviewing and health coaching modalities [22]. The RFIT collects basic demographic data from the patient and assesses patient risk behaviors (ie, physical activity, diet, smoking, and alcohol consumption) using previously validated tools [20,34-37]. In addition, the RFIT includes questions about self-perceived health and poverty (Multimedia Appendix 1). The RFIT uses a response-based algorithm. For example, the tool includes the CAGE [37] questions to assess alcohol dependency among patients who report alcohol consumption over the suggested age- and sex-based limits. The transtheoretical model used in the RFIT is widely accepted as a foundation for health behavior change and a basis for effective counseling approaches [23,30,38].

Recruitment

A convenience sample of one rural clinic and one urban clinic was recruited in Manitoba, Canada. One clinic had a previous relationship with the research team. The medical director of the other clinic approached research staff at a conference about participating in research. The study team presented to interested primary care clinicians at each site, who then signed the information and consent forms. Participating clinicians offered the RFIT to patients attending a routine care appointment focused on health maintenance. Patients accepted the information and the consent form on the tablet prior to completing the RFIT and could stop the RFIT at any time.

RFIT Implementation

Each site created a clinic-specific implementation plan that could be incorporated within their workflow. Nurses at the included clinics would often conduct a brief same-day assessment prior to the patient seeing the physician. Depending on the patient, this initial assessment may include documentation of height and weight, preappointment tests, and brief review of the patient's concerns. Depending on clinic workflow, the patient may have completed RFIT before or after meeting with the nurse. After patients completed the RFIT, the responses were electronically transmitted as an encounter note into the EMR accessed by the physician using the Ocean App developed by CognisantMD [39] (Multimedia Appendix 2).

The participatory nature of this study allowed refinement and adjustment of the RFIT and EMR encounter note to meet the unique needs of each clinic. Ongoing feedback between clinic staff and the research team provided information regarding implementation progress and outcomes. The Ocean online platform provides user log and tablet audit reports to assess use and survey completion.

There were 3 focus groups held with a total of 10 clinic staff and 8 clinicians to discuss the RFIT. The clinic manager assisted the research team in arranging the lunch time focus groups. To accommodate clinic schedules, the first clinic held 2 focus groups, 1 for clinic staff and 1 for clinicians. The second clinic offered 1 focus group attended by both clinic staff and clinicians. Focus groups were led by 2 members of the research team. The

majority of focus group participants were female and ranged in age from early 20s to mid-60s. Focus groups were attended by the clinic managers, physicians, nurses, and reception staff. The focus group addressed RFIT implementation, feasibility, and integration with questions focused on (1) experience with the tablet-based RFIT, (2) perceived value, (3) well-received features, (4) challenges experienced, (5) proposed solutions, (6) perception of increasing risk factor awareness, and (7) recommendations for expanded implementation of RFIT to other clinics. Consent was obtained prior to the focus groups. Focus groups were recorded and transcribed by the research team.

Analysis

Qualitative results from clinicians and clinic staff presented details of RFIT feasibility, integration, and acceptance. Two team members who attended the focus groups reviewed the resulting transcripts. A preliminary coding dictionary was developed based on the focus group guide. Two researchers analyzed the transcripts from focus groups using the coding dictionary. Through consensus, team members generated common themes that emerged within each of the overarching categories (eg, implementation, feasibility, and integration). The implementation category had 1 theme focused on introduction of the tablet and RFIT to clinic processes. There were 4 themes within the feasibility category focused on well-received aspects of new technology, technology-related disruptions, establishing a new routine, and disruption in clinic workflow. Within the integration category, we describe 3 themes: information gain and clinical value of RFIT, patients' reactions, and solutions to meet identified challenges (ie, tailoring the survey and adjustment to the process). Themes were shared with the clinic staff and clinicians to verify that themes matched participants' experience(s). Focus group findings were supplemented with notes from virtual and in-person visits provided by the study team to the clinic to support implementation at each clinic.

Quantitative data including user logs, audit reports, and patient RFIT responses were recorded in Excel spreadsheets. RFIT responses included patient demographics, risk behaviors, self-perceived health, and self-reported low income (ie, do you find yourself running out of money to pay for food or shelter; do you have trouble paying for medications; do you receive any monthly benefits; do you have a clean and safe place to live). Descriptive statistics including frequency, mean, SD, and range describe the data. The Health Research Ethics Board at the University of Manitoba approved this study.

Results

Implementation

Eight clinicians in 2 Manitoba clinics offered the tablet-based RFIT to patients attending routine care appointments at the primary care clinic for 6 months. There were 6 female and 2 male clinicians that used RFIT. Participating clinicians ranged in age from 28 years to 64 years. Although the study team provided implementation suggestions, each site developed their own implementation plan (Figure 1).

At the first site, reception staff added flags in the EMR for patients that were scheduled for routine care with 1 of the 3 participating clinicians. The clinician would review and, as appropriate, remove flags if the patient should not receive the RFIT. Staff at the clinic explained, "When the patient checks in at the clinic, a flag [in the EMR] will remind the front desk to provide them with a tablet." At the second site, 5 clinicians participated using 2 tablets. The reception team provided the tablet, as available, to anyone arriving at the office for whom a routine visit was scheduled.

In total, there were 207 patients that started the RFIT, with a completion rate of 86% (179/207). Table 1 provides key characteristics from responses of patients who used the RFIT at each clinic. Overall, participant characteristics were similar in both sites. A notable exception was the number of respondents who were flagged by a CAGE question. Interestingly, the majority of patients from both sites chose not to respond to the self-reported low-income questions.

Figure 1. Each clinic designed their own Risk Factor Identification Tool (RFIT) implementation process to fit within the clinic workflow. EMR: electronic medical record.

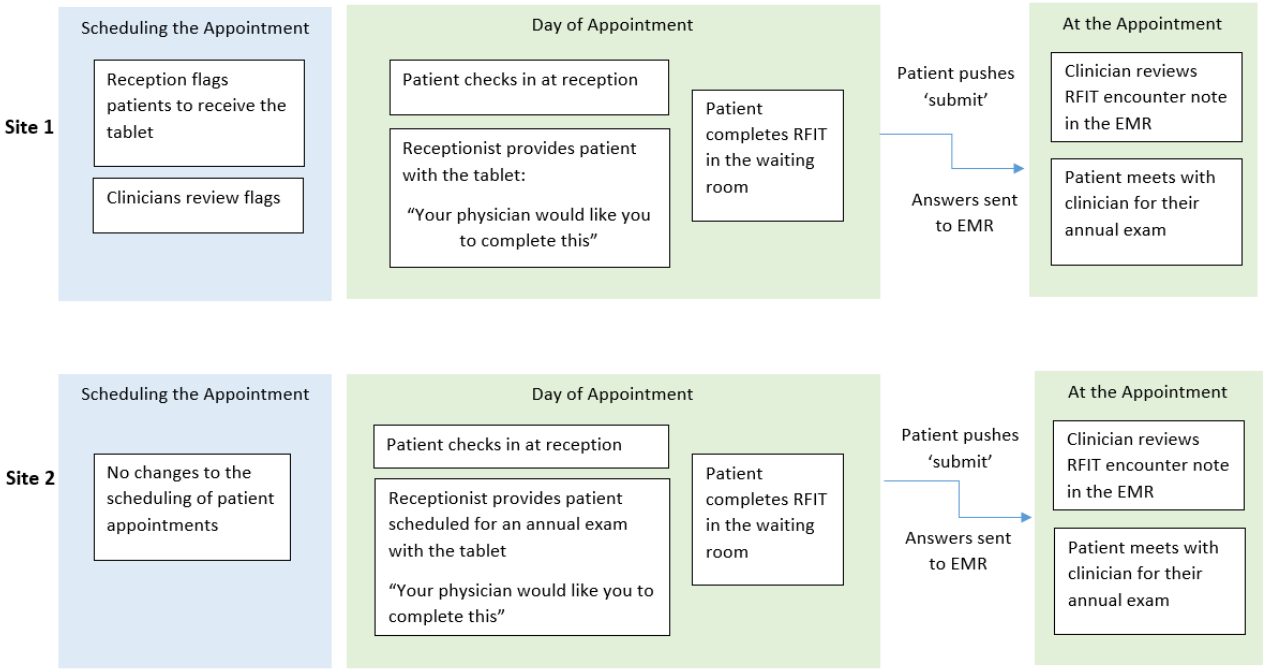

Table 1. Characteristics of patients that responded to the Risk Factor Identification Tool (RFIT) on the Ocean tablet (n=207).

Variable[a]	Site 1: rural clinic (n=116)	Site 2: urban clinic (n=91)	Missing responses
Patient characteristics			
Age (years), mean (SD)	53 (16.8)	54 (15.1)	1
Female patient, n (%)	83 (80.6)	62 (72.9)	20
BMI, mean (SD)	26.6 (6.5)	28.4 (8.5)	31
Health status			
Excellent, very good, or good self-perceived health, n (%)	91 (91.0)	69 (83.1)	25
Self-perceived health unchanged from last year, n (%)	70 (71.4)	57 (69.5)	25
Risk factors			
Self-reported smoker, n (%)	11 (10.9)	11 (13.6)	25
Self-reported healthy diet, n (%)	80 (79.2)	65 (78.3)	23
CAGE flag for alcohol consumption, n (%)	7 (7.5)	13 (17.3)	40
Less than 150 minutes of physical activity, n (%)	56 (54.9)	47 (58.8)	26
Employed, n (%)	56 (55.4)	50 (64.1)	28
Low income, n (%)	5 (10.9)	1(3.6)	134

[a]Questions were not mandatory; patients could choose whether to answer a question.

Assessing Feasibility

Feedback from the clinic staff and clinicians suggested there were benefits and challenges to both implementation strategies (Figure 1). Overall, the use of a tablet to facilitate the RFIT was well-received. However, reception staff mentioned that there were some technology-related disruptions and connectivity problems. When this occurred, the patient was unable to complete the RFIT. In addition, both clinics found there were some disruptions in clinic workflow. However, reception staff indicated that once they had established a routine, the use of the tablet increased (Table 2).

Table 2. Assessing feasibility themes with illustrative quotes from clinicians and clinic staff.

Themes and respondent roles	Illustrative quotes
Well-received aspects of new technology	
Clinician	*"The tablet to EMR[a] connection is quick, with information appearing in the EMR immediately following the patient pressing the 'submit' or 'quit' buttons."*
Technology-related disruptions	
Reception	*"You type in the PHIN[b], and then it says unable to connect..."*
Disruption in clinic workflow	
Clinician	*"This avenue* [Ocean app] *for the RFIT[c] survey is preferential to paper. It increases its utility. However, you would need more tablets, and it still does slow down the clinic."*
Reception	*"Entering the tablet password and patient PHIN can be difficult if there is a long line at reception. If there was more… tablets and more physicians participating, it would be very difficult to set-up the tablet for each patient..."*
Establishing a new routine	
Reception	*"Once we became more used to handing out the tablet and it became a habit, it really was not extra work administratively. It was easy in that sense."*

[a]EMR: electronic medical record.

[b]PHIN: personal health information number.

[c]RFIT: Risk Factor Identification Tool.

The RFIT did require some adjustments to clinic workflow. On average, patients took 11 minutes to complete the RFIT. Clinic staff suggested older patients were initially flustered or anxious about using a tablet, and some patients found the RFIT lengthy. Both sites did mention that there were patients that did not complete the RFIT prior to their appointment.

> *Some patients were asked by their physician [if they could] complete the [RFIT] survey after their appointment… The physician can review the information before their next appointment.* [Clinic staff]

Physicians were reluctant to request patients arrive early for their appointment. There were very few patients that did not want to complete the tool. Reception explained:

> *Approximately 3%-4% of patients decline to complete the survey. Either they do not want their information to be entered on a tablet [due to privacy concerns], they do not know how to use a tablet, or there is a language barrier… Some patients felt questions in the survey… would be discussed with their physician...* [Clinic staff]

> *Older patients who come in for an annual physical will also be required to have some tests… Sometimes patients do not want to complete the survey if they have already completed other tests, they just want to see the doctor.* [Clinic staff]

Assessing Integration

During the 6-month study period, patients completed the RFIT on 35.8% of the clinic days, with an average of 2 patients completing the RFIT each day it was administered. Clinic staff explained that routine care appointments are often scheduled for select days or times. Acute care appointments make up the majority of care provided, with only 1 or 2 routine care appointments scheduled per physician a couple days a week. Some clinic staff suggested tablet use might increase by providing, *"a dropdown list on the tablet...* [to] *select the physician and patient* [by name]..."

Clinicians felt that the tablet provided new information by creating a space to discuss alcohol and smoking. The summarized responses that appear in the EMR suggest topics to discuss with patients that may not be "*immediately visible or easily known, unless the patient is asked about it specifically… in that respect, RFIT was useful...*" Clinicians did not always review the encounter note created from RFIT responses, and neither of the sites continued to use the RFIT after the study. Additionally, a physician mentioned (Table 3), "*Filling out the survey on the tablet slows down the flow of the clinic, and information acquired as a result does not add value to the patient's appointment or care provision.*"

Table 3. Assessing integration themes with illustrative quotes from clinicians and clinic staff.

Themes and respondent roles	Illustrative quotes
Information gain and clinical value of RFIT[a]	
Clinician	"*The tablet enables discussions around areas such as alcohol and smoking. It allows GPs*[b]*to gage a patient's exercise levels and therefore starts a discussion around physical activity.*"
Clinician	"*If you read the note while the patient is in the room, you can refer to their responses* [from RFIT] *to initiate the discussion.*"
Clinician	"*I am intrigued by the Ocean app, but if the only survey I was using was RFIT, I would not spend the money...*"
Clinician	"*I guess it assisted in the conversation on these topics... But our EMR*[c] *also prompts us to discuss many of these topics already. Patients also seem more engaged these days on their health and primary prevention. Patients did not use questions from RFIT as prompts or starting points for discussion* [with their clinician]... *The piece that is missing is, what do you do with this information? How do you help or what resources are available... You end up doing what you always would've done.*"
Solutions to meet identified challenges (ie, tailoring the survey and adjustment to the process)	
Clinician	"*I could see this working well for other types of appointments and surveys. It would be very helpful for necessary* [mental health] *paper forms that have to be typed into the computer* [EMR]... [or for] *walk-in appointments...* [or] *to assess risk factors for prenatal [visits].*"
Clinician	"*Nutrition flag might be more meaningful if you could say how poor the patient's nutrition is compared to other patients. A comparative measure of nutrition... Or focusing on some specific areas such as 'how often do you eat out' and 'where do you usually eat out'.*"
Patients' reactions	
Reception	"*There has been a good response to the tablet by patients. Patients have found no issues with the interface.*"
Reception	"*Most patients were happy with something to occupy their time in the waiting room.*"

[a]RFIT: Risk Factor Identification Tool.

[b]GP: general practitioner.

[c]EMR: electronic medical record.

One site did continue to use Ocean for other surveys that are available and suggested that RFIT could be improved by tailoring the survey to the appointment type or using comparative measures that may be more meaningful to the patient (Table 3): "*you are in the bottom 10% for adequate nutrition*" [Clinician]. Overall, the clinic staff reported that most patients did not have concerns about using the tablet-based RFIT and most patients were happy to complete the survey in the waiting room (Table 3).

Discussion

This study adds to the literature informing the utility of information technology to support primary care practice with a focus on preventative care. Our findings are useful to others exploring this potentially transformative approach to primary care service delivery. We address 3 critical components of this change in practice. First, we address the acceptance and usability of technology. Clinicians and clinic staff reported that the tablet and Ocean connection to the EMR provided a user-friendly interface. Clinicians, clinic staff, and patients that used RFIT ranged in age from young adults to seniors. In particular, RFIT was used by early-career, mid-career, and late-career clinicians that all reported benefits to the use of technology for the collection of risk factors. Similarly, other research has found computer-assisted assessments provide a useful, feasible tool for identifying health risks and are favorably reviewed by clinicians and patients of varying ages and demographics [21,32,40]. Approximately 3%-4% of patients required assistance or declined the use of the tablet. Psychosocial considerations and factors that may be subject to social desirability biases were particularly well-received due to their ability to inform individual patient counseling [32,33]. Further refining the BMI and nutrition questions on the RFIT can avoid duplication with what is currently available on the EMR and can make resulting notes more meaningful to initiate patient discussions.

Using this particular technology, RFIT responses are immediately transferred into an encounter note and are permanently recorded in the EMR. Reminders during a clinical visit can effectively prompt the primary care clinician to attend to a broad range of topics.[33] Similar to the Case Finding Health Assessment Tool (CHAT), we found that the RFIT was an efficient means for identifying risk factors [40]. However, some clinicians participating in this study did not review the RFIT responses regularly. Most participants preferred the direct tablet-to-EMR response transfer over a paper format. They reported less disruption to clinic workflow with minimal negative feedback from patients. To further decrease disruption to clinic workflow, further research should assess the use of email correspondence that can provide RFIT to patients prior to their appointment.

Second, we present a flexible, pragmatic approach to introduce a new workflow into primary care clinics. By adapting our tool and process to fit local needs and assessing both process and outcome indicators, we ensured rapid learning and enhanced utility of the resulting tool [25]. For example, during the study, adjustments were made to the location of the tablets in the clinic to facilitate increased use, and encounter notes were adapted to highlight key RFIT responses as requested by the clinicians. Traditional approaches would not enable adjustments during the research process [25]. As suggested by Ahmad et al [32], implementation strategies need to consider diversity in clinical settings and populations. Adjustment and preparation of the tool for implementation created a tool with a range of implementation options for a variety of primary care settings and patient populations. Implementation may include EMR prompts or summarized EMR input focused on topics for discussion.

Third, appropriately tailored tools can support acquisition of information to inform care. Primary care clinicians in the United States reported spending on average 16% of office visits on health counseling [13]. Katz et al [15] reported that 87%-89% of Canadian family physicians indicated they were comfortable counseling patients on risk behaviors, with smoking most commonly discussed (79%). In our study, 12% of patients indicated that they smoked. Physical inactivity was common; 56% of patients were not sufficiently active. Clinicians in our study reported less need for primary prevention tools for long-term patients. Long-term patients that attend routine care appointments are more likely to have risk factor documentation in the EMR and therefore may not require the RFIT. The RFIT may be better suited for new patients, patients with infrequent appointments, or patients experiencing life transitions, such as pregnancy. The literature supports an increasing need for low-cost, practical tools to address patient risk behaviors. Complementing risk factor identification with linkages to allied health professionals who are able to provide practical interventions can support primary care clinicians when providing primary prevention counseling and encourage the formation of healthy habits in patients [14,41-43].

Limitations

This study represents 2 clinics and 8 primary care clinicians in Manitoba. Our findings are not based on a representative sample of primary care clinicians. This study only represents consenting patients at each of the clinics. Clinicians and patients that chose to participate in this study may have a greater interest in primary prevention or the use of technology. Participating clinicians may also be more likely to discuss risk factors with their patients. We purposely chose clinics located in both a rural and urban area of the province and with different patient populations to elicit a range of views. Similar responses across the 3 focus groups offered convergence in forming themes.

We look forward to continuing our research on primary prevention and how to best meet the needs of clinicians and patients. Future research might consider if the RFIT can inform the care of other providers at the clinic such as nurses as well as if tailoring the RFIT to specific patient demographics and situations such as prenatal care may better inform primary prevention counseling.

Conclusions

Participants positively reviewed the use of the RFIT. Algorithmic information technology can collect, organize, and synthesize individual health information to inform and tailor primary care counseling to the patients' context and readiness to change their behavior. With this information, the clinician can individualize health promotion and prevention activities to the patients' social microcontext [17]. Ensuring accessibility of the tool, tailoring the tool to the appointment and patient, and making EMR notes meaningful for patient discussion can all enhance RFIT utility. The RFIT is a user-friendly tool that provides an effective method for obtaining risk factor information from patients. If implemented within a context that can support practical interventions to address identified risk factors, the RFIT can support brief interventions within primary care [15].

Acknowledgments

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Authors' Contributions

The RFIT study was conceptualized by LK, AK, GH, and AS. Focus groups were attended and transcriptions reviewed by LK and LL. The manuscript was prepared by LK and AK. The manuscript was edited and accepted in its final form by all authors.

Conflicts of Interest

None declared.

Multimedia Appendix 1
The Risk Factor Identification Tool (RFIT) questions.
[DOCX File , 42 KB - formative_v5i2e24382_app1.docx]

Multimedia Appendix 2

The electronic medical record (EMR) encounter note created for the physician from the Risk Factor Identification Tool (RFIT) Responses.
[PNG File , 249 KB - formative_v5i2e24382_app2.png]

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Abbreviations

CHAT: Case Finding Health Assessment Tool
EMR: electronic medical record
RFIT: Risk Factor Identification Tool

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Original Paper

Administering Virtual Reality Therapy to Manage Behavioral and Psychological Symptoms in Patients With Dementia Admitted to an Acute Care Hospital: Results of a Pilot Study

Lora Appel[1,2], PhD; Erika Kisonas[2,3], BHSc; Eva Appel[2], MSc; Jennifer Klein[1], BScN; Deanna Bartlett[1], BScN; Jarred Rosenberg[3], MD; Christopher NC Smith[3], MD

[1]Faculty of Health, School of Health Policy and Management, York University, Toronto, ON, Canada

[2]OpenLab, University Health Network, Toronto, ON, Canada

[3]Michael Garron Hospital, Toronto, ON, Canada

Corresponding Author:
Lora Appel, PhD
Faculty of Health
School of Health Policy and Management
York University
426 Health, Nursing and Environmental Studies Building
4700 Keele Street
Toronto, ON, M3J 1P3
Canada
Phone: 1 6475046537
Email: lora.appel@uhn.ca

Abstract

Background: As virtual reality (VR) technologies become increasingly accessible and affordable, clinicians are eager to try VR therapy as a novel means to manage behavioral and psychological symptoms of dementia, which are exacerbated during acute care hospitalization, with the goal of reducing the use of antipsychotics, sedatives, and physical restraints associated with negative adverse effects, increased length of stay, and caregiver burden. To date, no evaluations of immersive VR therapy have been reported for patients with dementia in acute care hospitals.

Objective: This study aimed to determine the feasibility (acceptance, comfort, and safety) of using immersive VR therapy for people living with dementia (mild, moderate, and advanced) during acute care hospitalization and explore its potential to manage behavioral and psychological symptoms of dementia.

Methods: A prospective, longitudinal pilot study was conducted at a community teaching hospital in Toronto. The study was nonrandomized and unblinded. A total of 10 patients aged >65 years (mean 86.5, SD 5.7) diagnosed with dementia participated in one or more research coordinator–facilitated sessions of viewing immersive 360° VR footage of nature scenes displayed on a Samsung Gear VR head-mounted display. This mixed-methods study included review of patient charts, standardized observations during the intervention, and pre- and postintervention semistructured interviews about the VR experience.

Results: All recruited participants (N=10) completed the study. Of the 10 participants, 7 (70%) displayed enjoyment or relaxation during the VR session, which averaged 6 minutes per view, and 1 (10%) experienced dizziness. No interference between the VR equipment and hearing aids or medical devices was reported.

Conclusions: It is feasible to expose older people with dementia of various degrees admitted to an acute care hospital to immersive VR therapy. VR therapy was found to be acceptable to and comfortable by most participants. This pilot study provides the basis for conducting the first randomized controlled trial to evaluate the impact of VR therapy on managing behavioral and psychological symptoms of dementia in acute care hospitals.

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KEYWORDS

virtual reality; wearable electronic devices; sensory art therapies; hospitalization; hospitals, community; hospitals, general; aged; humans; dementia; behavioral symptoms; nature; mobile phone

Introduction

Background

The term behavioral and psychological symptoms of dementia (BPSD) encompass a range of manifestations, including agitation, aggression, delusions, hallucinations, depression and apathy, sleep troubles, and wandering. These symptoms are complex, costly to treat, and lead to poor health outcomes; they are distressing both for people living with dementia and those who care for them [1]. For patients with dementia admitted to an acute care inpatient unit, the prevalence of associated BPSD is up to 75%, with aggression and activity disturbance being the most common [2,3]. Family caregivers have given rich reports about how BPSD may worsen during the acute care hospital stay and how hospital staff struggle to manage these symptoms adequately [2].

Current interventions to manage BPSD include pharmacological interventions, such as neuroleptic or sedating medications, and the application of physical barriers such as bed alarms, locks, Buxton chairs, and tethers. Many harmful consequences have been associated with pharmacological interventions, including cardiovascular events, falls, hastening of cognitive decline, and death [3]. Physical restraints are not any more benign, increasing the risks of pressure sores and infection and worsening anxiety, distress, and acts of physical violence; their use poses ethical and acceptability issues. New approaches are clearly needed, and many nonpharmacologic strategies have been attempted with varying levels of success. Following in the footsteps of music therapy and arts-based therapy [4-8], researchers have envisioned the application of virtual reality (VR) technology for dementia care [9-11].

VR is the term used to describe a 3D, computer-generated environment, which can be viewed and/or interacted with using special equipment such as head-mounted displays (HMDs) and haptic gloves to synchronously stimulate our senses to create the illusion of reality. VR provides a unique opportunity to expose individuals who are otherwise confined indoors (eg, in hospitals) to a variety of simulated natural and social environments that can be both calming and engaging (eg, peaceful beach, sunny autumn forest, and live music at a restaurant). Experiencing these environments may reduce symptoms such as depression and anxiety [12,13]. VR has been used in health care since the 1990s, developing into a tool that can address a variety of mental health concerns. The customizability of the illusion of reality created by VR environments has enabled clinicians to treat social anxiety disorders, specific phobias, eating disorders, substance misuse disorders, and depression using VR [14,15]. It has also been used in medical training, poststroke rehabilitation, and pain management [14,15]. Researchers and clinicians are eager to explore the potential of VR therapy to manage BPSD in the hope that this may prove to be a less expensive, noninvasive, and ethically acceptable means of engaging and distracting individuals with dementia, without the negative adverse effects associated with current approaches (eg, medication and physical restraints) [16,17].

Recent articles have reported a growing number of success stories of administering VR therapy to people living with dementia to alleviate stress, depression, and anxiety [18-21]. However, VR has yet to be rigorously evaluated as a type of therapy in various settings, including community care in private residences, rehabilitation centers, long-term care institutions, and acute care hospitals. We conducted a multisite feasibility study with 66 participants with varying severities and types of dementia or cognitive impairment recruited from a rehabilitation center, long-term care institution, or outpatient clinic day program [22]. On the basis of positive results of this study (ie, 85% of participants found the HMD easy to wear, 71% of participants would recommend VR therapy to a friend, and 76% of participants wanted to try VR therapy again) and a strong interest in nonpharmacologic solutions to help deprescribe antipsychotics for the management of BPSD from hospital clinicians, we designed a randomized controlled trial (RCT) to evaluate the impact of VR therapy on patients with dementia admitted to an acute care hospital. The design of the RCT was informed by this pilot study, which was reported in 2 papers. The first described protocol changes to processes, methods, workflow for the subsequent RCT, and learnings for introduction of a nonpharmacological intervention to an acute care hospital setting [23]. Second, this study reports on the feasibility (ie, acceptance, comfort, and safety) of administering immersive VR therapy (IVR) to patients with dementia in an acute care hospital.

Aims

The primary aim of the pilot study was to determine the feasibility of administering IVR therapy to inpatients at an acute care hospital in various stages of dementia, particularly those in moderate and advanced stages. This included assessing the tolerability or acceptability, comfort, and safety of the VR equipment and 360° film experiences. As an additional exploratory objective, the study looked at the potential of VR therapy to reduce the frequency and/or intensity of participants' BPSD during hospitalization.

Methods

Design

This study was a prospective, longitudinal pilot study. The study was nonrandomized and unblinded, and all participants received the study intervention.

Setting

The pilot study was conducted at a community teaching hospital affiliated with the University of Toronto, Toronto, Canada. Participants were recruited from the General Internal Medicine Department between July and October 2018. Ethics approval for the pilot study was obtained from the hospital research ethics board (reference number 748-1806-Mis-321).

Participants and Informed Consent

A total of 516 prospective participants were screened for possible inclusion in this study between July 31 and October 31, 2018. Of the 516 participants, 67 were eligible, and a total of 10 participants with dementia were recruited. Multimedia

Appendix 1 shows the recruitment process, which is further discussed in detail in a second manuscript [23]. Where applicable, the substitute decision maker (SDM) of prospective participants was contacted over the phone and introduced to the study. The SDM was also often the patient's primary caregiver. The research coordinator (RC) then employed a shared decision-making approach, whereby a signed informed consent (Multimedia Appendix 2) for the study was obtained from the SDM in person, and each study session was assented to by the patient. Although SDMs were permitted at study sessions, they were not formal participants in the study and therefore did not need to sign consent documents for themselves.

Inclusion or Exclusion Criteria

Patients were included if they were (1) aged >65 years, (2) diagnosed with dementia, and (3) admitted as inpatients at the study-site hospital. Patients were excluded if they (1) had open facial wounds, (2) had cervical conditions that would make use of a VR headset unsafe, and (3) had no contactable SDM (if applicable).

VR Therapy Intervention

The VR therapy intervention consisted of participants (individuals with dementia) viewing a sequence of 5 short 360° video clips (1-3 minutes each) depicting various natural scenes (rocky lakeshore, sunny forest, dense forest, floating icebergs, and sunny beaches) for a maximum of 20 minutes. Figure 1 shows a screenshot from 2 scenes. Participants could loop through the VR film sequence for up to 20 minutes. A nurse, SDM or caregiver, or RC helped them sit up in bed, and the RC assisted them to put on and remove the HMD. Figure 2 shows a patient trying the VR experience in a hospital bed.

Figure 1. 2D screen capture of 2 of the 5 virtual reality scenes (scene 2: open field with foliage and scene 5: Aquamarine beach).

Figure 2. Participant tries the virtual reality experience. Written informed consent was obtained from the individual for the publication of this image.

Participants used a Samsung Gear VR HMD and Sennheiser HD 221 headphones. The HMDs were equipped with individual removable foam inserts to meet the hospital's infection prevention and control hygiene requirements.

Data Collection

BPSD at Baseline and During Hospitalization

BPSD at baseline was reported using the Neuropsychiatric Inventory (NPI; 12-item), a validated scale that measures the presence or level of BPSD and reflects changes in patient behavior since the onset of dementia [24]. The NPI was administered to a primary caregiver (which was also the SDM)

who rated the patient's behavior from the past 4-6 weeks. In-hospital BPSD was measured by counting the total number of instances of BPSD (by category) from the nursing notes during hospitalization.

On the basis of recommendations by a geriatrician, instances of BPSD were grouped into the following categories: agitation, refusing or declining medical care, violence, wandering, vocalizations, insomnia symptoms, mood symptoms, disorganized thoughts and content (paranoia), perceptual disturbances, additional falls precautions applied, security personnel called, sitters or personal support workers at the bedside for patient monitoring purposes, physical restraints used, and chemical restraints used.

Baseline Health and Hospital Metrics

Demographic and health history information was gathered through survey questions from the participant, occasionally with support from the caregiver or SDM, during the first study session. This included the level of education, marital status, sensory or mobility impairments, and the use of assistive devices (eg, wheelchair, walker, cane, glasses, and hearing aids). Participants were also asked about previous experiences with VR technology. Other personal health information, including age, sex, cognitive diagnoses (as described in physician notes), markers related to participant hospital care (length of stay [LoS], discharge disposition, and all-cause mortality), dose and frequency of sedatives (daily and as-needed) administered during the hospital stay, Confusion Assessment Method scores, physical restraint use, number of pressure ulcers, and number of falls, were obtained through review of participants' electronic medical records (EMRs). Of note, because of the lack of standardization among the tools and infrequent recording of scores for instruments used to assess cognitive impairment (eg, Montreal Cognitive Assessment and Mini-Mental State Examination), in the patients' hospital EMR, dementia severity and cognitive status were based on the terminology used by physicians in their notes (ie, mild, moderate, and advanced) [23].

VR Acceptability, Comfort, and Safety

As an overall measure of VR acceptability (tolerability), we reported the number of sessions in which the participants were able to wear the HMD and recorded how long the participants kept the HMD on to view the films. A modified version of the State-Trait Anxiety Inventory (STAI Y) [25] was used to collect information about the participants' current state of anxiety pre- and postintervention. Post-VR therapy, open-ended questions were asked to capture feedback about any discomfort experienced; whether the HMD was too heavy, if it applied too much pressure on their head, face, or nose as well as sound quality and image focus. Safety was operationalized by the presence of adverse events or adverse effects.

A modified version of the Music in Dementia Assessment Scales (MiDAS) [26], developed and validated to evaluate music therapy for people with dementia, was completed by the RC to assess whether there were observable changes in the participant's mood or behavior and engagement (eg, interest, response, and enjoyment) while exposed to VR therapy. The RC recorded (through written notes that were later transcribed) any vocalizations, changes in facial expressions, breathing patterns, gestures, body movements, level of activity, and impressions of participant relaxation or enjoyment interpreted through observations of reactions and/or elicitation of spontaneous conversations such as recounting stories or pleasant life memories. Caregiver or SDM feedback regarding participant response to the VR intervention was also recorded. This included caregiver or SDM insights as to why participants reacted in certain ways to certain VR films. Finally, participants were asked about preferences for future VR film content and if they would be interested in additional VR therapy sessions.

Results

Participants

A total of 10 patients (8 female) with a mean age of 86.5 (SD 5.7) years participated in the study. Dementia severity ranged from mild (2/10, 20%), moderate (1/10, 10%), and advanced (4/10, 40%), with some unspecified (3/10, 30%). Half (5/10, 50%) the participants lived at home—3 (30%) lived alone, 1 (10%) lived with family members, and 1 (10%) had an other arrangement. The other half (5/10, 50%) of the participants lived in senior housing—4 (40%) lived in long-term care or assisted living and 1 (10%) lived in a retirement home or independent living. The majority of participants (8/10, 80%) were not in a relationship—3 (3/10, 30%) were widowed, 1 (1/10, 10%) was single, 1 (1/10, 10%) was separated, and 1 (1/10, 10%) had an other arrangement. Of the 10 participants, 2 (20%) were married.

Of the 10 participants, 6 (60%) were diagnosed with delirium during their hospital stay and 2 (20%) were diagnosed with comorbid cognitive conditions—1 (10%) had depression and 1 (10%) had depression, anxiety, executive dysfunction, and sleep issues. The majority of participants (8/10, 80%) were free of major visual or auditory impairments; 8 (8/10, 80%) wore glasses and 2 (2/10, 20%) used hearing aids. All participants used some form of mobility aid. The vast majority (9/10, 90%) of participants had normal head mobility, and most (8/10, 80%) had limited body mobility. Multimedia Appendix 3 provides more details.

BPSD at Baseline and During Hospitalization

Presentation of BPSD during hospitalization varied greatly: the majority of participants displayed agitation (8/10, 80%), refusal of medical care (6/10, 60%), wandering (6/10, 60%), vocalizations (7/10, 70%) and symptoms of insomnia (8/10, 80%) and required additional fall precautions applied by staff (7/10, 70%). Of the 10 participants, 2 (20%) displayed violent behavior and 3 (30%) required a sitter or patient care assistant and personal support worker at the bedside for patient monitoring purposes. Some participants also had chemical restraints (4/10, 40%) or physical restraints (3/10, 30%) administered during their hospital stay. Table 1 provides the baseline and in-hospital presentation of BPSD by participant.

Table 1. Behavioral and psychological symptoms of dementia at baseline and in-hospital (N=10).

Characteristics	Value
Total Neuropsychiatric Inventory score (12-item), mean (SD)	13 (8.87)
Behavioral and psychological symptoms of dementia behavior displayed, n (%)	
Agitation	8 (80)
Symptoms of insomnia	8 (80)
Additional fall precautions applied by staff	7 (70)
Vocalizations	7 (70)
Wandering	6 (60)
Refusal of medical care	6 (60)
Mood symptoms (depression or anxiety)	3 (30)
Required constant monitoring by sitter or personal care aide or personal support worker	3 (30)
Violent behavior	2 (20)
Perceptual disturbances	1 (10)
Paranoia	0 (0)
Chemical restraints	4
Physical restraints	3

Baseline Health and Hospital Metrics

The average hospital LoS for study participants was 11.1 (SD 7.2) days, which is 36% above the average LoS of 7 days for senior patients without dementia admitted to this hospital. Daily medications related to cognition, mental health, and sleep disorders were recorded; of the 10 participants, 4 (40%) were prescribed at least one cognition-enhancing medication (eg, galantamine, memantine), 4 (40%) were prescribed at least one antidepressant medication (eg, selective serotonin reuptake inhibitors, serotonin, and norepinephrine reuptake inhibitors), and 1 (10%) was prescribed at least one antipsychotic medication (eg, risperidone and quetiapine). Of 10 participants, 3 (30%) experienced falls during their hospital stay, of whom 1 (10%) had multiple falls without injury. Table 2 provides details on the factors related to hospital stay.

Table 2. Factors related to hospital stay (N=10).

Characteristics	Value
Length of stay (days), mean (SD)	11.09 (7.16)
Discharge disposition, n (%)	
Home	4 (40)
Transferred to another institution (Complex Continuing Care)	2 (20)
Transferred to another institution (rehabilitation center)	1 (10)
Transferred to another institution (unknown)	1 (10)
Expired	1 (10)
Number of daily medications prescribed, n (%)	
3-4	2 (20)
1-2	5 (50)
0	3 (30)
Number of participants who fell with injury, n (%)	1 (10)
Number of participants who fell without injury, n (%)	2 (20)
Number of pressure ulcers, n (%)	0 (0)
Number of participants readmitted within 30 days of discharge, n (%)	1 (10)

VR Therapy Intervention

VR Acceptability, Comfort, and Safety

A total of 18 VR sessions were conducted with 10 participants. None of the participants kept the HMD on for the entire 20-min maximum allotted time. Table 3 details the reasons why the VR HMD was removed prematurely. Participants watched VR videos for an average of 6.2 (SD 5.5) minutes. After completing the first study session, most participants (7/10, 70%) opted for additional sessions during their hospital stay.

Participants who had body mobility limitations (8/10, 80%) experienced the VR sessions in their hospital bed, seated in Fowler's position (an almost upright position). Participants without body mobility limitations (2/10, 20%) viewed VR sitting independently on the side of their bed (1/10, 10%) or in a nonswivel chair (1/10, 10%).

Table 3. Reasons for premature removal of virtual reality head-mounted display (N=18).

Characteristic	Value
Sessions stopped before maximum allotted time, n (%)	18 (100)
Stopped as per participants choice without distress	12 (67)
Stopped due to low interest	3 (17)
Stopped due to head-mounted display slipping off	1 (6)
Stopped due to participant falling asleep	1 (6)
Stopped due to negative side effects	1 (6)

The majority (7/10, 70%) of participants reported that they found the headset comfortable. Of the 10 participants, 1 (10%) found the VR headset too heavy; they also mentioned that they would like to own VR at home if a lighter model were available. Moreover, 2 participants (20%) were unable to provide feedback regarding comfort. No participants reported feeling pressure on their nose from the HMD.

Of the 10 participants, 1 (10%) experienced negative side effects of self-limiting dizziness with mild nausea but no vomiting from the VR session. There were no reports of interference between the VR equipment and any medical devices (eg, hearing aids).

VR Impact on Enjoyment and Relaxation

We found that 6 of the 10 (60%) study participants had difficulty answering the pre- and postsurvey questions about their mood before and after VR therapy, and the RC often relied on caregiver input and participant body language to make educated estimations of participants' moods that they recorded as being communicated by the participants themselves. Multimedia Appendix 4 provides the results of the mood questions for each of the 18 sessions. To consolidate the table, where the participant was unable to respond (response recorded as N/A), we provided the response noted by the caregiver or researcher. Precedence was always given to the participant's response.Multimedia Appendix 5 summarizes the instances across the 18 VR sessions in which patients were able to respond to the mood questions; patients were able to respond 53% of the time in the prequestions and 58% in the postquestions.

In the majority of sessions (14/18, 78%), participants made some substantial conversation or vocalizations. Although multiple participants simply described what they were seeing, one participant expressed interest and desire to engage with their (virtual) surroundings:

> *"look at the waves there!" "I'd love to be there and paddle" "all I need is a swimsuit" "I have to get in, it's too cold" "the forest! The tall trees… and lots of weeds… I wonder if there's any deer in there."'* [P8-1]

In more than half of the VR therapy sessions (10/18, 56%), the RC perceived some substantial expression of enjoyment by the participant during the VR experience. Observed behaviors perceived as participant enjoyment included actively looking around and movements that suggested they were interacting with their environment, such as reaching out with hands or legs, pointing, waving, and wiggling toes. Participants also displayed enjoyment through laughter and verbal feedback such as: "I liked the pictures" and "well God gave us a beautiful world." Of the 10 participants, 1 (10%) expressed substantial enjoyment with frequent laughing every 10 seconds, pointing at scenery details and waving at people in the VR environment and one participant (10%) expressed significant enjoyment of the VR scene with many positive and repeated vocalizations such as "it's beautiful, waves coming in like soapy water," "time to go paddling" and engagement with the VR environment, including wiggling their toes during the beach scene. This participant even made jokes about the scenes saying, "I'm going to drown if you don't get me out of here" and "I think if I went here I would get lost"; the SDM confirmed that they were joking and the participant showed no signs of distress or agitation. During the post-VR interviews, 4 (40%) participants expressed enjoyment of VR therapy; 1 (10%) reported feeling bored but wanted to try VR again with different content and a lighter HMD, 1 (10%) had inconsistent feedback across sessions due to language impairments, 3 (30%) were unable to express any opinions because of language impairments or forgetting details of the experience, and 1 (10%) did not enjoy the experience because of side effects of nausea and dizziness.

The enjoyment caused by the VR session was often shared by caregivers or family members present during the VR session with the participants. In one of the 18 sessions (6%), the participant and 3 family members were all laughing so much that the nurse came to the room to see what was going on. During another session, the caregiver remarked that they had not seen anything (eg, television) hold the participant's interest

this well in over a year and recorded a video on their smartphone to share with friends and family. In another session, the participant was blowing kisses at the end of the session, which was enjoyed by the whole family who smiled and laughed along with the participant.

In almost two-thirds of the sessions (11/18, 61%), the RC perceived some to substantial participant relaxation from experiencing VR. Relaxation was perceived by observed behaviors during VR sessions and patient and caregiver feedback in post-VR interviews. Observed behaviors perceived as participant relaxation included deep, slow, and steady breathing, relaxed grip of the caregiver's hand, and caregivers noting that the participant looks relaxed or calmer than usual. Relaxation was also confirmed verbally by participants, for example, in one of the 18 sessions (6%), the participant responded "yes, calming" when asked if they liked the session.

VR Content

Half of the participants (5/10, 50%) were able to provide verbal feedback about the VR content. When the 10 participants were asked what they liked most about the VR experience, 2 (20%) responded that they enjoyed water scenes the most, 1 (10%) responded that they enjoyed everything, 1 (10%) responded that they enjoyed the sounds the most, and 1 (10%) was not sure. When asked what other places they would like to see in VR, each of the 5 participants had a different answer. Despite these differences, all participants were asked about nature scenery. Table 4 provides detailed responses to questions related to the content of the VR experiences by participants.

Table 4. Virtual reality content participant feedback (N=10).

Question and participant number	Feedback
What did you like most?	
P1	Unable to provide feedback
P2	Unable to provide feedback
P3	Unable to provide feedback
P4	Unable to provide feedback
P5	Provided different feedback during different sessions: 1. "Sounds" 2. Unable to provide feedback 3. Unable to provide feedback 4. "Very good" 5. "Very soothing" 6. Unable to provide feedback
P6	"Not sure"
P7	"Everything, liked it very much"
P8	Provided different feedback during different sessions: 1. "Swimming" 2. "It was good" "The water"
P9	"Beach"
P10	N/A[a]—did not enjoy the session due to side effects
Are there any other places you would like to see?	
P1	Unable to provide feedback
P2	Unable to provide feedback
P3	Unable to provide feedback
P4	Unable to provide feedback
P5	Provided different feedback during different sessions: 1. "Park" 2. Unable to provide feedback 3. Unable to provide feedback 4. Unable to provide feedback
P6	"A combination of videos" "more nature–forest+birds"
P7	"Liked water, seen too many forests, didn't like the forest"
P8	Provided different feedback during different sessions: 1. "The ocean" 2. "Would like to see more animals like reindeer"
P9	"Flowers, very nice, leaves" "Christmas trees+lights"
P10	"Not sure"

[a]Not applicable.

Discussion

Principal Findings

The main finding of this pilot study was that the VR intervention was well accepted by the patient participants, consisting of individuals with a multitude of sensory, cognitive, and physical health conditions, including advanced dementia, limited mobility, and use of hearing and vision aids. In addition, despite many observed BPSD symptoms during their hospitalizations, none of the patients displayed aggressive or agitated symptoms during VR therapy, and none were actively averse to its application.

The Samsung Gear VR HMD was well tolerated by the participants and was reported to be comfortable by 7 of 10 participants (2 participants were unable to answer). A few challenges arose related to the HMD comfort and fit; the adjustable head straps were ill-fitting and resulted in the HMD slipping down the participant's face.

VR exposure was considered acceptable by most (9/10, 90%) participants. For one participant who had nausea and dizziness,

the RC noted that the participant was "actively looking around in all directions, head moving quite quickly left and right," which may have contributed to these side effects. The outcomes indicate that in more than half of the immersive VR sessions, participants experienced enjoyment (10/18, 56%) and relaxation (11/18, 61%). Moreover, these effects were also felt by some caregivers and/or family members who were present. Most (7/10, 70%) participants expressed a desire to try immersive VR again, and there was interest in viewing more varied natural scenes and possibly personalized content. According to the participants' suggestions, the VR film offering should be expanded to include a greater diversity of experiences such as live music scenes, scenes featuring people walking around, and scenes featuring animals.

Despite being conducted in sicker patients admitted to an acute care hospital, including moderate and advanced dementia, the outcomes of this study align with those of a previous feasibility study with 66 well, ambulatory older people with various physical and cognitive impairments, using a similar VR therapy exposure [22]. It is encouraging that VR therapy is feasible and has promising results across a spectrum of patients and environments, as clinicians from different hospital departments (eg, nephrology, intensive care, respirology) showed strong interest in evaluating VR intervention in their departments. Overall, patients with dementia appear to accept immersive VR, although there is a need to conduct rigorous studies and establish guidelines to ensure reliability and consistency in evaluating VR interventions.

Limitations

The limitations of this research stem primarily from the small sample size and proof-of-concept approach characteristic of pilot studies. The design did not employ a control arm, and the sample size was not meant for statistical analysis of the significance of effects. With respect to outcomes regarding the feasibility of exposing patients with dementia to VR therapy in acute care hospitals, the main limitation was having no cases of patients in isolation because of infection control restrictions, patients with constant oxygen supplied through the nose, or patients fed through feeding tubes, as these are conditions that might be expected to influence the application of VR and would have been useful to study.

Another limitation of the study was the lack of validated instruments to measure the impact of nonpharmacological interventions in acute care hospitals. For the pilot study, we adapted existing scales (STAI, MiDAS), generally used in long-term care settings, to the relatively short-term stay in the acute care hospital.

In this study, we measured the impact on mood and symptoms (enjoyment and relaxation) based on the unblinded researchers' observations. This may have introduced researcher bias.

Conclusions

This was a small-scale pilot study carried out primarily to help identify feasibility issues in preparation for a large RCT designed to measure the impact of VR therapy on managing BPSD in acute care settings. The focus of the pilot was on testing various aspects of the proposed protocol (processes, methods, resources, etc) and validating the feasibility of using immersive VR technology for patients in all stages of dementia during their acute care hospital stay. The results demonstrate that VR therapy can be administered to patients living with dementia admitted to an acute care hospital, with patients accepting the hardware (equipment) and VR content very well with minimal, mild adverse effects. BPSD symptoms were not a barrier to using this equipment, and there were also no reports of audio frequency interference with hearing aids or with other medical devices while using VR.

These findings support conducting a large-scale RCT to investigate immersive VR therapy as a nonpharmacological intervention to manage BPSD in acute care hospitals. Particular interest should be given to people with more advanced stages of dementia (moderate to severe), as there are pervasive challenges in managing symptoms and improving the quality of life of these individuals using the current standard of care.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Recruitment flow diagram.
[PNG File , 27 KB - formative_v5i2e22406_app1.png]

Multimedia Appendix 2
Informed consent form.
[PDF File (Adobe PDF File), 207 KB - formative_v5i2e22406_app2.pdf]

Multimedia Appendix 3
Demographic and baseline information.
[PDF File (Adobe PDF File), 140 KB - formative_v5i2e22406_app3.pdf]

Multimedia Appendix 4
Responses to pre- and postmood questions by session.
[PDF File (Adobe PDF File), 123 KB - formative_v5i2e22406_app4.pdf]

Multimedia Appendix 5
Participants' ability to respond to mood questions.
[PDF File (Adobe PDF File), 101 KB - formative_v5i2e22406_app5.pdf]

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Abbreviations

BPSD: behavioral and psychological symptoms of dementia
EMR: electronic medical record
HMD: head-mounted display
IVR: immersive virtual reality
LoS: length of stay
MiDAS: Music in Dementia Assessment Scales
NPI: Neuropsychiatric Inventory
RC: research coordinator
RCT: randomized controlled trial
SDM: substitute decision maker
STAI: State-Trait Anxiety Inventory
VR: virtual reality

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Original Paper

Quantification of Smoking Characteristics Using Smartwatch Technology: Pilot Feasibility Study of New Technology

Casey Anne Cole[1], PhD; Shannon Powers[2,3], BS; Rachel L Tomko[4], PhD; Brett Froeliger[2,5], PhD; Homayoun Valafar[1], PhD

[1]Department of Computer Science and Engineering, University of South Carolina, Columbia, SC, United States

[2]Department of Psychological Sciences, University of Missouri-Columbia, Columbia, MO, United States

[3]Department of Psychology, University of Denver, Denver, CO, United States

[4]Department of Psychiatry & Behavioral Sciences, Medical University of South Carolina, Charleston, SC, United States

[5]Department of Psychiatry, University of Missouri-Columbia, Columbia, MO, United States

Corresponding Author:
Casey Anne Cole, PhD
Department of Computer Science and Engineering
University of South Carolina
1400 Assembly Street
Columbia, SC, 29208
United States
Phone: 1 9372067968
Email: coleca@email.sc.edu

Abstract

Background: While there have been many technological advances in studying the neurobiological and clinical basis of tobacco use disorder and nicotine addiction, there have been relatively minor advances in technologies for monitoring, characterizing, and intervening to prevent smoking in real time. Better understanding of real-time smoking behavior can be helpful in numerous applications without the burden and recall bias associated with self-report.

Objective: The goal of this study was to test the validity of using a smartwatch to advance the study of temporal patterns and characteristics of smoking in a controlled laboratory setting prior to its implementation in situ. Specifically, the aim was to compare smoking characteristics recorded by Automated Smoking PerceptIon and REcording (ASPIRE) on a smartwatch with the pocket Clinical Research Support System (CReSS) topography device, using video observation as the gold standard.

Methods: Adult smokers (N=27) engaged in a video-recorded laboratory smoking task using the pocket CReSS while also wearing a Polar M600 smartwatch. In-house software, ASPIRE, was used to record accelerometer data to identify the duration of puffs and interpuff intervals (IPIs). The recorded sessions from CReSS and ASPIRE were manually annotated to assess smoking topography. Agreement between CReSS-recorded and ASPIRE-recorded smoking behavior was compared.

Results: ASPIRE produced more consistent number of puffs and IPI durations relative to CReSS, when comparing both methods to visual puff count. In addition, CReSS recordings reported many implausible measurements in the order of milliseconds. After filtering implausible data recorded from CReSS, ASPIRE and CReSS produced consistent results for puff duration (R^2=.79) and IPIs (R^2=.73).

Conclusions: Agreement between ASPIRE and other indicators of smoking characteristics was high, suggesting that the use of ASPIRE is a viable method of passively characterizing smoking behavior. Moreover, ASPIRE was more accurate than CReSS for measuring puffs and IPIs. Results from this study provide the foundation for future utilization of ASPIRE to passively and accurately monitor and quantify smoking behavior in situ.

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KEYWORDS

smartwatch; CReSS; smoking topography; ASPIRE; automated; wearable technology; wearable computing; smoking

Introduction

Tobacco use disorder (TUD) is the leading preventable cause of death worldwide (including the United States) [1], and the costs associated with its treatment and prevention remain a major economic burden on society [2]. Therefore, a better understanding of the behavioral elements and mechanisms that maintain smoking behavior is critically important for preventing future smoking-related illnesses. While there have been substantial technological advances in studying the neurobiological and clinical bases of TUD and nicotine addiction, there have been relatively minor advances in technologies for monitoring, characterizing, and intervening on smoking behavior. Therefore, there is a critical need for leveraging emerging technologies that may help provide personalized strategies for smoking cessation.

Traditional approaches to the study of human behavior primarily rely upon self-reporting or laboratory observations. Despite strengths found in self-report and laboratory-based research, those techniques, by design, are prone to limitations in external validity and are subject to human error. To more fully and accurately characterize and understand factors influencing people's behavior, enabling technologies must be developed to allow nonintrusive and longitudinal observation of human behavior in natural settings. There are numerous advantages in passive and accurate characterization of smoking in real time with temporal precision [3] and without recall biases. Real-time quantification of smoking duration before and during a cessation attempt can help to develop a more personalized and effective cessation protocol. Wearable devices are well-positioned to passively assess a person's behavior in the aforementioned context.

Wearable devices are equipped with a rich array of sensors (accelerometer, gyroscope, magnetometer, barometer, GPS, heart rate, electrocardiogram, oximeter) and may serve as a powerful platform for nonintrusively capturing and studying human behavior. In addition, the availability of mobile and wearable devices is an international phenomenon, and their use is not confined to any particular socioeconomic class. Therefore, the use of these devices for sensing, recording, and identifying human activities has the potential to passively observe health behaviors and be deployed internationally without confinement by any socioeconomic, political, or geographical barriers.

In recent years, there have been several reports of utilizing commercially available smartwatches in studying human activities. These include generic activities such as step counts, sleep detection, and rest periods, while others include more specific activities such as eating [4], drinking [5], managing diabetes [6,7], or smoking [8]. Previous work has established the use of wristworn devices in observing and interpreting smoking behavior in laboratory settings [9-13] and in situ [8,14]. Some of these devices use proprietary sensors [5,15-17], while others use off-the-shelf devices such as smartwatches [8,9,14,18,19]. The use of smartwatches in continuous monitoring of human activities and behavior is compelling for several reasons including their availability, decreasing cost, popularity, and the convenience and completeness of data collection. The data connectivity that is afforded by smartwatches adds a critical component to their appeal, allowing for real-time observation and interpretation of activities that can lead to immediate deployment of the appropriate intervention. Artificial intelligence (AI)-assisted detection of smoking with smartwatch technology [8-10,14,18-20] can reduce the burden of self-reporting by the user and automate notification of the team of research scientists and the caregivers. Despite their potential, the accuracy and resolution of data collected by smartwatches have not been comprehensively explored in comparison to traditional smoking behavior assessments. More specifically, while it has been shown that detection of smoking a cigarette is possible with a smartwatch [8,9,14,18,21,22], the use of smartwatches in better exploring more detailed smoking characteristics of human subjects remains unanswered. Smoking characteristics (eg, number of puffs, the length of smoking session, duration of puffs) vary across smokers, are associated with overall toxicant exposure [23], and are subject to modification with smoking cessation pharmacotherapy [24]. Therefore, accurate quantification of smoking characteristics using a smartwatch in naturalistic settings is advantageous in order to estimate smokers' toxicant exposure in daily life.

Observation of smoking using smartwatches has several compelling aspects. First, smartwatches have sufficient storage capacity to record and store sensor data for a duration longer than 24 hours. The recording duration can be extended into months by the addition of micro-SD storage media to the companion phone. Second, the collected data will require no additional action (other than periodic charging of the device) by the user or the participant of a study, qualifying this method of data acquisition to be highly unobtrusive. Third, unlike self-reporting approaches, continuous recording of sensor data can provide a comprehensive report of a person's activities in natural settings prior to and after the event of interest. For instance, proper interpretation of the sensor data can provide a detailed view of related human activities such as drinking, eating, sleeping, exercising, and smoking all in one experiment. The collection of such a detailed ensemble of activities is nearly infeasible through self-reporting when observed in situ. Fourth, the real-time connectivity of smartwatches allows for real-time observation of human behavior, which can be used in numerous ways to study or augment human behavior. For example, the adherence of a subject to study protocols can be viewed and confirmed, and if necessary, notifications and reminders can be sent to the participants. Real-time and continuous connectivity with participants allows for the initiation of the appropriate actions, paving the way for personalized intervention or cessation approaches.

In this report, we present an evaluation and comparison of the quality of smoking data collected by smartwatches, Clinical Research Support System (CReSS), and video recordings of participants in a laboratory setting. In particular, we compared and contrasted the accuracy of observing interpuff intervals (IPIs) and puff duration (PD) using the Automated Smoking PerceptIon and REcording (ASPIRE) smartwatch application and the CReSS device. We resorted to human annotation of visual recordings of smoking sessions when possible to resolve

substantial disagreements between the ASPIRE and CReSS approaches. We also explored the additional capabilities of the ASPIRE-based method and comment on the significant advantages that it affords and its novel future utilities.

Methods

CReSS Device

The CReSS Pocket (Borgwaldt KC Inc, Richmond, VA) is widely used for studying smoking in a laboratory setting [25-28] and is considered the gold standard of data collection in the field of smoking research. Though the CReSS device provides objective measures of smoking topography and is amenable to use in a laboratory setting, it is relatively expensive (US ~$5500) and interferes with the natural smoking experience. These issues limit its utility for characterizing ad lib smoking in a smoker's natural environment, while interfering with normal smoking patterns in a laboratory.

Characterization of Smoking Topography Using a Smartwatch

Smoking topography has been used to refer to a number of specific aspects of smoking behavior such as puff volume, maximum puff velocity, IPI, PD, number of puffs per cigarette, and total smoking duration.[25] In this study, we adopted a condensed set of smoking characteristics, namely IPI and PD, as the topography of smoking. These 2 characteristics (IPI and PD) can be used to calculate nearly all of the remaining measures such as the total duration of smoking, puff velocity (and therefore maximum, minimum, and medial puff velocity), and number of puffs per smoking session (or a cigarette). However, the measure of puff volume is the only parameter that cannot be directly calculated from the accelerometer data.

A smartwatch-based method allows participants to smoke freely in their natural settings without the need to use an intermediary device. Our previous work reported the development of an Android Wear OS-based software (ASPIRE) package that is capable of recording [9] and automating detection of smoking gestures (puff) [14]. ASPIRE incorporates a hierarchy of AI techniques in order to achieve automated detection of smoking sessions with as high as 97% success in laboratory settings [9,18] and 90% success in natural settings [14]. Previous work has established the high accuracy of ASPIRE in detection of smoking sessions, but its performance in the quantification of detailed smoking characteristics has not been reported. The more fine-grained assessment of a smoking session is clearly a more challenging task and provides useful information that can be invaluable in efforts to develop personalized cessation plans.

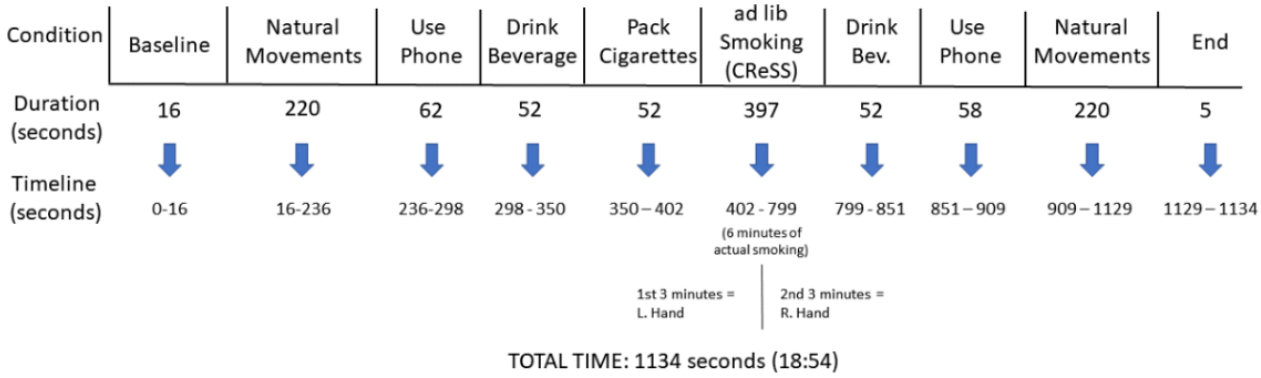
In the current study, participants were provided a smartwatch (Polar M600) and Android smartphone for the duration of data collection. Our selection of the smartwatch (Polar M600) primarily was based on a balance between the cost of the equipment (limited to US $150), availability of the needed sensors (accelerometer and gyroscope), programmability using the common Android Studio framework, battery life that exceeded 1 day of use, and Wear OS compatibility. The ASPIRE app listens and collects data from the participant and then sends the data via a Bluetooth connection to the companion smartphone app. The smartphone then uploads the data to a secure server for storage and analysis. The current version of ASPIRE can be obtained from the corresponding author and installed on either a phone/watch pair or as a standalone app on the watch. ASPIRE can be deployed on any smartwatch that is Wear OS compatible.

Data Collection Protocol

Participants were first outfitted with a Polar M600 to wear on their left hand. Participants were asked to follow a prompt screen on a computer in the laboratory that gave them precise instructions on what behaviors to perform as well as how long to execute each behavior. An overall view of the experimental paradigm with associated durations is shown in Figure 1. For this study, participants were asked to smoke a total of 6 minutes, in which they were asked to split evenly between their left and right hands. In addition to smoking, they were also asked to record over 7 minutes of other movements including 52 seconds of "packing" their cigarette package. It is important to note that the experimental protocol defined here was designed to address a number of questions in a single recording session to optimize the use of human subjects. Some of the targeted investigations in this experiment included the difference in smoking gestures when recorded from left versus right hands, the ability to detect smoking-related activities from the nonsensor hand (the hand without the smartwatch), and recording of other gestures such as packing and opening of a cigarette pack. In addition to recognition of smoking-related activities, other psychological and cognitive parameters related to smoking were measured for other investigations. In this study, we only utilized data related to quantification of IPI and PD.

The CReSS device was used to record the following measures: puff volume, average flow, peak flow, time of peak flow, PD, and IPI. The two measures of interest for this study were PD and IPI. The PD is the length of time in milliseconds that a person inhales for a given intake. The IPI is the number of milliseconds between the end of one puff and the beginning of the next. CReSS records both a high-level and detailed view of these measures. A median measure is used for the high-level view due to the small sample size and existence of outliers that are inherent to the device. The detailed view contains information about each one of the measures per puff. In addition to the data collected by the CReSS and smartwatch devices, videos of each session were recorded and annotated by 2 independent raters (interrater reliability=1.0).

Figure 1. Outline of the protocol used for data collection in the laboratory. CReSS: Clinical Research Support System.



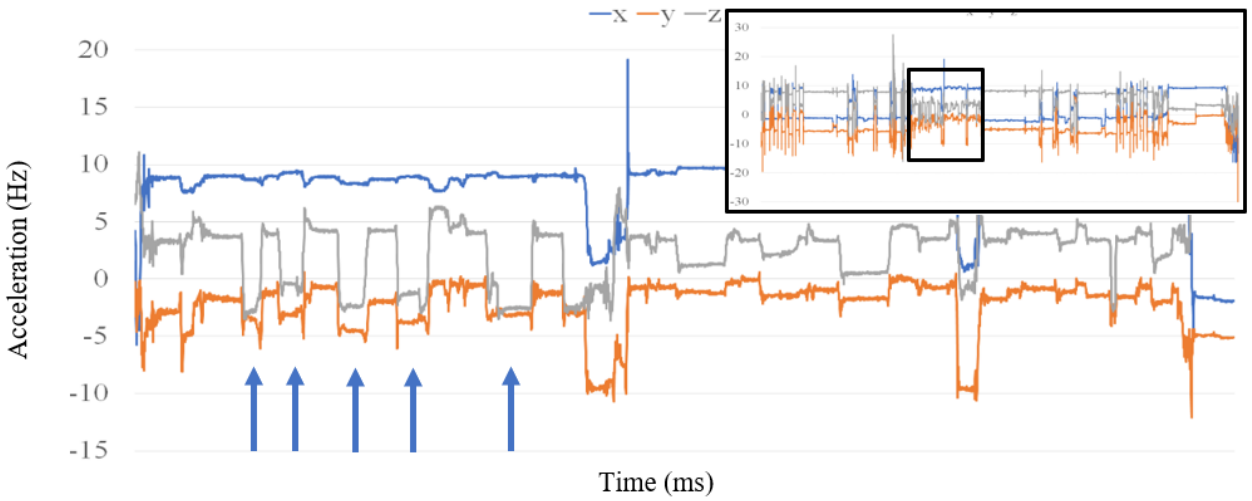
Participants

Participants were recruited via community advertisements, attended an in-person screening visit to determine eligibility, and then attended an experimental smoking visit. Participants gave written informed consent approved by the Medical University of South Carolina Institutional Review Board and received financial compensation for study participation. Inclusion criteria were age ≥18 years, having an expired carbon monoxide concentration ≥6 ppm (to confirm smoking status), and being willing and able to comply with protocol requirements. The participants (N=35; 13 women, 22 men) were an average age of 43.91 years (SD 12.76 years) with a mean carbon monoxide level of 26.57 ppm (SD 12.32 ppm). Due to recording errors, 8 participants had incomplete CReSS (5/35) or ASPIRE (3/35) data, resulting in a final analytic sample of 27 participants. The primary source of recording errors was deviation from the study protocol.

Data Annotation Procedure

The first step in the evaluation procedure was to annotate the data collected from smartwatch, CReSS, and video recordings. Due to the time and effort required for the video recordings, only the puff count from each hand was visually enumerated. The annotation for the smartwatch and CReSS device consisted of a well-trained researcher marking the timestamp associated with the beginning and end of each puff. Using this information, PD and IPI were measured. Each puff is easily identifiable as first starting with a slight or negligible change in the x dimension (±1), a moderate decrease in the y dimension (–4), and a sharp decrease in the z dimension (–8) from a resting position (as shown in Figure 2). This is then followed by a period of uninterrupted and equilibrated values of x, y, and z at around 9 m/s^2, –5 m/s^2, and –3 m/s^2, respectively. The end of a smoking gesture was marked as the return of the x, y, and z values to a "resting" state. These numbers vary per participant but will follow the same general pattern.

Figure 2. A sample of Automated Smoking PerceptIon and REcording (ASPIRE)'s recording session illustrated in the upper right corner. The main and larger figure depicts the portion of the image that corresponds to a smoking session (arrows indicate the start of a puff).



Evaluation and Exclusion of Data

The first step in the evaluation of this work was to annotate the data collected from the participants' puffs. The PDs and IPIs were calculated using these annotations. In the case of ASPIRE, the known sampling rate of 30 Hz was used to convert the timesteps into millisecond units. Figure 2 shows an example of a full set of data (shown in the upper right box) recorded by ASPIRE and a subsection of the data that contained smoking (annotated puffs are denoted with arrows). The period of smoking shown in Figure 2 accounts for approximately 3 minutes of data.

The second phase of the evaluation consisted of calculating the Pearson correlation coefficients between the extracted PDs and IPIs reported by CReSS and ASPIRE. Correlations were first examined using the reported median data for all subjects and then followed by analysis of the data for each individual subject.

Due to the switching of the smoking hand without the transfer of the smartwatch, half of the smoking session was not recorded by the smartwatch. Therefore, using the video recordings of the smoking sessions, we limited our comparison exercise to the portion of the smoking sessions that was recorded by both CReSS and ASPIRE. In addition, in some instances, CReSS reported implausible measures, inclusion of which would provide an inaccurate comparison of the 3 methods. For instance, CReSS reported puffs with a duration of 5 milliseconds or IPIs of >1 minute at the beginning of each smoking session. The long IPI at the beginning of the smoking session is the time the device was turned on to the time of the first puff and was therefore removed from our analysis. The implausibly short puffs reported by CReSS can be explained by a participant performing rapid and multiple puffs such that neither ASPIRE nor the video recordings could identify them. In such instances, we report results with and without the included implausible data since they serve as clear demonstration of some nuances of the CReSS device.

Results

Overview of the Collected Data

Each accelerometer data file collected by ASPIRE contained 20 minutes of data, which is consistent with the experimental protocol. As a first step in our comparison of the 2 methods, histograms were created for individual PDs and IPIs aggregated across all subjects (shown in Figure 3 and Figure 4). The blue bars in these figures correspond to the values produced by the CReSS device, and the orange bars correspond to the values produced by ASPIRE. Although the distributions of the PDs were very similar between the 2 methods, the distributions of IPI values were different (Figure 4). While the 2 histograms demonstrate general agreement, they differ notably in reporting the number of small IPIs. For the CReSS data, there is a spike in very low values corresponding to an IPI value of 0-1 second. The median of the IPIs reported by CReSS in this range was 0.33 seconds.

Figure 3. Comparison of individual puff durations collected via the Clinical Research Support System (CReSS; blue) and Automated Smoking PerceptIon and REcording (ASPIRE; orange).

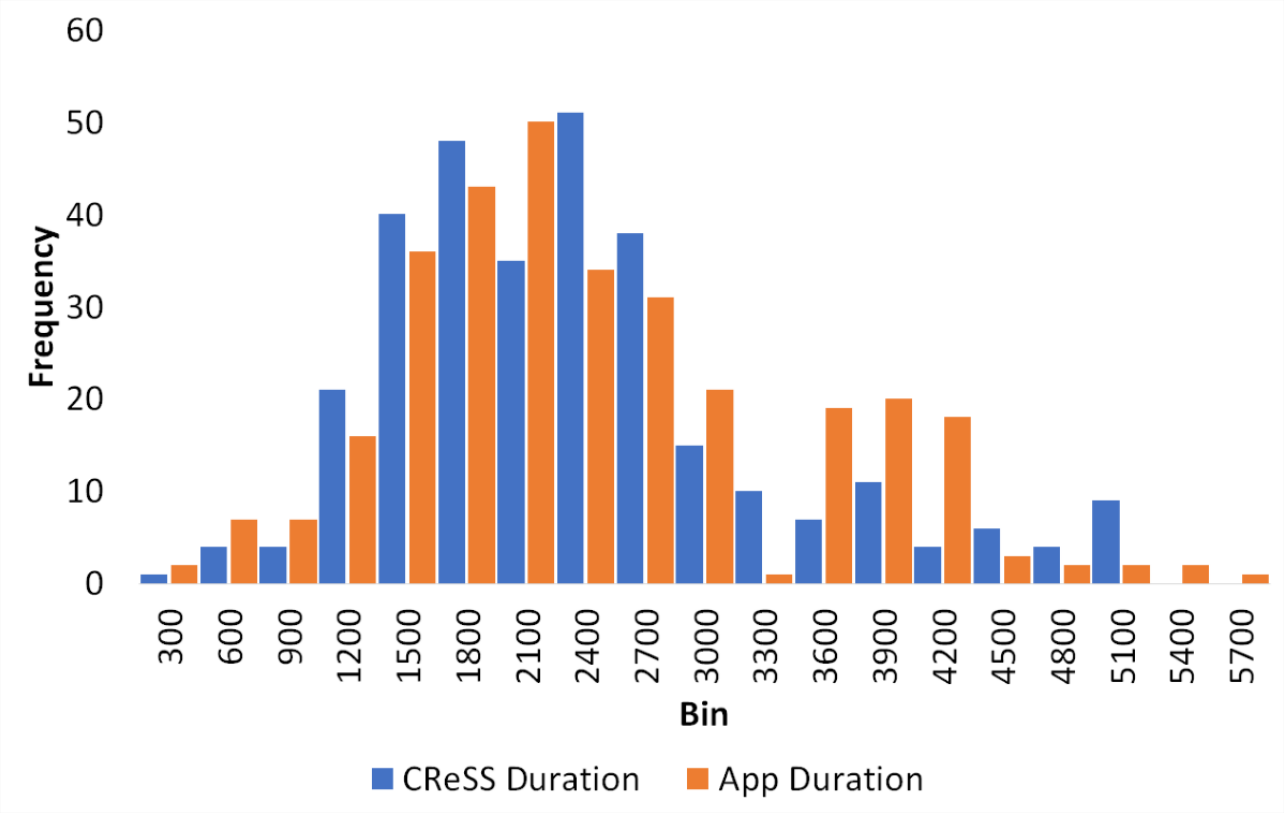
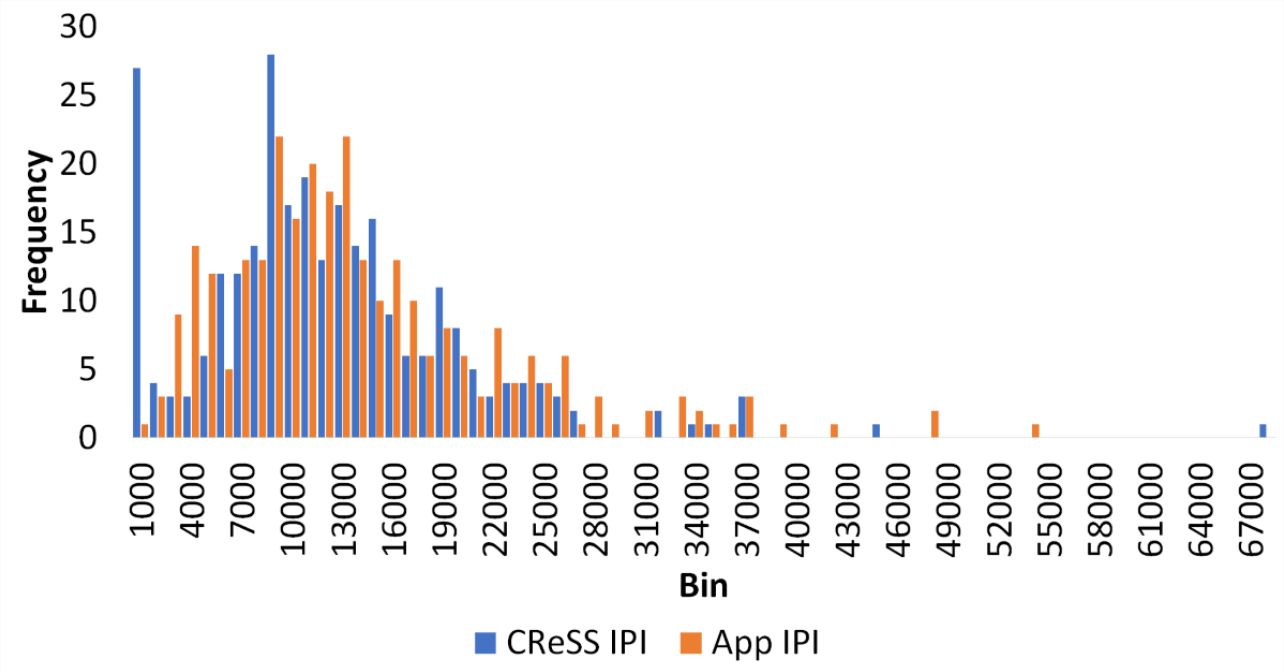


Figure 4. Comparison of individual interpuff intervals (IPIs) collected via Clinical Research Support System (CReSS; blue) and Automated Smoking PerceptIon and REcording (ASPIRE; orange).

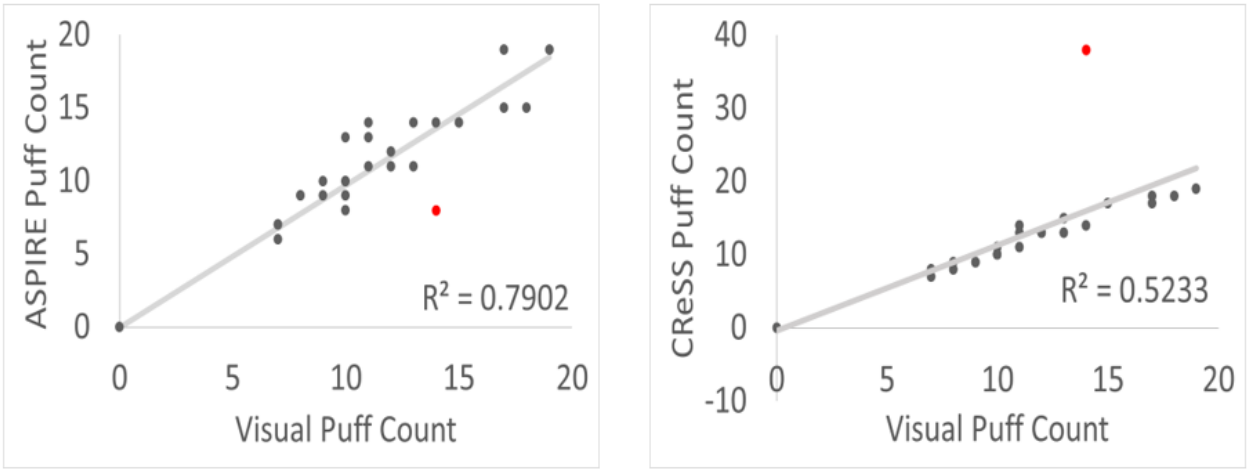


Comparison of Overall Statistics

The number of puffs that the CReSS device recorded was compared to a visual inspection of each participant's respective video recordings. In 80% of cases, the visual puff count and the count reported by CReSS were within ±2. However, in 4 participants, the puff counts differed by as much as ±6. Figure 5A and Figure 5B show the correlations between the overall visual puff counts for the left hand of each participant compared to the puff counts reported by ASPIRE and CReSS, respectively. The R^2 value for the visual puff count and counts reported by ASPIRE was 0.79, whereas the R^2 between the visual puff count and the CReSS reported count was 0.52. The participant that caused the most deviation in both comparisons was P14 (in red in Figure 5A and Figure 5B) with reported visual, ASPIRE, and CReSS counts of 14, 8, and 38, respectively.

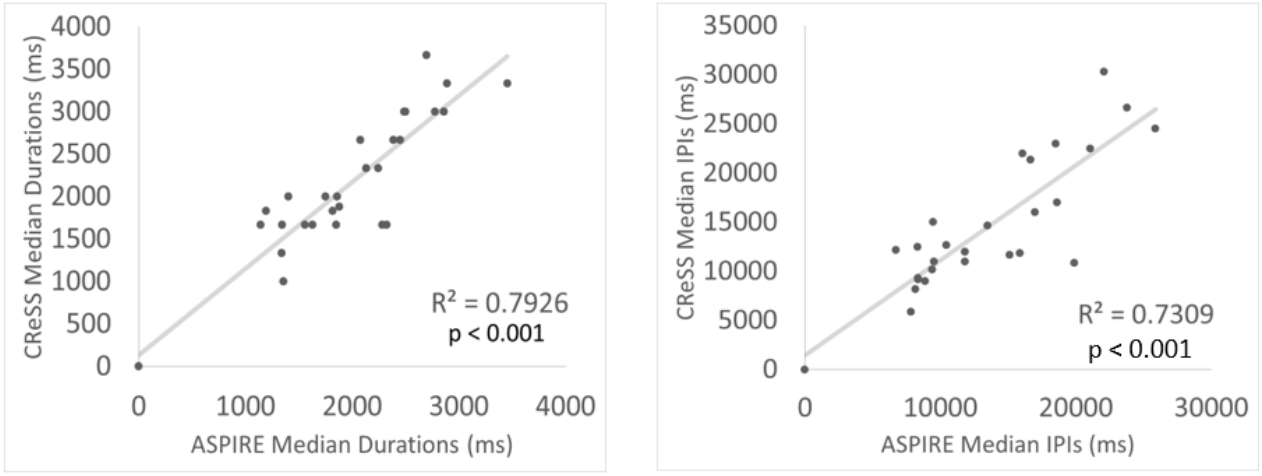
The correlations between the CReSS and ASPIRE data for the median PD and median IPI across all patients are illustrated in Figure 6A and Figure 6B, respectively. R^2 values of 0.7926 and 0.7309 (P<.001) were calculated for the median PDs and median IPIs, respectively, indicating a high level of correlation between the data reported by the 2 methods.

Figure 5. Comparison of the visual puff count versus the (A) Automated Smoking PerceptIon and REcording (ASPIRE) puff count and (B) Clinical Research Support System (CReSS) puff count. In both figures, participant P14 was an outlier and is colored red.



A B

Figure 6. Comparison of the overall reported median (A) Clinical Research Support System (CReSS) versus Automated Smoking PerceptIon and REcording (ASPIRE) puff duration and (B) CReSS versus ASPIRE interpuff interval (IPI).



A B

Comparison of Individual Puffs

Due to potential error in smoking topography data acquired by CReSS, the data are not usually used to perform detailed statistical analyses or inferences, and instead, the median values for PD and IPI are used. The developer of CReSS, Borgwaldt, recently released a method for correction of these errors, but it still remains widely variable in its success. However, in contrast to CReSS, detailed recording by ASPIRE allows for the meaningful study of mean, standard deviation, and other statistical moments of PD and IPI for each participant. Figure 7 illustrates the smoking topography for a representative participant (P2) reported by CReSS and ASPIRE. Both methods reported a total of 10 recorded puffs (illustrated in green bars) separated by 9 IPI intervals (illustrated in blue bars). Also, both methods reported similar values for the median PD and IPI. However, it is clear that the duration of the entire event is highly discrepant across the 2 methods. Furthermore, visual inspection of the smoking session reported by CReSS consists of only 8 decipherable puffs (green regions). This is due to very short IPIs of 5 milliseconds that render 2 puffs unseparated in the figure. On the other hand, the same smoking session reported by ASPIRE is well organized into the expected shorter puffs that are separated by longer IPIs. The trend marked as cCReSS in this figure corresponds to the corrected CReSS data by only correcting 5 elements (puffs or IPIs out of 20) of the smoking session. These were corrected by substituting the abnormally short or long IPIs with the average of the remaining IPIs in the CReSS data for the participant. The correlation between the CReSS and ASPIRE reported data improved from 0.05 to 0.80 after correcting for the discrepant data. Figure 8 and Figure 9 demonstrate other examples of similarity between the CReSS and ASPIRE data after correcting for outliers. These examples have R^2 values in the ranges of 0.77-0.83 for PD and 0.97-0.99 for IPI. These correlation values indicate a similarity reported by the 2 different methods with statistical significance of $P<.005$.

Figure 7. An illustration of smoking topography reported by Clinical Research Support System (CReSS), Automated Smoking PerceptIon and REcording (ASPIRE), and corrected CReSS (cCReSS). The puff durations and interpuff intervals are illustrated in green and blue, respectively.

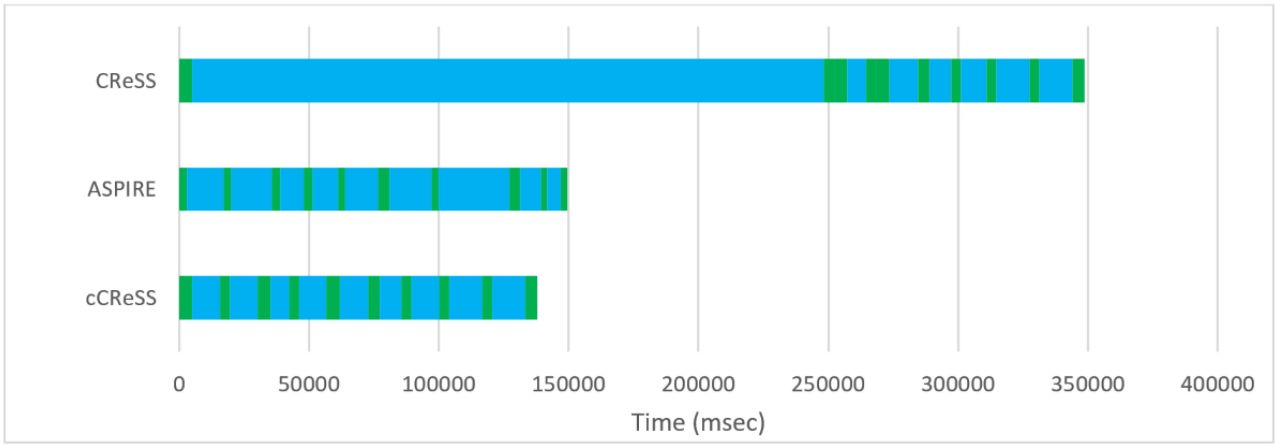


Figure 8. Correlations of individual puff durations collected via the Clinical Research Support System (CReSS) device and Automated Smoking PerceptIon and REcording (ASPIRE) for participants (A) P15, (B) P17, (C) P19, and (D) P8.

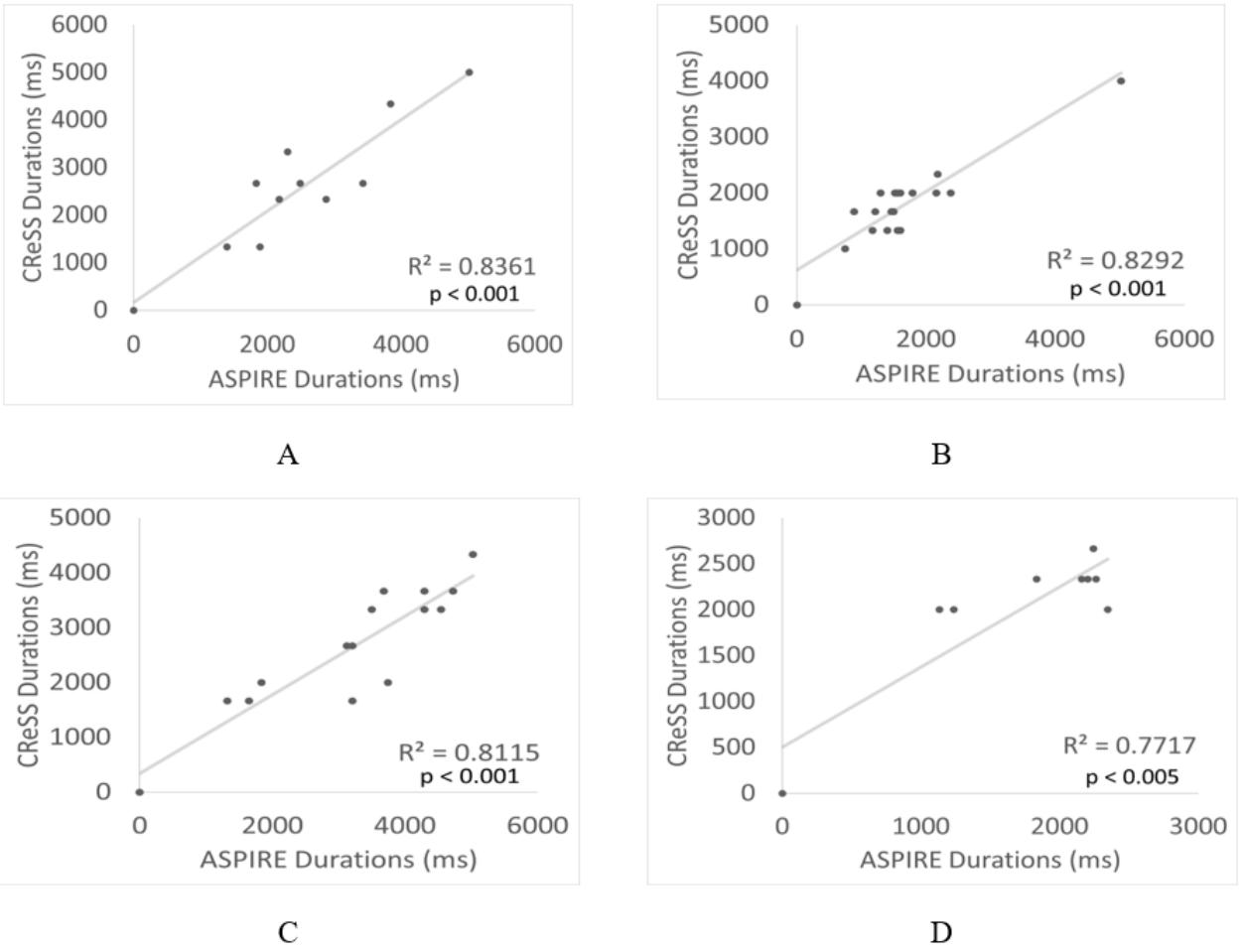
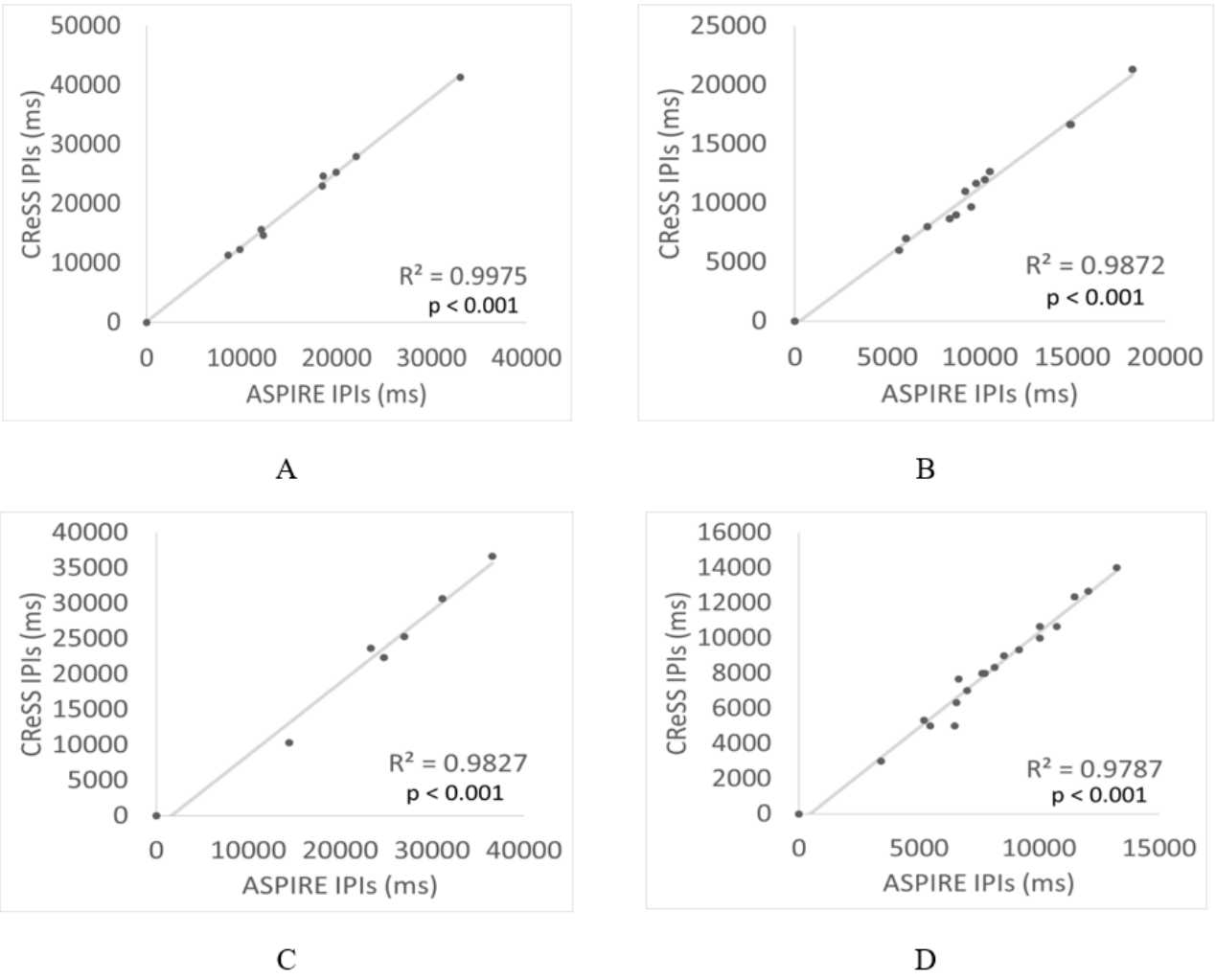


Figure 9. Correlations of individual interpuff intervals (IPIs) collected via the Clinical Research Support System (CReSS) device and Automated Smoking PerceptIon and REcording (ASPIRE) for participants (A) P15, (B) P19, (C) P7, and (D) P17.



Discussion

Principal Findings

Findings from this study provide direct evidence that ASPIRE accurately assesses multiple components of smoking behavior in controlled laboratory settings. Our study revealed 3 important findings. First, ASPIRE is highly effective in accurately detecting when a person initiates smoking and how many puffs of a cigarette is inhaled. Second, ASPIRE may be used to accurately characterize the duration of each puff—which may provide a dose indicator when used in conjunction with puff count. Finally, ASPIRE can detect time between each puff (IPI), which may provide a meaningful metric of episodic smoking compulsivity. These findings suggest that ASPIRE can be tested in naturalistic settings as a potential means to assess smoking behavior in daily life.

Smartwatches have the potential to significantly advance the study of human behavior in situ; however, the reliability of the information reported by wearable devices has been questioned. In this study, we investigated and demonstrated the reliability of the data reported by ASPIRE in the laboratory setting compared to the CReSS and visual recording of the smoking sessions. Moreover, though other technologies have been recently developed to detect smoking behavior at the puff or session level [8,14,19], this is the first study to demonstrate characterization of smoking topography (namely PD and IPI) as performed by ASPIRE.

The ability to passively collect and accurately characterize multiple components of smoking behavior in the natural environment is a critical step in monitoring smoking, characterizing smoking outcomes in outpatient clinical trials, and developing real-time adaptive interventions or personalizing smoking cessation interventions. Much of our knowledge about the mechanisms that elicit smoking behavior is obtained from observation of behavior in laboratory settings. For example, research has examined how exposure to smoking stimuli (for example, image of cigarette lighter) [29], acute stressors or mood inductions [eg, 30,31], fasting [30], and interventions [31,32] affect smoking behavior under controlled laboratory conditions. Upon validation of ASPIRE in naturalistic settings, ASPIRE can be used to examine whether laboratory-based findings generalize to real-world settings. In future studies, ASPIRE-detected smoking may be developed to incorporate randomly prompted app, text, or smartwatch surveys asking about precipitants of smoking behavior (eg, stress, craving, environmental contexts). Alternatively, several passive technologies can be combined. For example, measures of

electrodermal activity or heart rate (ie, physiological arousal) recorded via mobile devices may be collected in addition to assessing the timing, count, and characteristics of cigarettes smoked in real-world settings. The combination of these active and passive measures will significantly improve fidelity for characterizing the factors that maintain smoking behavior among individuals and thus facilitate precision medicine and treating TUD.

In addition, real-time technology has the potential to greatly improve assessment of smoking outcomes in smoking cessation clinical trials [33]. The traditional outcome measure in smoking cessation clinical trials is biomarker-confirmed abstinence [34,35]. Typically, this is assessed via participant report of abstinence for a certain number of days (ie, 7-day abstinence) and confirmed in laboratory via carbon monoxide or cotinine. These outcomes are subject to errors in retrospective recall and intentional misreporting. ASPIRE can provide objective evidence of smoking while also indicating when the smartwatch is removed for the purposes of determining adherence with wearing the smartwatch. Remote technologies also help to extend the reach of clinical trials. Individuals with the necessary technology can participate in a smoking cessation trial remotely (ie, at a different location than the research team) while still providing rigorous evidence of smoking or abstinence.

Finally, the incorporation of AI and machine learning techniques to automatically detect and report smoking behavior can assist in the delivery of personalized and just-in-time interventions. AI algorithms can incorporate the precise information regarding the context and timing of cigarettes smoked gained from ASPIRE to determine when an individual is most likely to smoke. Interventions can be delivered pre-emptively to prevent smoking or relapse [eg, 38].

Limitations

A number of limitations must be considered when interpreting the current findings. First, validation of ASPIRE requires comparison to a gold standard measure. However, CReSS, as the gold standard comparator used in this study, suffers its own limitations. The CReSS device identifies smoke topography only based on the inhalation patterns and does not incorporate any information regarding the exhalation activity. Therefore, the CReSS device may identify a single puff that is composed of numerous discontinuous puffs as multiple short puffs separated by short IPIs. For instance, in Figure 4, it was shown that CReSS recorded a significant number of IPIs of 1 second or less. While IPIs of this length are theoretically possible, their appearance in such an abundance reported by CReSS is highly suspect. The short IPIs reported by CReSS contribute to skewing the overall statistics presented, which lowered concordance between the CReSS puffs and ASPIRE-collected puffs. Based on the review of the visual recordings in this study, we have confirmed that the ASPIRE approach provides a more consistent and reproducible report of the smoking topography than the CReSS device. Furthermore, we have also demonstrated the consistency of smoking topography reported by smartwatches and the CReSS device in laboratory settings. Our results conclude that the PD and IPI reported by both devices exhibit a substantial degree of correlation after the exclusion of the outliers reported by the CReSS device.

A second limitation of this study is that the laboratory is an unnatural smoking environment that may elicit unnatural smoking behavior from the participants, including the use of CReSS to smoke. ASPIRE can record and report smoking behavior in natural settings, though it is possible that the accuracy of ASPIRE in the laboratory does not generalize to these settings or to cigarettes not smoked via CReSS. Thus, future efforts should examine the comparability of cigarettes smoked with and without CReSS and the applicability of ASPIRE in studying smoking behavior in natural settings.

Comparison to Prior Work

Although there have been prior reports [8,9,12-14,18] of identifying smoking sessions using smartwatches, to our knowledge, there has been no other smoking topography work with which to compare these results. Our reported results constitute the first instance of comparing smoking data collected from smartwatches to smoking data collected from the industry-standard CReSS device.

Conclusions

In summary, this study provides preliminary evidence of ASPIRE's potential to accurately and reliably detect smoking characteristics passively and in real-time. The ability to observe smoking behavior in situ holds great promise in advancing research on the mechanisms that maintain cigarette smoking, measuring behavior change in the context of clinical trials, and the development of novel, real-time interventions for smoking cessation and just-in-time relapse prevention interventions.

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Conflicts of Interest

None declared.

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Abbreviations

AI: artificial intelligence
ASPIRE: Automated Smoking PerceptIon and REcording
CReSS: Clinical Research Support System
IPI: interpuff interval
PD: puff duration
TUD: Tobacco Usage Disease

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Original Paper

Preliminary Screening for Hereditary Breast and Ovarian Cancer Using a Chatbot Augmented Intelligence Genetic Counselor: Development and Feasibility Study

Ann Sato[1], MSc; Eri Haneda[1], MSc; Nobuyasu Suganuma[2], MD, PhD; Hiroto Narimatsu[1,3,4], MD, PhD

[1]Department of Genetic Medicine, Kanagawa Cancer Center, Yokohama, Kanagawa, Japan

[2]Department of Breast and Endocrine Surgery, Kanagawa Cancer Center, Yokohama, Kanagawa, Japan

[3]Cancer Prevention and Cancer Control Division, Kanagawa Cancer Center Research Institute, Yokohama, Kanagawa, Japan

[4]Graduate School of Health Innovation, Kanagawa University of Human Services, Kawasaki, Kanagawa, Japan

Corresponding Author:
Hiroto Narimatsu, MD, PhD
Department of Genetic Medicine
Kanagawa Cancer Center
2-3-2 Nakao, Asahi-ku
Yokohama, Kanagawa, 241-8515
Japan
Phone: 81 045 520 2222
Email: hiroto-narimatsu@umin.org

Abstract

Background: Breast cancer is the most common form of cancer in Japan; genetic background and hereditary breast and ovarian cancer (HBOC) are implicated. The key to HBOC diagnosis involves screening to identify high-risk individuals. However, genetic medicine is still developing; thus, many patients who may potentially benefit from genetic medicine have not yet been identified.

Objective: This study's objective is to develop a chatbot system that uses augmented intelligence for HBOC screening to determine whether patients meet the National Comprehensive Cancer Network (NCCN) BRCA1/2 testing criteria.

Methods: The system was evaluated by a doctor specializing in genetic medicine and certified genetic counselors. We prepared 3 scenarios and created a conversation with the chatbot to reflect each one. Then we evaluated chatbot feasibility, the required time, the medical accuracy of conversations and family history, and the final result.

Results: The times required for the conversation were 7 minutes for scenario 1, 15 minutes for scenario 2, and 16 minutes for scenario 3. Scenarios 1 and 2 met the BRCA1/2 testing criteria, but scenario 3 did not, and this result was consistent with the findings of 3 experts who retrospectively reviewed conversations with the chatbot according to the 3 scenarios. A family history comparison ascertained by the chatbot with the actual scenarios revealed that each result was consistent with each scenario. From a genetic medicine perspective, no errors were noted by the 3 experts.

Conclusions: This study demonstrated that chatbot systems could be applied to preliminary genetic medicine screening for HBOC.

(JMIR Form Res 2021;5(2):e25184) doi:10.2196/25184

KEYWORDS

artificial intelligence; augmented intelligence; hereditary cancer; familial cancer; IBM Watson; preliminary screening; cancer; genetics; chatbot; screening; feasibility

Introduction

Breast cancer is the most common form of cancer in Japan, with approximately 90,000 new cases every year. Approximately 10,000 patients in Japan die from breast cancer each year [1]. Approximately 5%-10% of breast cancers are strongly related to genetic background, and of these, hereditary breast and ovarian cancer (HBOC) is the most common [2-4]. HBOC is an autosomal-dominant disease that is diagnosed based on the presence of BRCA1 or BRCA2 (BRCA1/2) pathogenic germline mutations. The BRCA1/2 genes encode 2 proteins involved in DNA damage repair. Recent studies have shown that mutations

in BRCA1/2 and several other genes, including TP53 and PALB2, can lead to hereditary breast cancer in Japanese women [5]. Reportedly, BRCA1 and BRCA2 mutation carriers have cumulative breast cancer risks of 72% and 69%, respectively, and cumulative ovarian cancer risks of 44% and 17%, respectively, up to the age of 80 years. These risks are remarkably higher than those in the general population [6]. Therefore, genetic counseling and testing are recommended for individuals with suspected HBOC and relatives of carriers of the BRCA1/2 mutation. For carriers of the BRCA1/2 mutation diagnosed by genetic testing, appropriate countermeasures such as surveillance or risk reduction surgery can be considered [7].

A diagnosis of HBOC relies on a screening procedure to identify those at a high risk of disease, and therefore, the collection of information about family history is very important. However, genetic medicine is still developing in Japan. Even in the United States, many patients who might potentially benefit from genetic medicine have not been identified. A previous study suggested that this gap may be caused by a lack of awareness and knowledge among health care workers and patients, delays in updating information due to frequent revisions of the BRCA1/2 testing criteria, and a lack of human resources and health care workers responsible for identifying these patients [8].

In Japan, the preliminary screening of patients at high risk of HBOC is usually conducted by a certified genetic counselor (CGC). High-risk patients who undergo screening are recommended to receive genetic counseling to enable them to decide whether to undergo genetic testing. As of April 2020, however, there were only 267 CGCs in Japan [9], and it is difficult to rapidly increase this number because advanced specialized education is provided at a limited number of facilities.

In recent years, we have focused on developing augmented intelligence, which has been applied for practical use. Augmented intelligence has several functions, including a chatbot mechanism, which is software that allows users to interact with the system through an algorithm without the need for human back-end intervention. Chatbots have been applied in previous research as a communication support tool for patients with cancer [10-12]. Reportedly, chatbots improved medication adherence in patients with breast cancer and were able to provide support and anxiety reduction in young adults who underwent cancer treatment. The chatbot was useful for both younger patients with cancer as well as for the health monitoring of older patients (≥ 65 years) with cancer. These studies suggested that chatbots are useful in the medical field, especially in supporting patients with cancer.

There are many advantages of using chatbots for preliminary screening in medical practices. First, the chatbot can independently conduct preliminary screening automatically and could thus handle some of the CGC's routine work. The CGC would then be able to focus on more intricate work, such as personalized genetic counseling, which would improve productivity. Second, a chatbot for preliminary screening is easy to create because the purpose of the conversation is clear, and the flow of information collection used for determining whether the BRCA1/2 testing criteria are met has a pattern. Lastly, the chatbot will enable the identification of a larger number of patients; traditional preliminary screening requires time and effort, which could be resolved with the chatbot.

This study aims to develop a system based on IBM Watson (the chatbot system developed by IBM Corp) that would inquire about patients' family and medical histories and would identify which patients with breast cancer should be contacted by a CGC. The friendly interface created using augmented intelligence would be easy for the patients to understand. The study endpoint involves an evaluation of the developed system's clinical feasibility, which would ideally increase the number of targeted people who are identified by the preliminary screening and thus enable the provision of genetic medicine to a larger number of people in the future.

Methods

Chatbot System

This is a feasibility study by simulation using a scenario. The study's endpoint is to assess the accuracy of the family history heard by the chatbot system. Furthermore, as a preclinical study, we listened to the medical and family history of the actual medical staff and evaluated its accuracy.

We developed a system using the chatbot function of Watson, a service of IBM Corp's cognitive computing system. In this study, we used the real-time conversational interface LINE, a social network service (SNS) provided by LINE Corporation. LINE is the most popular SNS in Japan, and we assumed that it would be familiar to the patients [13]. Using this interface, we established a system that targeted patients with breast cancer who visited a designated hospital and assessed whether they met the National Comprehensive Cancer Network (NCCN) guidelines for BRCA1/2 testing criteria, version 3.2019, using information given in the patients' replies. The patients' responses were stored in the terminal (ie, a smartphone or tablet). Finally, the medical history, the family history, and the final results of preliminary screening appeared on the terminal screen. The development of this system was supported by the Advanced Integration Technology (AIT) Corporation. We set the genetic counselor, named "AI," as the persona to ensure that the patients could type to and interact with a familiar entity. Textbox 1 shows the persona of AI.

This study was approved by the institutional review board for the research of Kanagawa Cancer Center (2018 - epidemiology 55).

Textbox 1. Summary of the characteristics of the chatbot genetic counselor, AI.

Name: AI

Age: 26 years old

Gender: Female

Education: Graduate school

Occupation: Genetic counselor working in a general hospital

Hometown: Elsewhere in Kanagawa Prefecture, Japan

Family structure: Father (56 years old), Mother (58 years old, nurse), older sister (29 years old, has 1 daughter), younger brother (18 years old, college student), Grandfather (died when AI was a high school student), Grandmother

Lifestyle: Lives with brother

Hobby: Cooking

Modification of the Guideline

In this study, we partially modified the BRCA1/2 testing criteria according to our clinical practice at Kanagawa Cancer Center. The following items were omitted because the chatbot was not able to ask these questions of the patients: (1) individual from a family with a known BRCA1/2 pathogenic/likely pathogenic variant, including such variants found on research testing; (2) personal history of breast cancer diagnosed at 41-50 years old with ≥1 close blood relative with high-grade (Gleason score ≥7) prostate cancer; (3) personal history of breast cancer diagnosed at ≤60 years old with triple-negative breast cancer; (4) personal history of breast cancer diagnosed at any age with ≥1 close blood relative with metastatic prostate cancer or ≥2 additional diagnoses of breast cancer at any age in close blood relatives; (5) personal history of metastatic prostate cancer; (6) personal history of high-grade prostate cancer (Gleason score ≥7) at any age with ≥1 close blood relative with ovarian carcinoma, pancreatic cancer, or metastatic prostate cancer at any age or breast cancer <50 years old, or ≥2 close blood relatives with breast or prostate cancer (any grade) at any age; (7) BRCA1/2 pathogenic/likely pathogenic variant detected by tumor profiling on any tumor type in the absence of germline pathogenic/likely pathogenic variant analysis; (8) regardless of family history, some individuals with BRCA-related cancer who may benefit from genetic testing to determine targeted treatment eligibility.

The following item was omitted because it is rarely encountered in clinical practice in Japan: (1) personal history of breast cancer with Ashkenazi Jewish ancestry; (2) personal history of high-grade prostate cancer (Gleason score ≥7) at any age with Ashkenazi Jewish ancestry.

The final results were presented to demonstrate whether the patient met these modified criteria.

Evaluation of Feasibility

System development and evaluation were conducted by a doctor specializing in genetic medicine (author HN) and 2 CGCs (authors AS and EH). We prepared 3 scenarios with 3 pedigrees (Figures 1-3) and created a conversation with the chatbot along the lines of these scenarios. Then, we evaluated chatbot feasibility, the required time, the medical accuracy of the conversation and the family history, and the final result.

To test the system, 3 experts used this system based on their family histories and evaluated the accuracy of the family histories and the final results.

Figure 1. The family tree in scenario 1.

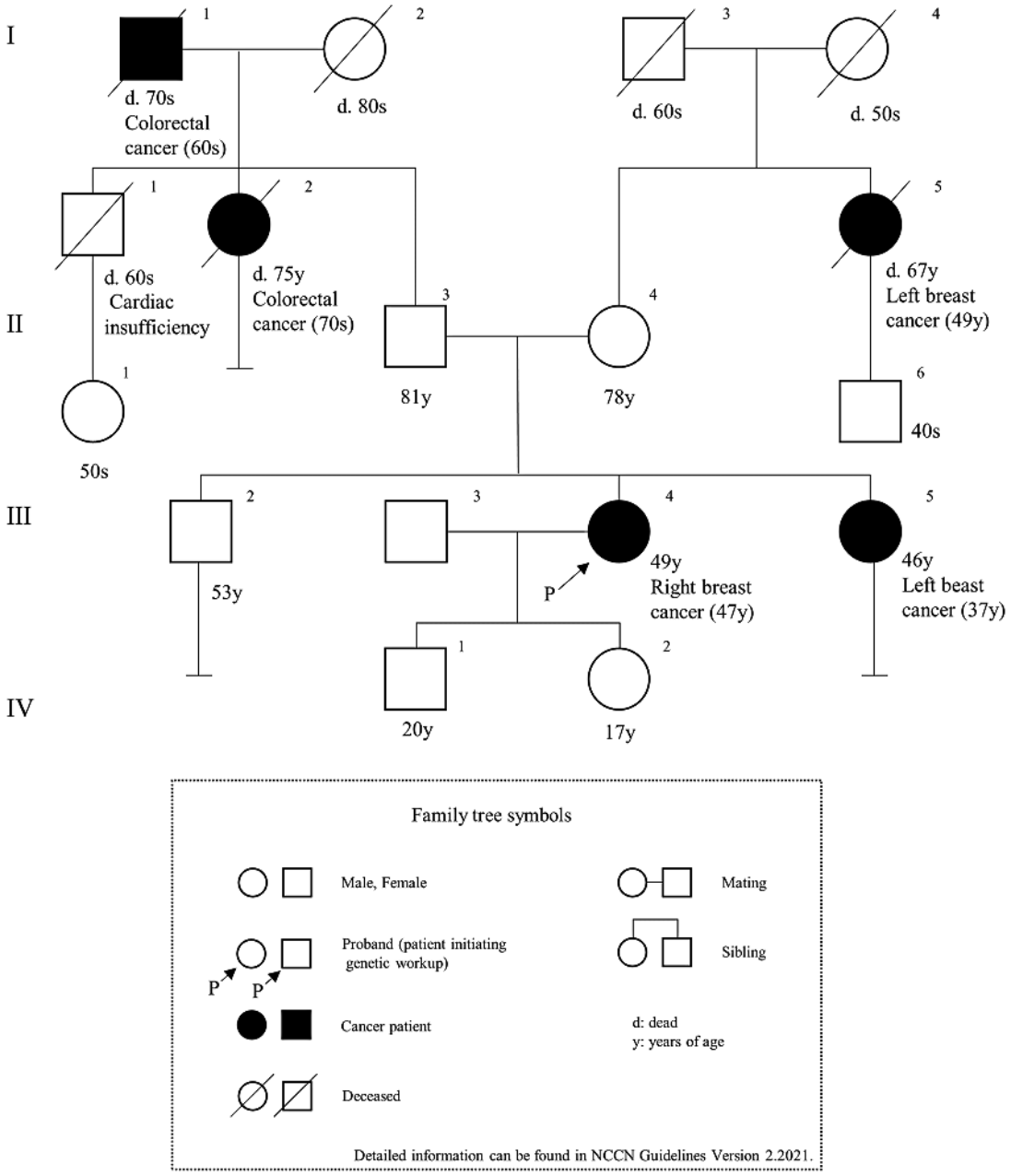


Figure 2. The family tree in scenario 2.

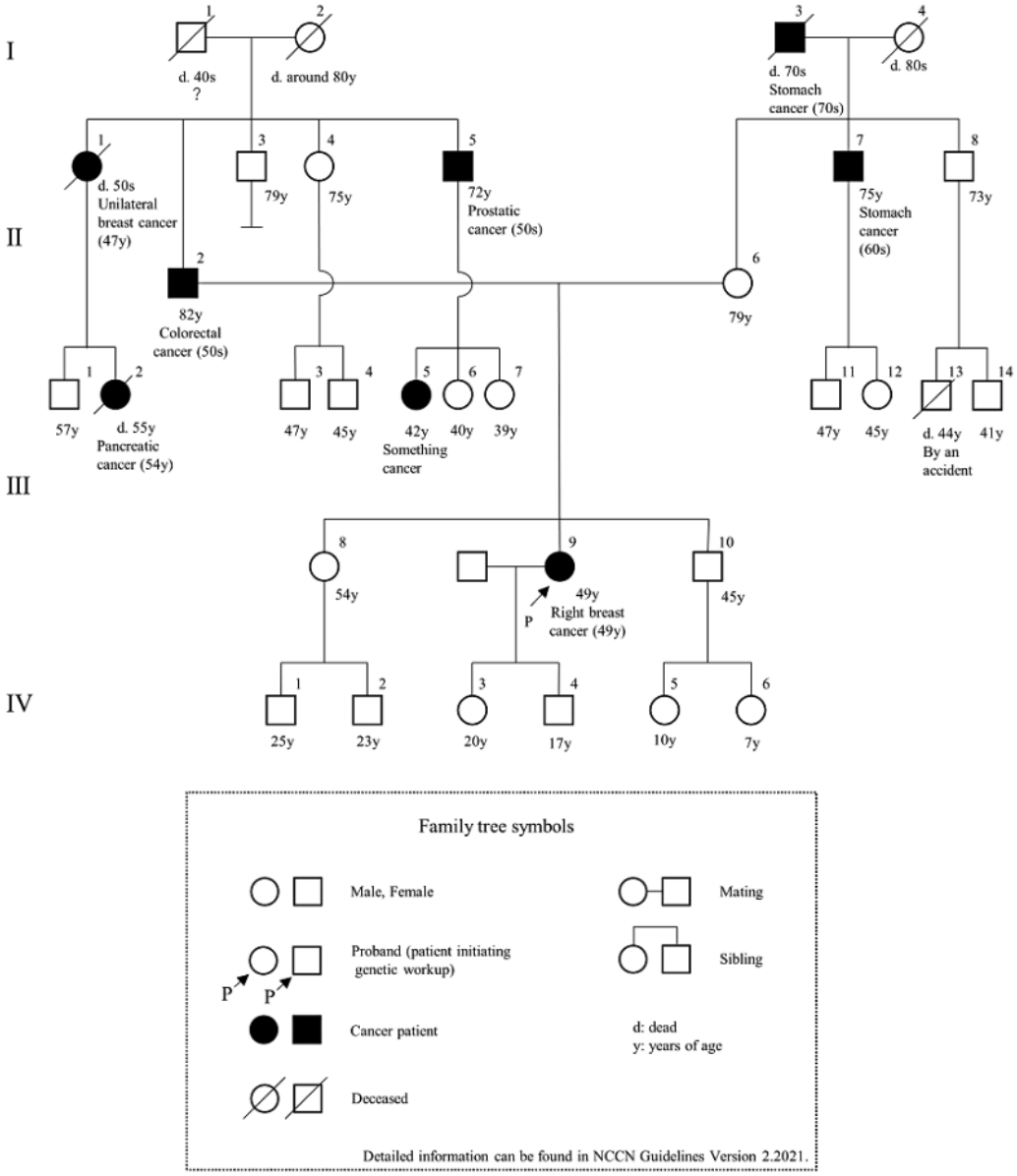
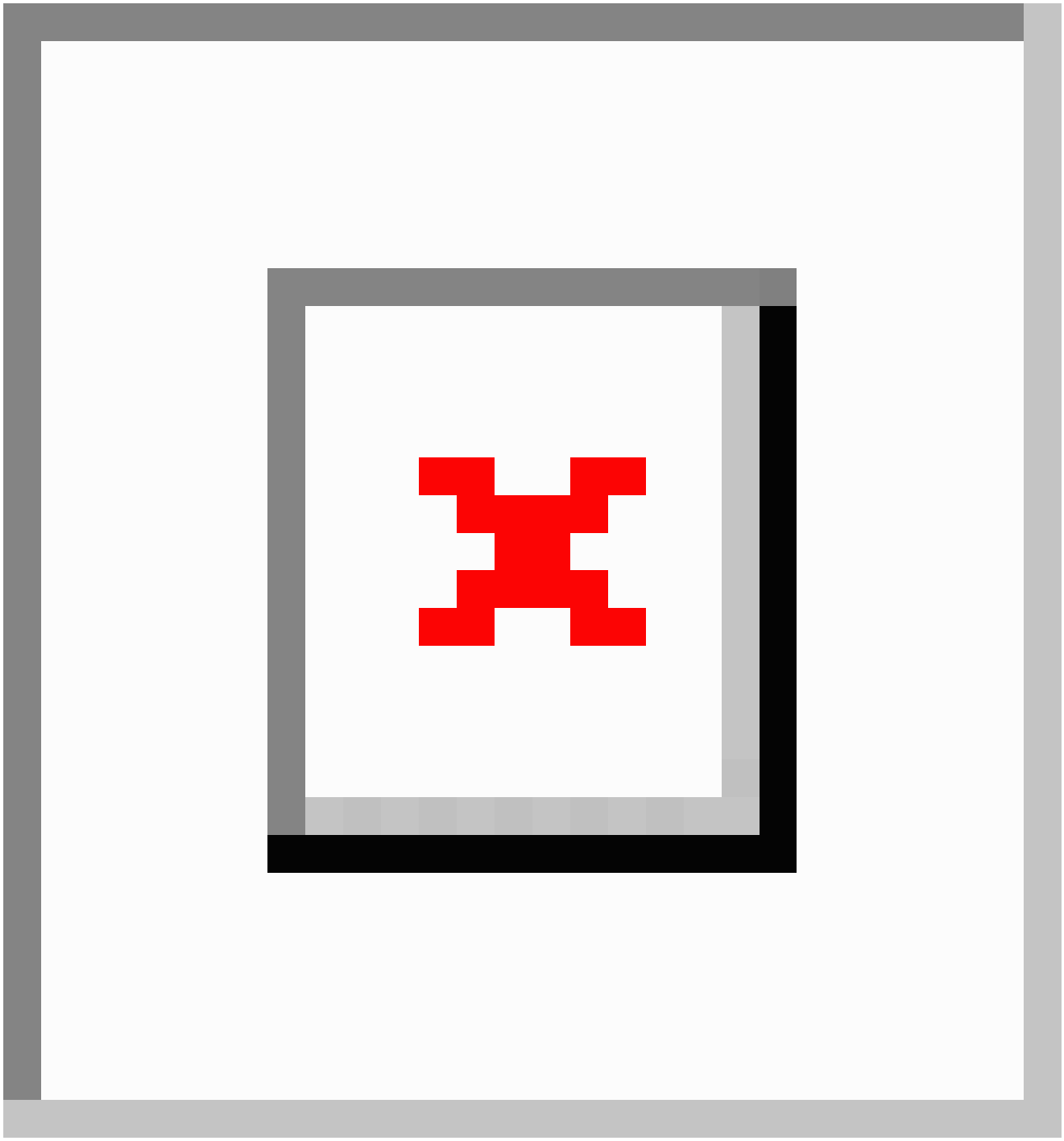


Figure 3. The family tree in scenario 3.



Results

We developed a system that applied the chatbot to the LINE interface (Figure 4). We then created a conversation with the chatbot according to the 3 devised scenarios. The interface is shown in Figure 5, and the contents of the conversation are shown in Multimedia Appendices 1-3. Figures 6 and 7 show examples of the results obtained during a conversation with the chatbot. Scenarios 1 and 2 met the criteria, whereas scenario 3 did not. This result agreed with the assessments of the 3 experts. Specifically, the comparisons of the family histories detected by the chatbot with the actual scenarios indicated that each result was consistent with each scenario. The times required for the conversations were 7 minutes for scenario 1, 15 minutes for scenario 2, and 16 minutes for scenario 3. The 3 experts retrospectively reviewed the conversations with the chatbot and noted no errors from the perspective of genetic medicine.

The 3 experts also confirmed the accuracy of the presented family histories and evaluated the accuracy of the presented final test results using the chatbot system.

Figure 4. The algorithm of the study.

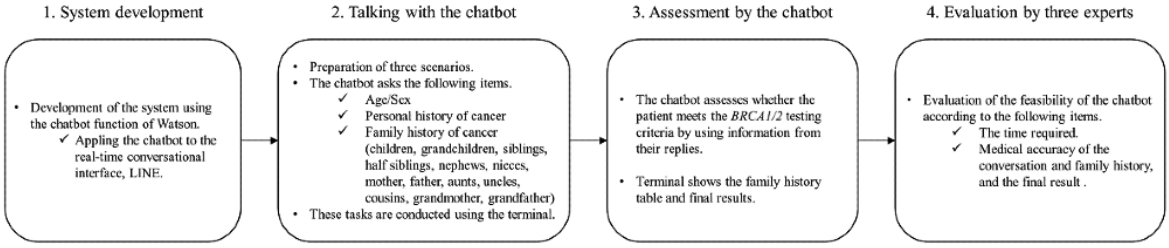


Figure 5. The interface of the chatbot. The LINE interface was used. The conversation in Japanese was translated into English.

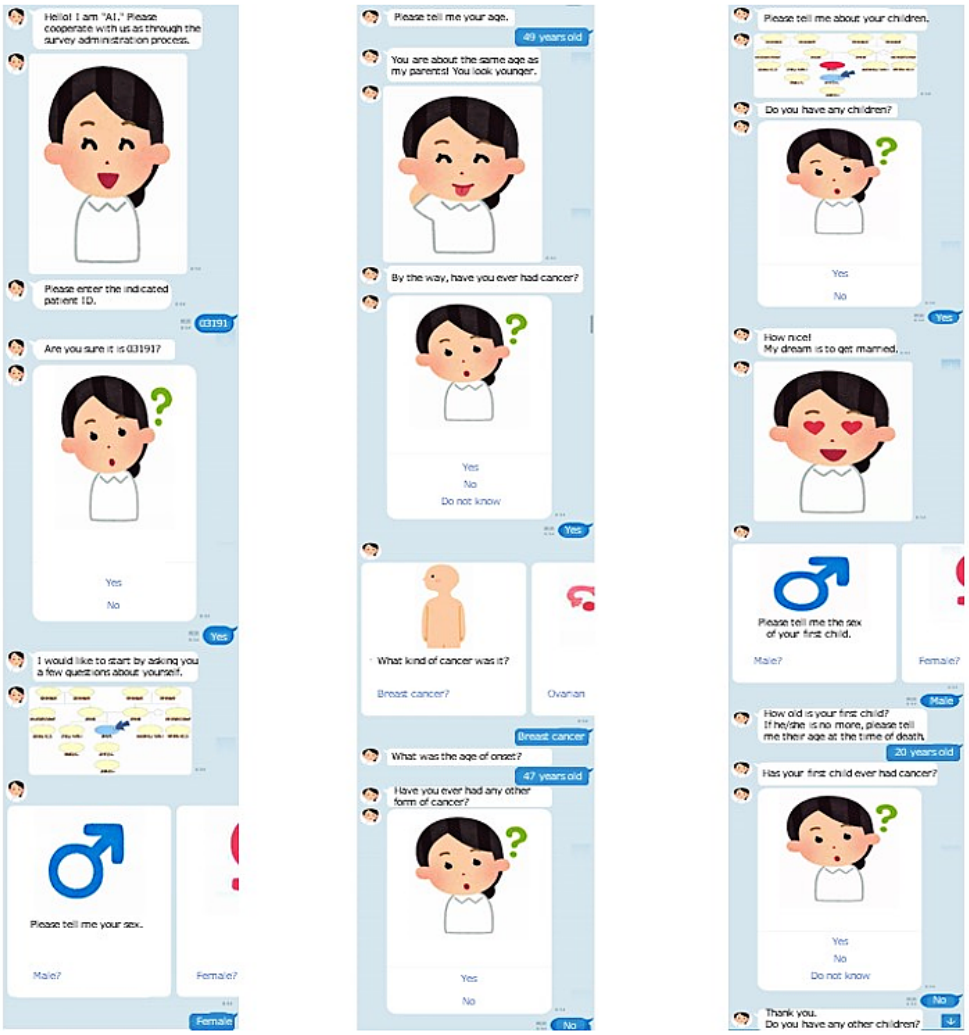


Figure 6. Snapshot of the results of a preliminary screening by the chatbot for scenario 1, according to the criteria of the National Comprehensive Cancer Network (NCCN). We have partially modified the criteria according to our clinical practice at the Kanagawa Cancer Center. The results were originally presented in Japanese and translated into English. Black font: unmet items; red font: met items; gray font: items that had not been asked by this system; yellow square: the final result; "close blood relative:" includes first-, second-, and third-degree relatives.

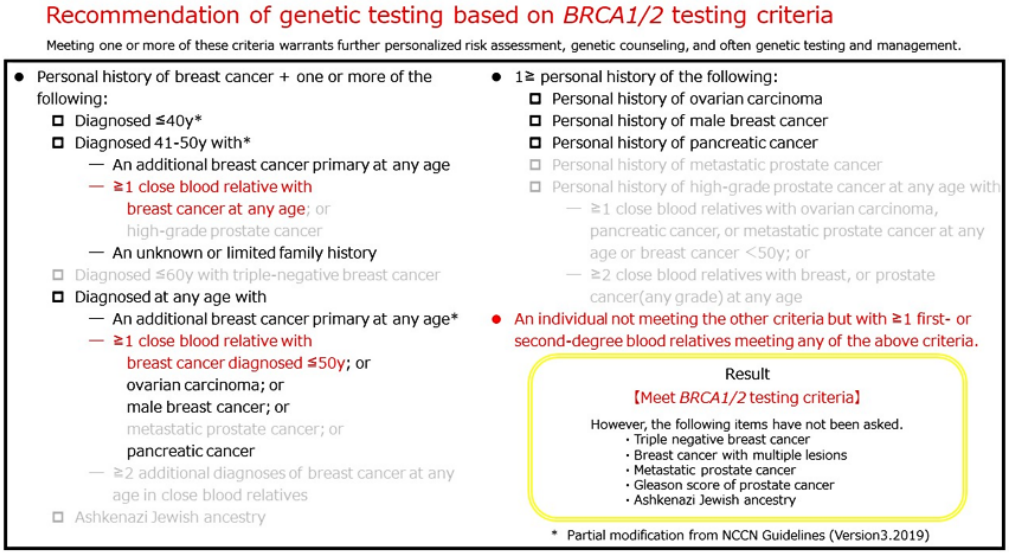
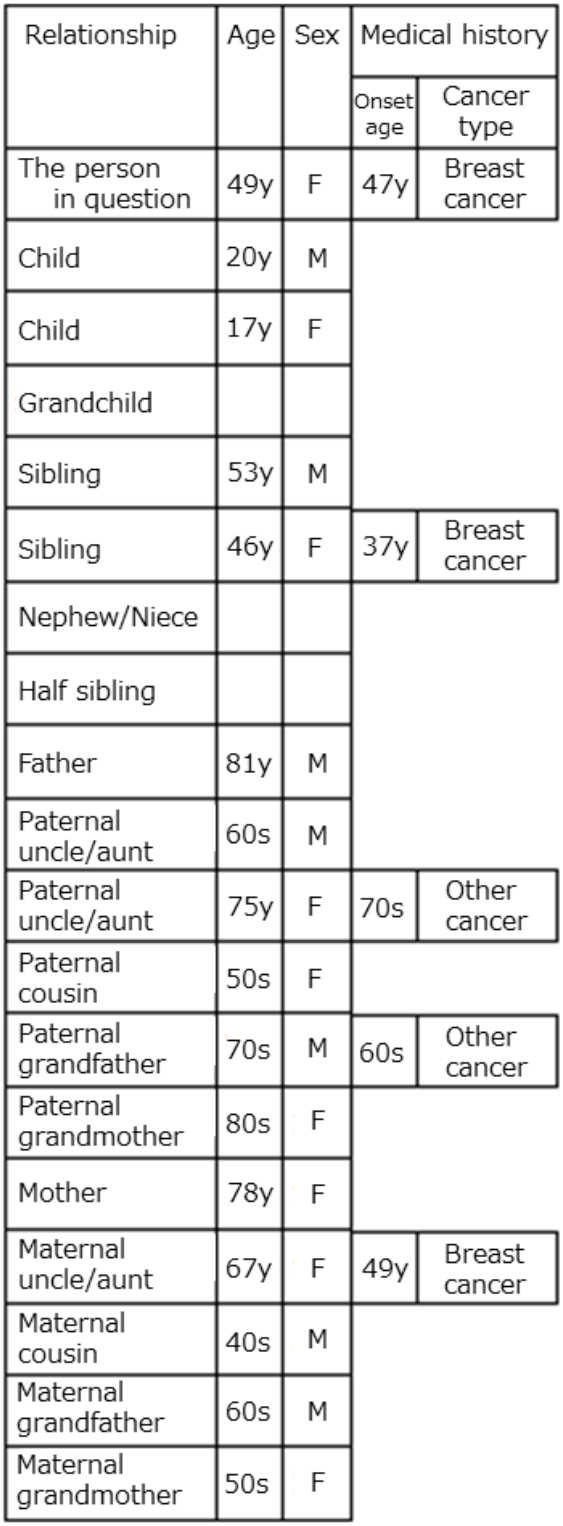


Figure 7. Snapshot of the family history obtained as a result of the preliminary screening by the chatbot for scenario 1. The results were originally presented in Japanese and translated into English. The screen of the terminal presents one of the results. F: female; M: male: y: years of age.



Relationship	Age	Sex	Medical history	
			Onset age	Cancer type
The person in question	49y	F	47y	Breast cancer
Child	20y	M		
Child	17y	F		
Grandchild				
Sibling	53y	M		
Sibling	46y	F	37y	Breast cancer
Nephew/Niece				
Half sibling				
Father	81y	M		
Paternal uncle/aunt	60s	M		
Paternal uncle/aunt	75y	F	70s	Other cancer
Paternal cousin	50s	F		
Paternal grandfather	70s	M	60s	Other cancer
Paternal grandmother	80s	F		
Mother	78y	F		
Maternal uncle/aunt	67y	F	49y	Breast cancer
Maternal cousin	40s	M		
Maternal grandfather	60s	M		
Maternal grandmother	50s	F		

Discussion

Principal Findings

This study demonstrated that the chatbot system could be applied to preliminary screening for HBOC in a genetic medicine setting. Our developed system allowed us to achieve the following points required for clinical application: First, our system automatically asked for information items about family history that addressed most of the NCCN guidelines. Thus, the preliminary screening can be performed by a chatbot rather than by a CGC. It cannot completely substitute for a CGC; however, using a chatbot for simpler tasks such as a primary screening would allow a CGC to focus on more complicated clinical practices that require more effort. Second, it was possible to ensure medical accuracy; although the development of the system received technical support from information technology

companies, the design was created by health care professionals. Accordingly, health care professionals can also change and modify the contents of the conversations regarding the clinical application and continue developing the system while ensuring medical accuracy. Third, the number of correspondences could theoretically be increased to an infinite degree, and therefore, the scale could also be increased. Consequently, the numbers of identified high-risk patients and hospitals performing preliminary screenings could be increased. This offers great promise for the field of genetic medicine.

In this study, we communicated with the chatbot by description-type responses and selection-type responses. This approach was adopted to obtain regular information from existing chatbots [14,15]. As a result, the response time could be reduced relative to the time required to provide only descriptive responses. Furthermore, although selection-type responses are frequently used in chatbots that are commercialized for customer services, our preliminary screening scenario was different. Here, the patient did not voluntarily access the chatbot for the purpose of inquiry but was asked to engage with the system by health care professionals. Therefore, it was necessary to devise an order of questions that would enable an easy recall of the family history and develop a persona that would enable the patient to complete the answers without getting tired. However, previous studies have not emphasized the application of the persona setting in chatbots in the medical field [10-12].

When collecting a family history using our newly developed chatbot, we assumed that AI and the patient would discuss family. Therefore, we created detailed family information for AI and included this in her persona. To improve the response rate, the development of more useful and effective personae is warranted in future studies. It would also be useful to personalize the chat, which is based on the persona of AI, by selecting from among several personae according to the patient's age. Moreover, chatting based on the persona of AI may or may not be considered excessive, depending on the patient's background.

Limitations

Several issues should be addressed to ensure the practical application of this system in terms of efficiency and convenience. First, the system must be easy to operate by the patient. A user-friendly interface is desirable. Therefore, we developed a chatbot system using the LINE interface. As noted, LINE is the most popular SNS in Japan, and we assumed that it would be familiar to the patients [13]. However, older adults who are not used to smartphones may need a friendlier interface or human assistance. In Japan, the personal ownership rate and use of smartphones have been increasing since 2010. Remarkably, the associated generational gap is large, as only 18.8% and 6.1% of those in their 70s and 80s have reported owning such phones, respectively, compared to more than 90% of those in their 20s and 30s [16]. Therefore, the development of a system that considers both age and information technology literacy would be required. Although the supporting personnel would not necessarily need to be CGCs, sufficient personnel would be required to support multiple patients in parallel. Moreover, both elderly and visually impaired patients may find it difficult to operate a smartphone without voice assistance. In this case, it may be difficult to determine the significance of using the AI screening system.

Second, the patient must complete all queries during the screening process. In addition to the persona setting, a device that does not bore the patient is required. A change in the depth of the information heard during preliminary screening would also be necessary. We identified high-risk patients in our institution by interviewing all patients with breast cancer who visited the outpatient department (preliminary screening). As there is a limited amount of time before the medical examination, the information reported by the patient is often limited to relatives who have had cancer rather than the family structure (grandparents, parents, uncles and aunts, cousins, siblings, nephews and nieces, and children) and medical histories. Although our new system allows us to listen to each person's medical history after determining the family structure, it may be useful to adjust the system further depending on the purpose (eg, focusing only on family members suffering from cancer).

Third, we must consider how to handle personal information. We developed a system that is interacted with using a terminal (ie, a smartphone or tablet). However, the secure retention of data requires further exploration. The linking of the obtained results with electronic medical records would be an appropriate handling method.

Finally, clinical trials using this system are required; here, the device would be returned to the health care professionals once the patient has finished the conversation. In this study, the experts responded to the items based on the created scenarios. Evaluation by 3 predefined scenarios is limited system validation. Thus, we have conducted a study with a small number of patients. We would expect that the time required to input answers for actual patients would be longer because they would also need to recall the family history. In addition, human error (such as incorrectly entering a patient ID or confusing the appropriate terminal with another patient's terminal) may occur when patients being screened are also simultaneously treated at the outpatient department. Measures to prevent such errors may also be required. Therefore, it is first necessary to conduct further studies to solve any problem with this system on a small number of people before further investigation is engaged.

Conclusions

We demonstrated that the chatbot system could be applied to preliminary screening for HBOC in a genetic medicine setting. Our system could automatically ask for family history items that covered most of the NCCN guidelines without requiring an actual person and remained automated up to the screening result. Health care professionals determined the system design; thus, it was possible to ensure medical accuracy. Theoretically, the number of correspondences and interactions could be increased to an infinite degree, and therefore, the scale could also be increased. The system may also apply to other diseases for which the screening criteria are based on family history. For future clinical applications, it will be necessary to conduct clinical research and to further improve the efficiency and convenience of the system.

Acknowledgments

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Conflicts of Interest

Hiroto Narimatsu received a research fund from Chugai Pharmaceutical Co., Ltd. The other authors have no conflicts of interest to declare.

Multimedia Appendix 1
Summary and chat contents of scenario 1.
[DOCX File , 23 KB - formative_v5i2e25184_app1.docx]

Multimedia Appendix 2
Summary and chat contents of scenario 2.
[DOCX File , 22 KB - formative_v5i2e25184_app2.docx]

Multimedia Appendix 3
Summary and chat contents of scenario 3.
[DOCX File , 30 KB - formative_v5i2e25184_app3.docx]

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Abbreviations

AI: augmented intelligence
BRCA1/2: BRCA1 or BRCA2
CGC: certified genetic counselor
HBOC: hereditary breast and ovarian cancer
NCCN: National Comprehensive Cancer Network
SNS: social network service

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Original Paper

Attitudes Toward a Proposed GPS-Based Location Tracking Smartphone App for Improving Engagement in HIV Care Among Pregnant and Postpartum Women in South Africa: Focus Group and Interview Study

Kate Clouse[1,2], PhD, MPH; Tamsin K Phillips[3], PhD, MPH; Phepo Mogoba[3], MPH; Linda Ndlovu[3], MPH; Jean Bassett[4], MBChB; Landon Myer[3], MBChB, PhD

[1]Vanderbilt University School of Nursing, Nashville, TN, United States

[2]Vanderbilt Institute for Global Health, Vanderbilt University Medical Center, Nashville, TN, United States

[3]Division of Epidemiology and Biostatistics, School of Public Health and Family Medicine, University of Cape Town, Cape Town, South Africa

[4]Witkoppen Clinic, Johannesburg, South Africa

Corresponding Author:
Kate Clouse, PhD, MPH
Vanderbilt University School of Nursing
461 21st Avenue South
Nashville, TN, 37240
United States
Phone: 1 (615) 343 5351
Email: kate.clouse@vanderbilt.edu

Abstract

Background: Peripartum women living with HIV in South Africa are at high risk of dropping out of care and are also a particularly mobile population, which may impact their engagement in HIV care. With the rise in mobile phone use worldwide, there is an opportunity to use smartphones and GPS location software to characterize mobility in real time.

Objective: The aim of this study was to propose a smartphone app that could collect individual GPS locations to improve engagement in HIV care and to assess potential users' attitudes toward the proposed app.

Methods: We conducted 50 in-depth interviews (IDIs) with pregnant women living with HIV in Cape Town and Johannesburg, South Africa, and 6 focus group discussions (FGDs) with 27 postpartum women living with HIV in Cape Town. Through an open-ended question in the IDIs, we categorized "positive," "neutral," or "negative" reactions to the proposed app and identified key quotations. For the FGD data, we grouped the text into themes, then analyzed it for patterns, concepts, and associations and selected illustrative quotations.

Results: In the IDIs, the majority of participants (76%, 38/50) responded favorably to the proposed app. Favorable comments were related to the convenience of facilitated continued care, a sense of helpfulness on the part of the researchers and facilities, and the difficulties of trying to maintain care while traveling. Among the 4/50 participants (8%) who responded negatively, their comments were primarily related to the individual's responsibility for their own health care. The FGDs revealed four themes: facilitating connection to care, informed choice, disclosure (intentional or unintentional), and trust in researchers.

Conclusions: Women living with HIV were overwhelmingly positive about the idea of a GPS-based smartphone app to improve engagement in HIV care. Participants reported that they would welcome a tool to facilitate connection to care when traveling and expressed trust in researchers and health care facilities. Within the context of the rapid increase of smartphone use in South Africa, these early results warrant further exploration and critical evaluation following real-world experience with the app.

(JMIR Form Res 2021;5(2):e19243) doi:10.2196/19243

KEYWORDS

HIV/AIDS; South Africa; smartphone; mobile health; pregnancy; GPS tracking

Introduction

The World Health Organization endorsed universal, lifelong antiretroviral therapy (ART) for all pregnant and breastfeeding women in 2013 [1], followed in 2015 by universal ART for all adults and children with HIV [2]. Expansion of HIV treatment delivers undeniable health benefits, including substantial gains in life expectancy [3]; however, challenges arise in ensuring continuous, lifelong engagement in HIV care [4]. Peripartum women living with HIV are at especially high risk of dropping out of care, particularly after delivery [5,6]. South Africa is home to the world's largest ART program, and the country adopted universal ART in 2016; however, studies have found suboptimal engagement in peripartum HIV care [7-9].

Population mobility affects engagement in HIV care as a barrier to both individual access to health care facilities and the ability to determine if an individual is truly lost from care. Individuals who drop out of care at one facility may continue at a second facility, known as "silent" or "unofficial" transfer [10]; this may underestimate engagement [11], given the absence of linked data networks at health care facilities [12]. Long-distance travel or relocation may also result in disengagement from HIV care or treatment disruption if an individual is unable to locate a new facility.

The population of South Africa is highly mobile both internally (circular migration) and across international borders [13]. Peripartum women are a particularly mobile population, with one study finding that nearly half of pregnant and postpartum women traveled during the peripartum period—especially after delivery—to destinations including eight of South Africa's nine provinces and four foreign countries [14]. To understand the impact of mobility on engagement in HIV care, better measurement tools must be implemented to accurately track individuals' movements [15]. With the rise in mobile phone use worldwide, there is an opportunity to use smartphones and GPS location software to characterize mobility in real time.

Previously, researchers have demonstrated the use of bulk cell phone data to model infectious disease spread due to mobility [16], internal mobility within a country [17], and population movement after a major natural disaster [18]. These studies were conducted using proprietary network data from commercial cell phone service providers; however, this requires the cooperation of each provider. Also, use of aggregate cell phone service data requires intense computational power, does not allow for individual consent, and may be subject to breaches of security and misinterpretation of data [15].

In South Africa, smartphone ownership has seen tremendous growth [19]; concurrently, mobile health (mHealth) interventions have demonstrated acceptability among local populations [20-22]. This context provides an ideal opportunity to explore population mobility and intervene in health outcomes at an individual level, given that individuals typically carry their mobile phones with them all day [23]. Although the use of GPS to track individual movement is a common feature of commercial smartphone apps, it has not been widely reported in the context of mHealth. However, two New York City–based studies of wearable GPS devices for the purpose of tracking daily mobility were found to be acceptable among people living with HIV [24,25].

Given the rising use of smartphones and the urgent need to better understand population mobility and its impact on engagement in HIV care, we set out to develop a smartphone app, CareConekta, with two primary functions. Firstly, the app will prospectively collect consenting individuals' GPS "fuzzy" location data (within one kilometer of their actual location) to better understand patient mobility; importantly, it will also enable real-time intervention to improve engagement when an individual has traveled away from their primary facility. Parameters can be set, such as a time or distance from the clinic area, to initiate contact and assist with facility transfer and medication refills. Secondly, the app will contain nationwide facility information to serve as a "clinic finder" when seeking a new facility. Initially, the app will be aimed at pregnant and postpartum women, a population known to be mobile and at high risk of disengagement from HIV care. The results presented here are part of the formative research undertaken prior to developing this app, assessing attitudes toward this concept among pregnant and postpartum women living with HIV in South Africa.

Methods

We used two approaches (detailed below) to collect data for this analysis.

In-depth Interviews

We conducted semistructured in-depth interviews (IDIs) with 50 adult (aged ≥18 years) pregnant women living with HIV recruited during routine antenatal care at two primary care facilities in Johannesburg and Cape Town, South Africa. Interviews were conducted from September 2016 to September 2017 by an experienced qualitative researcher based at each site in the preferred local language of the participant and were recorded, transcribed, and translated into English as previously reported [26]. The primary objective of the IDIs was to characterize and understand motivations for mobility during the peripartum period; however, we also asked a series of open-ended questions to assess respondents' attitudes toward proposed interventions to improve engagement in HIV care among peripartum women. Of these open-ended questions, only one related to a proposed location-tracking intervention:

> *Some cell phone programs can track where a person travels. For example, a program could use the signal from someone's cell phone to alert the clinic to when that person was out of town, so that the clinic could check with her about her supply of tablets or upcoming visits. What do you think about this? Is this something that you would be interested in having on your phone?*

Due to the limited nature of this question, we did not take a typical qualitative approach to this part of the analysis but instead quantitatively assessed the proportion of participants responding favorably or unfavorably. Two reviewers (KC and TP) independently assessed each response and rated it as "favorable," "negative," or "neutral" based on whether the

participant would be interested in having the proposed intervention on their own phone. We then assessed the interrater reliability and reached agreement on discordant findings.

Focus Group Discussions

We also conducted focus group discussions (FGDs) at the same primary care facility in Cape Town where the IDIs were conducted, using a private room that accommodated seating for all participants. The objectives of the FGDs were to explore mobile phone use and preferences among postpartum women living with HIV in South Africa and to engage potential users to identify core design elements promoting the usability and acceptability of a mobile phone app. Focus group discussions were selected as the data collection method to enable group interaction and exchange of ideas as well as to foster deeper discussion than is possible with the open-ended questions in the IDI. The recruitment and enrollment information are described in greater detail elsewhere [27]. From January to March 2017, we enrolled 27 adult (≥18 years), recently postpartum (<12 months since delivery) women living with HIV who currently used smartphones and attended regular care at the study site in the 6 FGDs. The participants were asked to pick a color to use instead of their names during the discussion. The FGDs were moderated by a local research coordinator, conducted in isiXhosa (the predominant local language), recorded, transcribed, and translated to English. Approximately half of the FGD guide focused on questions related to the proposed CareConekta app (Multimedia Appendix 1).

Data Analysis

Quantitative data were analyzed using SAS 9.4 (SAS, Inc), reporting proportions for categorical data and medians and IQRs for continuous variables. The transcripts of the FGDs were analyzed in NVivo 11 (QSR International). We took a deductive approach to framework analysis by identifying codes using research questions [28]. We focused on 3 topics, guided by the interview questions: attitudes toward a clinic finder feature, attitudes toward a mobility tracking feature, and privacy concerns. Data were analyzed by grouping the text into themes. The text under each theme was then examined for convergent and divergent patterns, concepts, and associations. Illustrative quotes were selected to elucidate the findings.

Ethical Review Statement

All participants provided written informed consent prior to the study activities. The research activities were approved by the ethical review boards of Vanderbilt University, the University of the Witwatersrand, and the University of Cape Town.

Results

Participant Characteristics

The 50 IDI participants had a median age of 29.5 years (IQR 24-34) and a median duration on ART of 9.4 months (IQR: 2.0-38.6). The median age of the 27 FGD participants was 30 years (IQR 23-34), the median time since delivery was 6.5 months (IQR 2.4-9.4), and the median duration on ART was 16.1 months (IQR: 10.6-51.2).

IDIs

Of the 50 participants, 76% (38/50) responded positively to the proposed tracking intervention, 16% (8/50) were neutral, and 8% (4/50) responded negatively. Among those who responded favorably, their comments related to the convenience of facilitated continued care, a sense of benevolence on the part of the researchers and/or health care facility for providing this service, and the difficulties of trying to maintain care while traveling:

> *It would show me that I am cared for, and that would encourage me.* [Participant 15, favorable]
>
> *I think that would be fine because people sometimes travel unexpectedly and have not come to the clinic to get medication.* [Participant 17, favorable]
>
> *Maybe when I arrive at [village name], I might not adhere to my treatment. This will still help me, you understand. I might be followed up by the health care workers of the place, because they will be in possession of my details.* [Participant 18, favorable]
>
> *I would love that, because it would remind me.* [Participant 33, favorable]

Among the minority of participants who responded negatively and said they would not want the app, or who were neutral and said they were ambivalent about the app, the comments primarily related to the individual's responsibility for their own health care rather than the facility's:

> *I think the patient should be the one who is active about such a thing.* [Participant 42, neutral]
>
> *I have been out of town ever since I started my treatment. What would help me [more] is to come to the clinic to ask for transfer letter because it [the clinic] might not know if I will spend some time in Eastern Cape [Province].* [Participant 9, neutral]
>
> *That is somehow an invasion of privacy…I mean, we're all adults. If you have to travel and you know your status, you just need to make sure that you've got enough medication for you to be able to travel.* [Participant 29, negative]
>
> *If a person is serious about life, they will ask for a transfer letter.* [Participant 40, negative]

A small group of participants misunderstood the concept of tracking to mean that researcher would be able to see them through their phone, responding that researchers should not be able to "see things that you are not supposed to see" [Participant 41], such as when the participant is naked.

FGDs

Four key themes emerged during the FGDs: facilitating connection to care, informed choice, disclosure (intentional or unintentional), and trust in researchers.

Attitudes Toward the Clinic Finder Feature

Respondents were overwhelmingly positive toward an app that would offer clinic location information, as the improved ability to connect to care was perceived as a major benefit. Responses related to this theme included:

> *For example, I am going to Eastern Cape [Province]…Once I run out of my treatment, my pills, even if I don't have money, I would have to rush—even if I travel by debt—back to Western Cape again because I used to come to the clinic here. So, it would make my life on the other side to be so easy.* [Yellow, FGD1]

One respondent noted the benefit of linking to care for her child:

> *I think it is the right thing because I travelled with [my] boy to Durban; he was one month old. So when I got to Durban, there is no clinic I knew of…I was forced to come back to Cape Town because my baby had to get his injections. Do you see that if there was an app I would have been able to look which is the nearest clinic around. I think it would help very much.* [Pink, FGD5]

Similarly, respondents reported that a clinic finder feature would enable them to make a more informed choice by providing more information about clinic services and location: "Clinics are not the same; there are children's clinics and adults' clinics as well, so before I go I should know first if it is the right clinic" [White, FGD5]. One response highlighted issues of both continuity of care and informed choice, noting a clinic finder feature would allow her, when traveling, to "go with confidence so you know how to approach the nurses, because your app assured you that these services are available" [Maroon, FGD6]. Interestingly, respondents expressed a desire to use a clinic finder feature locally to find new clinics offering privacy and anonymity from community members who may not know their HIV-positive status. For example:

> *I think it would help very much because sometimes…your [HIV] status is unknown and you are not ready to tell in the area that you are in that I am this kind of person [HIV-positive], so it would be better to search for yourself and go without asking anyone.* [Green, FGD3]

In FGD1, two participants misunderstood the proposed feature, thinking that they would be required to go to the closest clinic identified by the proposed app. They noted that they wished to avoid this because "most of the people who are working at the [closest clinic], they are from my village, so I am afraid" [Gold, FGD1]. These responses underscore the issue of the desire to choose one's clinic to avoid disclosure of disease status.

Attitudes Toward the Mobility Tracking Feature

Overall, the respondents were supportive of the idea of allowing researchers to track their location. Positive responses noted the usefulness of this idea for connecting to care in the event of missed clinic visits, informing the home clinic about the participant's current location, and providing potential for information to be shared back to the participant:

> *I think it is good that they know your location, for maybe you have missed the [visit] date.* [Red, FGD2]
>
> *I think it is right to record [location] so that they are able to get [connect] you.* [White, FGD2]
>
> *You would be in East London, perhaps, in the meantime it [clinic] would still assume that you are here in Cape Town, so I think it is right about recording [location] because it would know that you are in East London now, so it should search for nearby ART clinics there.* [Red, FGD5]

Sharing of location information with researchers was noted as acceptable, suggesting that the participants find it easier to discuss HIV with researchers than with people in their family or community to whom they may not wish to disclose their HIV status:

> *I would like that. I just would not like to share information with my neighbors. Researchers from UCT [University of Cape Town] do not know me anyway.* [Black, FGD6]
>
> *I also would love to be located by UCT, not people who know me.* [White, FGD6]

A few participants misunderstood the concept of a mobility tracking feature, confusing the concept of "recording" location with "recording" a message: "Something that is recorded stays, so you will be able to listen again or to call it again" [Yellow, FGD2]. Additionally, a few participants believed that a mobility tracking feature could function as a "find my phone" device, which is outside of the scope of this feature.

Privacy Concerns

When asked about privacy-related issues related to a clinic finder or mobility tracking feature, few concerns were noted. Most privacy concerns related to the clinic finder feature and receiving messages informing participants of nearby facilities rather than to the location tracking feature. Respondents indicated that prior disclosure of their HIV-positive status to friends and family members meant that they had few concerns with unintentional disclosure via their mobile devices. Occasional phone sharing with sisters, mothers, and partners was noted, but unintentional disclosure to these individuals was not raised as a concern:

> *There is nothing that I am hiding.* [Black, FGD2]
>
> *I have no concerns because my phone doesn't stay with [is not shared with] many people; it stays with people who know my status.* [Red, FGD5]

However, one group raised fears of more general unintentional disclosure, possibly misunderstanding the tracking feature: "In this app, names of [HIV-] positive people are going to be recorded" [White, FGD2].

Overall, however, this was a minority perspective, and the idea was raised that the researchers were "helping" participants by offering these app features. An understanding of the confidentiality of research was noted by statements such as "I am not worried at all because my name is not used in the study. It remains confidential" [Black, FGD6]. Trust in the researchers was also noted, with one participant stating, "I don't see any issues because these people [researchers and health care providers] are helping us" [Maroon, FGD6].

Discussion

Through our research with pregnant and postpartum women living with HIV in South Africa, we found high potential acceptability for a proposed app that would use GPS location information to track mobility and provide a clinic finder function. In recent years, the high prevalence of cell phones has spurred the creation of numerous mHealth interventions [29,30]. South Africa has been a leader in the development and widescale implementation of mHealth interventions in sub-Saharan Africa, with the notable example of MomConnect, a text message–based health information program for peripartum women that reached >60% coverage of pregnant women attending antenatal care nationally [31]. With the increased availability of more sophisticated mobile devices, such as smartphones, potential has emerged to access individual GPS location information to improve health outcomes. Our work developing the novel CareConekta app represents an early example of using GPS technology and individual location tracking within the mHealth context.

From our earliest discussions about developing a smartphone app to collect individual location data, privacy has been at the forefront of our concerns. Our motivation for this work was to understand the attitudes of potential users—pregnant and postpartum women living with HIV—toward such an intervention as well as their privacy concerns prior to developing the app. In discussing privacy, we were surprised that respondents mentioned using a GPS-based clinic finder locally—in the absence of travel—to find a new facility that promised anonymity and security from unintentional disclosure. These remarks underscore the continued heavy burden of HIV stigma within the context of a generalized epidemic and universal testing and treatment [32]. Our findings also suggest a high level of trust between respondents and researchers, demonstrating an understanding of confidentiality practices within research and expressing a sense of helpfulness on the part of the researchers. Although few privacy concerns were raised, issues of stigma and individual privacy concerns could be addressed through an app design that is not specific to HIV. As previously reported, approximately half of the FGD participants shared their phones, primarily with family members and friends [27]. However, most of the participants suggested that this sharing was short-term, such as allowing a friend to check Facebook. Further research is warranted to investigate the feasibility of mHealth interventions specific to individuals, such as those tracking GPS location, in the context of potential phone sharing.

In both the IDIs and the FGDs, some misunderstandings of the proposed app and its features were expressed. These ranged from fearing that researchers would be allowed to see participants through the smartphone to incorrect assumptions of benefits, such as using the app to find one's misplaced phone. This emphasizes the need for substantial training of the staff responsible for implementation; also, a thorough introduction to the app will be needed for participants during enrollment, which must include the potential limitations of the app and also highlight these concepts.

Strengths of our study include representing participant responses at two geographic sites in South Africa and using two distinct methods for collecting extensive participant feedback: IDIs and FGDs. Study limitations include that the IDIs and FGDs were not designed to detect differences across study sites or to enable participant subgroup analyses. Participation in the FGDs was limited to women currently using smartphones attending a single clinic in Cape Town. Our sample size was small compared to those of quantitative studies but was appropriate for qualitative research and enabled meaningful discussion. Data were collected from September 2016 to September 2017 and represent the respondents' attitudes at that specific time. At both study clinics, the participants were aware of health research; therefore, research in different populations and settings is needed to determine whether the low privacy concerns and high trust in researchers reported are generalizable. The attitudes reported here are based on a hypothetical app that was only briefly introduced and not viewed or used by the participants. This required the participants to think abstractly about the proposed app and may have produced biased results that will be revealed when an actual app is developed and tested. Thus, it is important to follow this work with future exploration of postuse acceptability.

Overall, the respondents were overwhelmingly positive to the idea of an app that uses GPS to track an individual's location to facilitate connection to care. The respondents largely seemed to understand the concept and could articulate potential benefits. Few concerns with privacy were raised, and trust in researchers was noted. These results support continued development of GPS-based mHealth interventions to improve engagement in HIV care in this population.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Focus group discussion guide.
[DOCX File , 13 KB - formative_v5i2e19243_app1.docx]

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Abbreviations

ART: antiretroviral therapy
FGD: focus group discussion
IDI: in-depth interview
mHealth: mobile health
NIH: National Institutes of Health
UCT: University of Cape Town

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Original Paper

Effectiveness of Text Message Reminders on Adherence to Inhaled Therapy in Patients With Asthma: Prospective Multicenter Randomized Clinical Trial

Carlos Almonacid[1], MD, PhD; Carlos Melero[2], MD, PhD; Antolín López Viña[3], MD, PhD; Carolina Cisneros[4], MD, PhD; Luis Pérez de Llano[5], MD, PhD; Vicente Plaza[6], MD, PhD; Juan Luis García-Rivero[7], MD, PhD; Auxiliadora Romero Falcón[8], MD, PhD; Jacinto Ramos[9], MD, PhD; Teresa Bazús González[10], MD, PhD; María Andrés Prado[11], MD, PhD; Alfonso Muriel[12], MD, PhD

[1]Department of Respiratory Medicine, Instituto Ramón y Cajal de Investigación Sanitaria, University of Alcala de Henares, Madrid, Spain

[2]Department of Respiratory Medicine, Hospital Universitario 12 de Octubre, Institute for Health Research (i+12), Complutense University of Madrid, Madrid, Spain

[3]Department of Respiratory Medicine, Hospital Universitario Puerta de Hierro, Autonoma University of Madrid, Majadahonda, Spain

[4]Department of Respiratory Medicine, Hospital Universitario La Princesa, Autónoma University of Madrid, Madrid, Spain

[5]Department of Respiratory Medicine, Hospital Universitario Lucus Augusti, University of Lugo, Lugo, Spain

[6]Department of Respiratory Medicine, Hospital de la Santa Creu i Sant Pau, Institut d'Investigació Biomédica Sant Pau, Autònoma University of Barcelona, Barcelona, Spain

[7]Department of Respiratory Medicine, Laredo Hospital, Laredo, Spain

[8]Department of Respiratory Medicine, Hospital Universitario Reina Sofia, University of Cordoba, Córdoba, Spain

[9]Department of Respiratory Medicine, Hospital Universitario de Salamanca, University of Salamanca, Salamanca, Spain

[10]Department of Respiratory Medicine, Hospital Universitario Central de Asturias, University of Oviedo, Oviedo, Spain

[11]Department of Health Information Management, Fundación Jimenez Diaz, Madrid, Spain

[12]Unit of Clinical Biostatistics, Instituto Ramón y Cajal de Investigación Sanitaria, Consorcio Centro de Investigación Biomédica en Red de Epidemiología y Salud Pública, University of Alcala de Henares, Madrid, Spain

Corresponding Author:
Carlos Almonacid, MD, PhD
Department of Respiratory Medicine
Instituto Ramón y Cajal de Investigación Sanitaria
University of Alcala de Henares
Ctra. De Colmenar Viejo, km. 9,100
Madrid,
Spain
Phone: 34 655 534 475
Email: caralmsan@gmail.com

Abstract

Background: Poor adherence to inhaled medication in asthma patients is of great concern. It is one of the main reasons for inadequate asthma control.

Objective: The goal of the research was to determine if motivational messages using short message service (SMS, or text) improved adherence to inhaled medication in patients with asthma.

Methods: A prospective multicenter randomized parallel-group clinical trial was conducted in 10 asthma clinics in Spain. Adherence was assessed with electronic monitors (Smartinhaler, Adherium Ltd) connected to inhalers. Patients in the SMS group received psychologist-developed motivational messages every 3 days for 6 months.

Results: There were 53 patients in the SMS group and 88 patients in the control group. After 6 months, mean electronic adherence was 70% (SD 17%) in the intervention group and 69% (SD 17%) in the control group (P=.82). Significant differences between the study groups in morning and evening adherence to inhaled therapy, asthma control, exhaled nitric oxide levels, or improvement of lung functions were not observed.

Conclusions: Motivational messages were not useful to improve adherence to inhaled asthma medication compared with usual care.

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KEYWORDS

asthma; adherence; SMS; control; cell phone; inhaler; Smartinhaler

Introduction

Epidemiological studies show a high prevalence of poor asthma control [1-3]. Poor adherence is one of the most frequent causes of this problem [2-18]. The measurement of adherence to inhalers is a complicated task. Different methods have been used in daily practice, including clinical judgment, response to treatment, generally validated self-report questionnaires [19], or specifically designed instruments such as the Test of Adherence to Inhalers [20,21]. All these methods tend to overestimate treatment adherence [22,23]. Exhaled nitric oxide (FeNO) measurement has been proposed as an objective technique to measure treatment compliance [24]. In the last 30 years, electronic monitoring devices have been developed with this proposal [25-28]. These devices can record the time and number of doses taken and remind the patient to take medication.

Adherence to inhaled therapy depends on multiple factors. Asthma education programs plus information and communication technologies could be more useful to improve adherence than using them separately. All cell phones can send or receive short message service (SMS, or text) messages, which are a convenient, widely used mode of communication [29-32]. It has been shown that text messages improve appointment adherence [10], but very little research has focused on the effect of messages to reinforce adherence using SMS.

Several studies reviewed the effect of reminders on asthma control and adherence to treatment [33-40]. Only a few studies have used electronic devices to assess adherence to inhalers. In these studies, reminders were also sent through the same electronic device (SmartTrack or Smartinhaler [both Adherium Ltd]) that measured adherence to treatment, not through SMS [39,40]. Other studies used self-report questionnaires to measure inhaler adherence, but this leads to decreases the quality of the results. To date, a benefit in adherence to treatment from motivational text messages sent to a cell phone has not been reported.

The objective of this study is to measure the effect of motivational messages designed by a psychologist on treatment adherence compared with usual care in patients with moderate to severe asthma.

Methods

Trial Design

We conducted a parallel-group randomized controlled trial in patients with moderate or severe asthma at 10 university hospitals in Spain. Patients were recruited from 2013 to 2014. Patients were randomized to an SMS group or a control group; follow-up was for 6 months.

Participants

The eligibility criteria for participants were (1) aged 18 to 85 years, (2) asthma diagnosed according to the Global Initiative for Asthma (GINA) criteria [41], (3) all patients treated with maintenance therapy according GINA guidelines, (4) currently own cell phone, (5) not currently being treated with systemic corticosteroids or biologic drugs, (6) not currently participating in another research study.

Exclusion criteria were (1) inability to use inhaler devices [30]; (2) other associated chronic respiratory disease (eg, chronic obstructive pulmonary disease); (3) previous participation in a study using SMS-related asthma reminders (4) asthma exacerbation within 3 months of inclusion in the study (defined by oral corticosteroid use, emergency department visit, or hospitalization); (5) previous treatment with budesonide/formoterol as maintenance and reliever therapy; (6) other uncontrolled severe medical conditions.

Interventions

The SMS group received psychologist-developed motivational messages every 3 days for 6 months in addition to usual care recommendations according to GINA guidelines [41]. SMS messages were not reminders to take a dose of medication. The control group was treated with general care recommendations alone according to GINA guidelines [41]. Four study visits were required (1 for enrollment and 3 for follow-up) in both groups. Outcome data were collected at the clinic by study staff in V0, V1 (1 month later), V3 (3 months later), and V6 (6 months later—end of study).

Medications and Inhaler Monitoring

All patients received a SmartTrack device (Smartinhaler [Adherium Ltd]; Figure 1) that clipped on their ICS/LABA inhaler. SmartTrack is an electronic device that allows measuring adherence to the inhalers. Each puff is recorded in the device memory. SmartTrack records the date and time the inhaler was used and the number of puffs taken. SmartTrack features include reminders, onscreen questions about asthma control, and medication feedback viewing online, but these have been deactivated. After the device was activated during the enrollment (visit 0), it recorded the date and time of all maneuvers to measure adherence to treatment. The data were uploaded to a secure cloud server with local backup to the investigator's computer.

Figure 1. SmartTrack devices connected to pressurized metered-dose inhaler (left) and Turbuhaler inhalation device (right).

Patients were treated with an ICS/LABA inhaler for maintenance therapy (fluticasone propionate/salmeterol Accuhaler/Diskus inhaler, budesonide/formoterol Turbuhaler inhaler, or beclomethasone/formoterol metered-dose inhaler). They also used albuterol pressurized metered-dose inhaler as rescue medication. Device reliability and precision have been reported according to other publications [38].

SmartTrack Training and Monitoring

Electronic monitoring via the Smartinhaler was used to assess adherence to inhaled asthma therapy. All patients received brief instructions on the use of the SmartTrack. Patients with adherence higher than 80% were considered regular adherents. Electronic monitors were attached to participant controller medications in the SMS and control groups.

Text Messages

Patients assigned to the intervention group only received SMS communications about the importance of asthma medication every 3 days for 6 months; messages were not reminders to take a dose of medication. The messages, written by a psychologist in collaboration with pulmonologists, were randomly switched every 3 days and include the following:

- Remember that performing the treatment of inhaled medication keeps your asthma controlled.
- Inhaled medication helps to maintain asthma control.
- Remember to take inhaled medication; it keeps you well.
- Have you taken your inhaled medication?
- Do you take your inhaled medication in the morning and the evening?
- Maybe now is the time to take your inhaled medication.
- Remember to take inhaled medication as prescribed by your doctor.

Asthma Education

All patients were provided an asthma action plan on the first day written in accordance with the GINA guidelines. Inhaler technique was reviewed, and any problems were corrected. At each visit, inhaler technique and the asthma action plan were reviewed.

Asthma Control

Asthma control was measured using the Asthma Control Test (ACT) [42], and a score ≥20 identified well-controlled asthma patients.

Pulmonary Function

Spirometry with bronchodilator test was performed according to the European Respiratory Society/American Thoracic Society (ERS/ATS) guidelines [43]. Values for the Mediterranean population were used [44]. Forced expiratory volume in 1 second (FEV1) pre and postbronchodilator were measured.

Fractional Exhaled Nitric Oxide

An FeNO level was measured before spirometry using the equipment available in each center. The test was performed following the ERS/ATS recommendations [45].

Outcomes

Demographic data, ACT, lung function (spirometry), FeNO levels, and exacerbation history in the previous year were collected at the enrollment visit (V0). ACT, lung function, FeNO levels, and exacerbation history were also collected at V1, V3, and V6.

The primary outcome was adherence to inhaled medication. SmartTrack devices were used to quantify adherence to control medication. The secondary outcomes were asthma control measured by the ACT, spirometry parameters (FEV1, forced

vital capacity, and FEV1/forced vital capacity ratio), FeNO levels, number of asthma exacerbations, visits to the emergency department, and hospital admissions due to asthma.

Sample Size

The sample size was calculated according to an adherence rate to inhaled asthma therapy between 30% and 70% [9]. On the assumption of the maximal uncertainty of 50% and considering a clinically relevant difference of 25%, with a type I error of .05, a power of 80%, and a 20% loss, 73 patients per arm were needed (total 146 patients).

Randomization, Blinding, and Allocation Concealment

We generated the 2 comparison groups using simple randomization with an equal allocation ratio by referring to a table of random numbers. A mathematician, also in charge of randomization of the SMS sending, generated the sequences of random allocation, who enrolled participants, and who assigned participants to interventions and SMS sending.

Blinding of patients was not possible. To avoid bias and with ethics approval, physicians were not notified about the SmartTrack recording function or SMS intervention until the study ended.

Statistical Methods

Categorical variables were expressed as frequencies and percentages and continuous variables as means and standard deviations. The chi-square or Fisher exact test were used for the analysis of categorical variables, and the Student *t* test or Mann-Whitney *U* test were used for the comparison of quantitative variables according to the standard or nonnormal distribution of variables. Tests were 2-tailed. Statistical significance was set at $P<.05$. Statistical analyses were performed using the SPSS Statistics version 20.0 (IBM Corp).

Ethics Approval and Trial Registration

The clinical research ethics committees of the participating centers approved the study. All participants provided written informed consent. The study was classified by the Spanish Agency of Medicines and Medical Devices as a noninterventional imposed postauthorization safety study, and for this reason we were not required to register the clinical trial.

Results

Patient Participants

Of patients recruited, 63.8% (97/152) were women. At the first data collection time point, the mean age was 48.9 (SD 16.7) years, and the mean duration of asthma was 16.5 (SD 13) years. A total of 6.6% (10/152) of patients were current smokers. Most patients were well controlled at enrollment, with a mean ACT score of 20.2 (SD 4.5) points. The mean FEV1 before the bronchodilation test was 79% (SD 17.9%) predicted, the mean FEV1 after bronchodilation test was 82.5% (SD 16.2%) predicted, and the mean FeNO level was 37.9 (SD 35.9) ppb. A total of 13.2% (20/152) of patients reported one or more exacerbations during the last 12 months, 15.8% (24/152) reported an episode of asthma-related urgent health care utilization and prednisone use in the previous year, and 5.9% (9/152) required admission to hospital.

A failure with the randomization program unbalanced the number of patients in both arms. During the study period, 57 patients were assigned to the intervention group, and 95 to the control group. At follow-up, 11 patients were excluded because of the total failure of the electronic monitoring device. The final analysis included 53 patients in the intervention group and 88 in the control group. The flowchart of the study population is shown in Figure 2. Demographic and baseline characteristics were similar between groups, apart from a lower proportion of men and university education in the SMS group (Table 1).

Figure 2. Flow diagram of the progress through the phases of a parallel randomized trial of two groups.

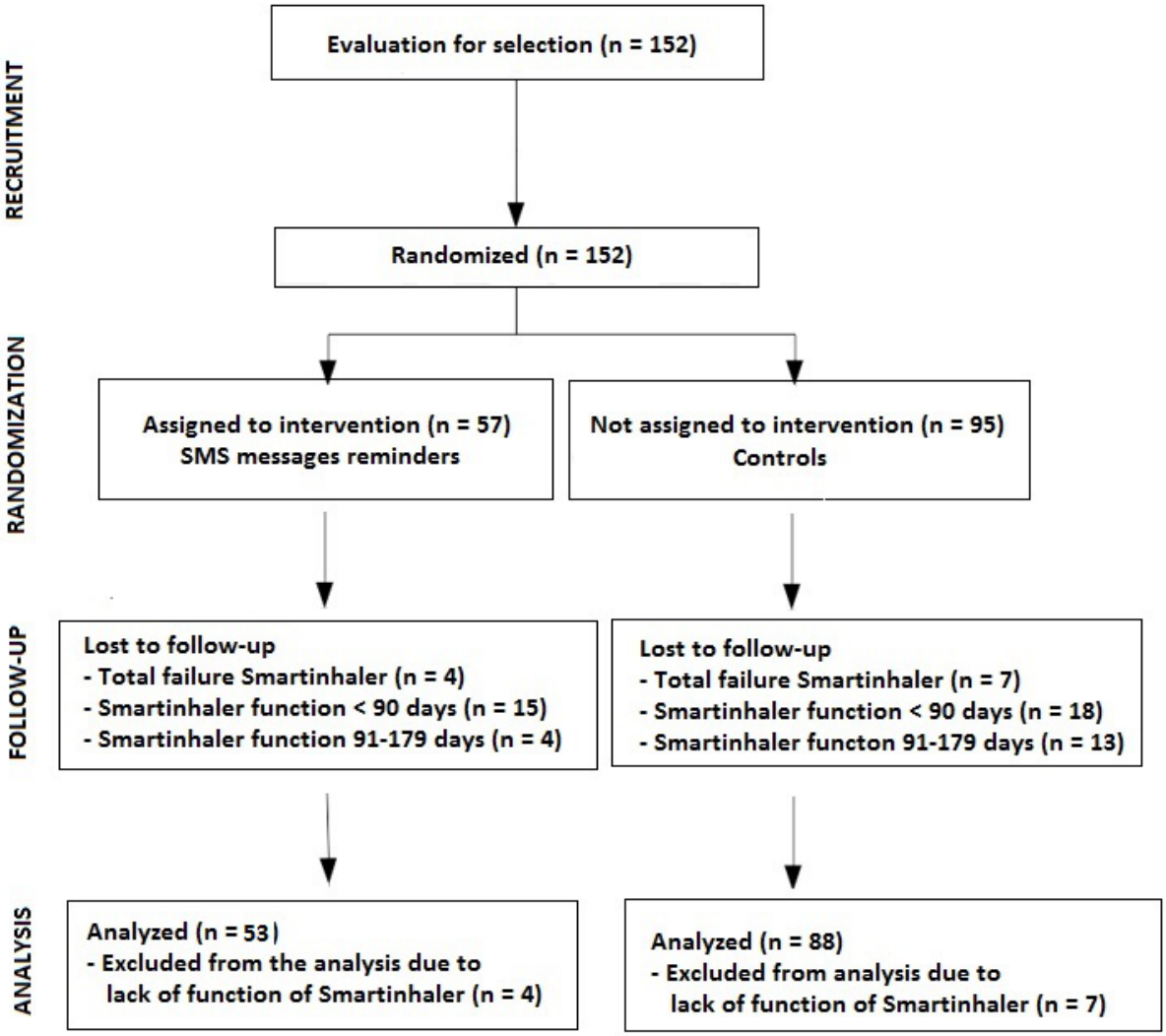

Table 1. Clinical characteristics of patients at baseline.

Variable	SMS[a] group (n=57)	Control group (n=95)	*P* value
Gender, male, n (%)	15 (26)	40 (42)	.05
Age in years, mean (SD)	50.4 (16.4)	48 (16.9)	.40
Education level, n (%)			
Primary/secondary studies	47 (82)	61 (64)	.40
University degree	7 (12)	20 (21)	.40
Working status, n (%)			
Unemployed	6 (11)	10 (11)	.79
Employed	34 (60)	54 (57)	.79
Housewife	4 (7)	11 (12)	.79
Retired	13 (23)	18 (19)	.79
Smoking history, n (%)			
Current smoker	4 (7)	6 (6)	.75
Ex-smoker	17 (30)	34 (36)	.75
Never smoker	36 (63)	55 (58)	.75
Self-management education program, n (%)	10 (18)	16 (17)	.91
Asthma history, mean (SD)			
Years from diagnosis	16.6 (11.6)	16.5 (14.3)	.98
Years from starting treatment	13.3 (10.3)	13.2 (12.1)	.10
Years from follow-up in outpatient clinics	7.2 (7)	6.8 (7.8)	.78
Inhaler type, n (%)			
Accuhaler/Diskus	18 (32)	38 (40)	.57
Turbuhaler	26 (46)	37 (39)	.57
pMDI[b]	13 (23)	20 (21)	.57
Inhalation technique, correct steps, n (%)			
Acceptable	40 (70)	75 (79)	.22
Unacceptable	17 (30)	20 (21)	.22
Asthma-related events in the previous 12 months, mean (SD)			
Exacerbations	0.6 (1.2)	0.4 (0.8)	.21
Emergency department visits	0.2 (0.6)	0.2 (0.7)	.79
Hospital admission	0.05 (0.2)	0.04 (0.2)	.76
Asthma Control Test, mean (SD)	20.3 (4.2)	20.0 (4.8)	.69
FeNO[c] level, ppb, mean (SD)	42.2 (37.5)	33.7 (34.3)	.18
FEV1[d] before bronchodilation test, % predicted, mean (SD)	79.0 (17.5)	79.5 (18.4)	.92
FEV1 after bronchodilation test, % predicted, mean (SD)	79.6 (16.7)	85.3 (15.7)	.16

[a]SMS: short message service.

[b]pMDI: pressurized metered-dose inhaler.

[c]FeNO: exhaled nitric oxide.

[d]FEV1: forced expiratory volume in 1 second.

Adherence to Treatment

Primary Outcome

Adherence data were recorded throughout the study starting from enrollment, and 92.8% (141/152) of patients had analyzable SmartTrack data. No adherence data were available for 7.2% (11/152) of patients due to device failure; 21.7% (33/152) of SmartTracks monitored adherence for at least 90 days, 11.2% (17/152) operated fine for between 90 and 179 days, and 59.9% (91/152) worked precisely until the study ended.

The data transmission software that communicated with the Smartinhaler platform failed throughout the study in most of the participating centers since it did not work with the hospital proxy servers. Due to this failure, the backup files generated during each visit were used for the analysis. Differences between the study groups were not found in SmartTrack failures (*P*=.51).

After 6 months, the mean electronic adherence was 70% (SD 17%) in the intervention group and 69% (SD 17%) in the control group (*P*=.82). Adherence to inhalers was higher in both groups in the morning (control group 79% [SD 19%] vs 60% [SD 24%] in the afternoon and SMS group 80% [SD 23%] vs 59% [SD 29%] in the afternoon; Table 2).

Table 2. Results at the end of the study.

Variables	SMS[a] group (n=53)	Control group (n=88)	*P* value
Adherence %, mean (SD)	70 (17)	69 (17)	.82
Morning adherence %, mean (SD)	80 (23)	78 (19)	.44
Evening adherence %, mean (SD)	59 (29)	60 (24)	.75
Asthma Control Test score, mean (SD)	21.6 (3.7)	22.1 (3.5)	.46
FeNO[b] level, ppb[c], mean (SD)	36.5 (35.5)	28.3 (22.0)	.14
FEV1[d] before bronchodilation test, % predicted, mean (SD)	77.3 (16.2)	80.9 (18.0)	.42
FEV1 after bronchodilation test, % predicted, mean (SD)	85.9 (12.4)	84.5 (16.2)	.73
Exacerbation episodes , n (%)			.22
0	37 (84)	68 (92)	—
1	7 (16)	5 (7)	—
≥2	0	1 (1)	—
Visits to emergency department, n (%)			.43
0	40 (91)	71 (95)	—
1	4 (10)	4 (5)	—
≥2	0	0	—
Hospital admission for asthma, n (%)	0	0	—

[a]SMS: short message service.

[b]FeNO: exhaled nitric oxide.

[c]ppb: parts per billion.

[d]FEV1: forced expiratory volume in 1 second.

Secondary Outcomes

At the end of the study (V6), no differences were found between the SMS and control group in ACT, FEV1, FeNO levels, exacerbations, emergency department visits, or hospital admissions (Table 2).

Discussion

Principal Findings

In this study, motivational SMS was not associated with an improvement in adherence to inhaled medication. We also found no significant differences in secondary variables, asthma control, lung function, exhaled nitric oxide levels, or exacerbations due to asthma.

Education strategies are useful to improve adherence to asthma therapy [10]. Few studies have examined the effect of SMS reminders on adherence to asthma treatment. Strandbygaard et al [46] conducted a 12-week study with 26 asthma patients randomized to the SMS group (n=12) or control group (n=14). The SMS group received this message daily: “Remember to take your asthma medication morning and evening. From the Respiratory Unit.” A medicine dose-count for Diskus inhaler was used to assess adherence. The mean adherence rate increased in the SMS group and decreased in controls, with a difference in mean adherence rate between the 2 groups after 12 weeks of 17.8% (95% CI 3.2%-32.3%; *P*=.02). Changes in adherence in the SMS group, however, were not associated with clinical or functional improvement. Few patients were included in this study, and adherence may have been overestimated due to the possibility to take actions before the medical visit.

In another study, Charles et al [47] used the audiovisual reminder function on the Smartinhaler metered-dose inhaler device. After 12 weeks, the absolute difference in the median percentage of medication taken between the intervention (n=55) and control (n=55) groups was 18% (95% CI 10%-26%; *P*<.001). But, again, no improvements in clinical or lung functions were observed.

In a 6-month cluster-randomized study, Foster et al [35] assessed the effect of inhaler reminders plus adherence feedback (n=21) versus usual care or personalized discussion with the general practitioners (n=22) in the primary care setting. Reminders were associated with improvements in adherence (73% [SD 26%] vs 46% [SD 28%] of prescribed daily doses, *P*<.001) as well as with an improvement in the ACT but without differences between the study groups.

In a recent systematic review of interventions aimed at improving adherence to inhaled corticosteroids for asthma, 11 studies assessing electronic trackers or reminders versus control were analyzed [10]. Electronic trackers or reminders led to better adherence of 19 percentage points (95% CI 14.47-25.26; 6 studies; moderate-quality evidence), but a clear benefit on clinical outcomes was not found.

Limitations

In our study, a simple intervention based on motivational SMS sent every 3 days for 6 months was not adequate to improve adherence. Different reasons may account for this adverse finding. First, the messages sent were motivational; they were not reminders for taking medication. Second, the pattern of nonadherence behavior (eg, erratic, deliberate, unwitting) [21] was not evaluated nor were patients stratified according to a nonadherent model. Third, asthma was well controlled at baseline as shown by high ACT scores and lung function parameters; the magnitude of improvement depends to a large extent on the degree of control of the disease before the intervention.

An interesting finding of this study, in which all patients had twice-daily medication schedules, is that adherence rates were higher in the morning than in the evening. It is possible that in patients on single-dose inhaled medication regimens, SMS could have had a more significant impact on adherence.

Although the Smartinhaler is accurate in recording and retaining actuation data [48,49], potential malfunction during real-life use by patients is possible. In our study, failure of communication technology occurred in all centers without differences between the study groups; in these cases, however, analyses were performed using backup files. Only 91% (SD 59.9%) of the Smartinhalers worked fine and collected information until the study ended.

In our study, patients were recruited in specialized asthma units established in different hospitals throughout Spain for the management of patients with severe and difficult-to-control asthma [50]. Therefore, it is possible that this particular circumstance may account for the adequate adherence at baseline and proper control of asthma before enrollment and at the end of the study.

Conclusions

In summary, in this prospective randomized clinical study, reinforcement of adherence to inhaled asthma medication using motivational SMS via cell phones was not capable of improving adherence. Mobile health interventions are increasingly popular for implementing on a large scale in different chronic health conditions [51-53], but further research into these issues is needed. Despite the negative results that may be justified because of the study's limitations as described above, the study's results are not conclusive. However, an interesting fact that can be seen in both groups is that morning adherence to the inhaler is much higher than afternoon adherence. These data should be verified in a new well-designed clinical trial that could reinforce the use of ultralong action treatments, which only need to be taken once a day, in order to improve the adherence and control of asthma.

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Authors' Contributions

CM and ALV conceived the study. MA and AM verified the analytical methods. CA supervised the findings of this work. All authors discussed the results and contributed to the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

ACT: Asthma Control Test
ERS/ATS: European Respiratory Society/American Thoracic Society
FeNO: exhaled nitric oxide
FEV1: forced expiratory volume in 1 second
GINA: Global Initiative for Asthma
ICS/LABA: inhaled combination of corticosteroids and a long-acting beta 2 agonist
SMS: short message service

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Original Paper

Designing a Personalized Health Dashboard: Interdisciplinary and Participatory Approach

Miriam Weijers[1,2*], MSc, MD; Caroline Bastiaenen[3], PhD; Frans Feron[2], Prof Dr; Kay Schröder[4*], Prof Dr

[1]Department of Preventive Child Health Care, Municipal Health Services, Southern Limburg, Heerlen, Netherlands

[2]Department of Social Medicine, Faculty of Health, Medicine and Life Sciences, Care and Public Health Research Institute, Maastricht University, Maastricht, Netherlands

[3]Department of Epidemiology, Faculty of Health, Medicine and Life Sciences, Care and Public Health Research Institute, Maastricht University, Maastricht, Netherlands

[4]Data Visualization, Zuyd University of Applied Sciences, Heerlen, Netherlands

[*]these authors contributed equally

Corresponding Author:
Miriam Weijers, MSc, MD
Department of Social Medicine
Faculty of Health, Medicine and Life Sciences
Care and Public Health Research Institute, Maastricht University
Postbus 616
Maastricht, 6200 MD
Netherlands
Phone: 31 +31646442957
Email: miriam.weijers@ggdzl.nl

Abstract

Background: Within the Dutch Child Health Care (CHC), an online tool (360° CHILD-profile) is designed to enhance prevention and transformation toward personalized health care. From a personalized preventive perspective, it is of fundamental importance to timely identify children with emerging health problems interrelated to multiple health determinants. While digitalization of children's health data is now realized, the accessibility of data remains a major challenge for CHC professionals, let alone for parents/youth. Therefore, the idea was initiated from CHC practice to develop a novel approach to make relevant information accessible at a glance.

Objective: This paper describes the stepwise development of a dashboard, as an example of using a design model to achieve visualization of a comprehensive overview of theoretically structured health data.

Methods: Developmental process is based on the nested design model with involvement of relevant stakeholders in a real-life context. This model considers immediate upstream validation within 4 cascading design levels: Domain Problem and Data Characterization, Operation and Data Type Abstraction, Visual Encoding and Interaction Design, and Algorithm Design. This model also includes impact-oriented downstream validation, which can be initiated after delivering the prototype.

Results: A comprehensible 360° CHILD-profile is developed: an online accessible visualization of CHC data based on the theoretical concept of the International Classification of Functioning, Disability and Health. This dashboard provides caregivers and parents/youth with a holistic view on children's health and "entry points" for preventive, individualized health plans.

Conclusions: Describing this developmental process offers guidance on how to utilize the nested design model within a health care context.

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KEYWORDS

visualization design model; dashboard; evaluation; personalized health care; International Classification of Functioning, Disability and Health (ICF); patient access to records; human–computer interaction; health information visualization

Introduction

The Dutch Preventive Child Health Care (CHC), as part of public health, monitors children's health and their continuum of development with focus on protecting and promoting health and providing context for optimal development. This implicates preventing disease progression at early stages of a "growing into deficit," when symptoms do not cluster to a diagnosis or are even absent yet [1]. It is not easy to timely redirect these complex dynamics underlying health. The Bio-Psycho-Social perspective on health (BPS) displays the complexity by conceptualizing health as a result of lifelong, multidimensional interactions between individual (biological–genetic) characteristics and contextual factors [2].

This makes prevention challenging, but it is crucial to effectively address current burden of chronic diseases [3]. It is even a prerequisite that the current health care system, which is mostly reactive (ie, treatment after a diagnosis), transforms toward personalized health care (PHC) [4]. According to Snyderman, PHC includes the concepts prevention, prediction, personalization, and participation and to fully adopt these concepts within practice, the availability of qualitative, holistic health information is required [5,6].

The preventive CHC offers a unique platform to adopt these PHC concepts, as CHC (from birth on) digitally registers a broad spectrum of information about interrelated health determinants in child and environment [1,7]. Yet, the holistic health information, stored in the CHC's electronic medical dossier (EMD), is insufficiently accessible to effectively perform PHC. The actual data flow is time-consuming due to an inconsistent, nontheoretical structure of the EMD [8-10]. This challenges CHC professionals to gain clear overview of relevant CHC data within the limited timeframe available during consultations with parents and other caregivers. Consequently, CHC professionals are hindered in obtaining integral insight into the interrelated health determinants in child and environment, let alone parents and youth.

To acquire better overview of meaningful data, indispensable for interpretation of holistic health information, the idea was initiated from CHC practice to develop a novel approach for summarizing health data about child and its environment in 1 image [2,11]. Visualization design offers efficient opportunities to make holistic health information accessible at a glance and conform to the relevant theoretical perspective [12,13].

The initial idea was first converted into rough drafts of representation of CHC health information. To enable generation of informal development ideas, the researchers presented first drafts to parents, youth, and CHC professionals and asked for their reaction. Stakeholder's feedback on these first drafts during interviews (parents) and focus group meetings (professionals) was positive concerning comprehensibility, relevance, acceptability, and feasibility. A pilot study of an early-on version of the 360° CHILD-profile also showed positive results regarding reliability and validity, when used by CHC medical doctors to assess child functioning [14].

The 360° CHILD-profile seemed a promising new tool, but further development was needed to deliver a suitable and functional dashboard, ready to be introduced to CHC practice. To realize meaningful visualization of complex health information with sufficient user satisfaction and essential performance in practice, it is important that such a developmental process is guided by appropriate design models.

The main aim of this paper is to offer guidance on how to utilize a design model to visualize and structure health data in a health care context with a heterogeneous target group. As an example, we describe the systematic development and immediate validation (as far as possible) of a comprehensible 360° CHILD-profile: an online accessible visualization of CHC data. The ultimate goal of this multifunctional tool for preventive CHC practice is to visualize the coherence between health domains in a way that it guides analytic thought processes of both care providers and parents/youth in line with BPS perspective on health and PHC. This paper focusses on describing the overall development process of a visualization tool to offer a clear, representative content generalizable to various subfields and disciplines in health care.

Methods

Process Development and Prototype

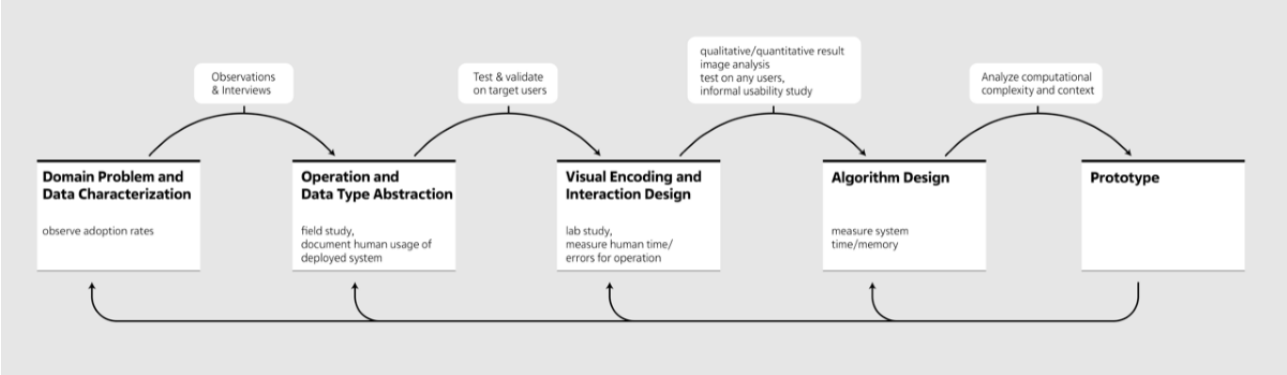
The developmental process of the 360° CHILD-profile is based on a nested design model, adapted from Munzner [15] (Figure 1). This model describes different levels of design that are structured within 4 cascading levels that consider an immediate upstream validation (toward delivering a suitable prototype of the dashboard) as well as impact-oriented downstream validation of the prototype (toward the effective performance of the dashboard in daily CHC practice).

The prototype of the CHILD-profile is developed within a user-centered design process [16] and relevant stakeholders were involved during every level of design. For each design level, new participants were recruited. During this project, we collaborated in an interdisciplinary expert group including CHC professionals and researchers with expertise on CHC context, epidemiology, human–computer interaction, and information visualization in health care. This approach, combining expertise from the medical field with expertise on information visualization, is rather new but particularly useful in this health care context to increase the likelihood of the intended health outcome [17].

The Medical Ethics Committee of the Maastricht University Medical Centre approved this design process (METC azM/UM 17-4-083).

Before starting the first level of the nested design model, a literature research was performed with focus on theoretical models for health and background of the Dutch preventive CHC to identify the information needed for each design level.

Figure 1. The nested design model, adapted from Munzner [15]. The upper part shows the relevant stages of upstream validation, while the bottom part shows the different dimensions of downstream validation.



Domain Problem and Data Characterization

On the first level, it was of vital importance to bridge the information asymmetry between relevant stakeholders, researchers, and designers to get a common understanding of user, domain, and task [18]. To achieve this while considering the privacy of the users, we first conducted role games, in which CHC consultations were re-enacted in a real-life situation with key stakeholders (CHC professionals, parents, and youth). A schematic approach (summative representation of data to make sense of complex, nuanced information and enable team-based analysis) was used to observe and interpret interpersonal interactions [19]. In the second step, interviews with participants of the role games as well as other CHC professionals were carried out to get a deeper understanding of the process and related requirements from the perspective of individual stakeholders. Role games and interviews were audio recorded. Recordings were summarized and, after discussion by a team of researchers, relevant findings were listed.

Finally, the resulting conclusions about user's perspectives were immediately validated in real-life by observing consultation hours. During the observations, field notes were taken. Based on the information collected within the previous steps, personas and empathy maps were created to visualize users' characteristics, goals, and skills, to become more aware of their real needs and to help the research group align on a deep understanding of end users [20,21].

In parallel, the relevant domain knowledge was discussed and summarized with all involved stakeholders to ensure that the involved researchers/designers share a common understanding of the underlying concepts and mechanisms. Furthermore, related work in the field and visual artifacts were discussed.

In summary, all our findings formed the domain-specific basis for the other levels (Figure 1).

Operation and Data Type Abstraction

The focus of the second level was on mapping the underlying data in a more abstract description of operations, data types, and structure to form the input required for the visual encoding stage.

Different theoretical frameworks were explored to choose the most relevant framework for prioritizing and ordering data. The International Classification of Functioning, Disability and Health: Children and Youth version (ICF-CY) framework appeared to be the most appropriate to comprehensively and accurately describe individual health situations [22]. The classification systems ICD-11 (International Classification of Diseases, 11th revision) and DSM-5 (Diagnostic and Statistical Manual of Mental Disorders, version 5), commonly used in health care, were also considered. However, these frameworks do not fit preventive CHC because they are based on a biomedical model of health and focus on diseases and diagnosis and not on prevention [23,24]. The ICF-CY framework was chosen because it represents the broad BPS perspective on health and adequately fits the preventive CHC. The ICF-CY framework enables to display the broad variety of information on characteristics of a child and its environment, collected by CHC. Strengths and protective factors, inevitable for protection and promotion of health and prevention of diseases, are included in the ICF-CY framework. Next, symptoms, diseases, and determinants that challenge health can be presented. And, last but not least, information is formulated in concrete and neutral, if not positive, terms with little to no valuation. The ICF-CY structure was customized to integrate it into a profile that fits CHC practice and theoretical background.

During 2 review group meetings, the 360° CHILD-profile was presented and profile's content, terminology, and ordering were discussed with experienced CHC professionals. During the review meetings, field notes were taken and summarized and discussed to reach consensus.

For immediate validation, a static, adapted, early-on version of the 360° CHILD-profile was presented to parents and youth and semistructured interviews were performed to gain insight into user experience (comprehensibility and usability), requirements, and coverage of meaningful topics. Audio recordings of the interviews were transcribed, field notes were taken, and data were analyzed according to previous steps.

Findings were discussed in brainstorming sessions with the research team to verify coherence with scientific and practical purpose of the profile and generate developmental ideas. The resulting findings were not just limited to the data structure and detailed task definitions, but also included meaningful ordering of the information.

Visual Encoding and Interaction Design

The first 2 levels of design (Domain Problem Characterization and Operation and Data Type Abstraction) formed the primary input for the visual encoding and interaction design on a content level. The development of the formal level was based on 2 additional pillars: the consideration of international standards of human–computer interaction for information representation (ISO 9241-12) [25] as well as theoretical aspects of design based on prior research in this field [26,27] and the systematic integration of users within iterative validation and optimization cycles.

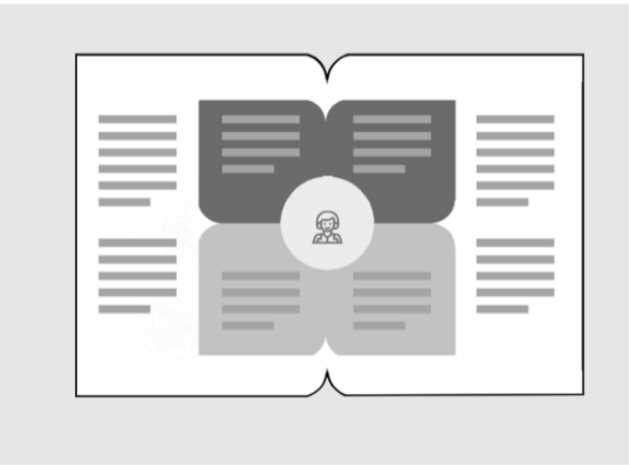
In early stages of the design process, prior findings were integrated into low-fidelity prototypes to conceptually visualize the relevant CHC data and test them with users.

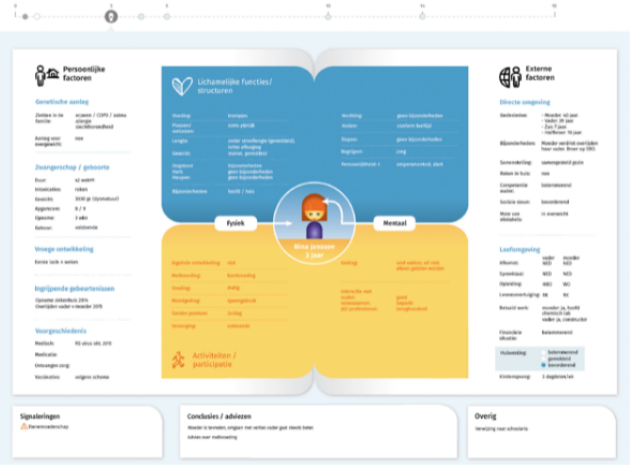
A clear and accessible information structure appeared to be of vital importance to address requirements of the given scenario and a clear visual structure plays a major role in reducing the cognitive load and controlling the perceptual ordering [28]. Therefore, the design was developed based on a sectional grid system and information was structured into areas. The key areas were placed within the center (Figure 2, left) and to facilitate the understanding, key concepts were illustrated through icons in combination with text [29].

The resulting sketch was operationalized into a digital prototype, suitable for informal, qualitative tests with relevant stakeholders (CHC professionals and parents). Participants performed tasks within representative scenarios (to prepare for or to reflect upon a CHC consultation) while considering the profile in all its bearings. Participants were asked to express their first impression on the profile, line out the profile's structure, seek and interpret specific information, and indicate comprehensibility of information. A researcher guided and facilitated the participants during the sessions. To gain feedback on accessibility, comprehensibility, and usability of the 360° CHILD-profile for each user group, a "think aloud" procedure was conducted [30]. A second researcher observed the session and conducted interviews with the stakeholders. Audio recordings of the interviews were summarized, field notes were taken, and data were analyzed according to previous steps.

For this visualization in accordance with the ICF-CY framework, it is crucial that it stimulates viewers to take into account all domains and choose a routing from central (child) toward outside (environmental factors). Therefore, a gaze tracking evaluation was applied (Tobii X1 Light eye tracker 30 Hz) to gain indirect feedback on what parts of the profile the stakeholders looked at and in which order. Results were discussed in the research team meetings and eventually processed to deliver a digital application of the final version of the online accessible CHILD-profile.

Figure 2. The figures illustrate relevant steps of our iterative design process. The first phase resulted in a global composition design that accurately reflects the content structure (grid layout on the left). In a next step, the design was optimized through additional dimensions such as color, visual language elements such as icons, and illustrations (prototype on the right).





Algorithm Design

The prototype was developed as a web application based on JavaScript and embedded within an HTML website to ensure an integration into real-life scenarios. Data parsing and mapping were realized through Data Driven Documents (D3) Version 4, while the interactions were implemented using jQuery, JavaScript, and CSS.

The technical implementation was immediately validated in 2 ways: the application was tested by analyzing computational complexity and content and optimized with Chrome DevTools (developer tools) as well as user tests with representative data samples.

Prototype and Downstream Validation

Downstream validation at the level of algorithm design and visual encoding and interaction design was immediately tackled within the described levels: application test and user tests (see the "Algorithm Design" section) and informal qualitative tests (see the "Visual Encoding and Interaction Design" section).

Downstream validation of the delivered prototype at the level of operation and data type abstraction is beyond the scope of this article. For this dimension of validation, a field study is planned to evaluate CHILD-profile's feasibility (usability and potential effectiveness) and feasibility of performing a randomized controlled trial (RCT) within the preventive CHC context [31]. This feasibility RCT aims at generating knowledge

on how to build follow-up studies directed toward downstream validation at the level of domain problem and data characterization.

Results

Domain Problem and Data Characterization

Within more age categories, a total of 3 role games were performed and all involved CHC professionals (nurses or medical doctors or both), parents, and in one case youth (age >12) were interviewed. For field validation, for 2 days, CHC consultation hours were observed in more age categories.

Observations and interviews showed that CHC nurses mainly perform regular, protocoled tasks, and CHC medical doctors mostly explore indicated concerns and problems more in depth. An example of schematic description of a professional within the CHC context (an integration of empathy map and persona) is provided in Multimedia Appendix 1. One of the key challenges we could identify within this level was that the visual structure and interaction design of the current EMD did not sufficiently address the informational needs of the target group. During the interviews and observations, it became apparent that this leads to fundamental problems to fulfill several tasks in the given time due to an ineffective information and interaction structure. Both CHC nurses and medical doctors noted that data registration in the EMD is time-consuming and that they are hindered in quickly referring to registered data and gaining clear overview of health information. Discussion between researchers on visual artifacts revealed the lack of overview and theoretical ordering of data within the EMD. During consultations, CHC professionals pursue active participation of parents and youth but they indicated the need for visual support for communicating health information with parents. Parents indicated the importance of being able to decide for themselves and feeling free to make their own choices during the upbringing of their child. Related work regarding visual support on health communication and revealing parent's perspectives did not provide a holistic and structured display (in accordance with the ICF-CY framework) of the large and complex electronic CHC data sets [32].

Together with users we developed a description of formal requirements for the CHILD-profile to be designed. The design of the CHILD-profile should be:

- lively and user-friendly with neutral, serene, and warm (fear reducing) appearance to create a positive experience;
- targeted at supporting communication between CHC professionals and parents/youth and providing comprehensible and accurate overview of health determinants in child and its environment.

The pursued ordering effects were allocating the child in a central position, visualizing the coherence between the multiple features in child and context (in accordance with the ICF-CY framework), and making complex health information tangible. Technical requirements for the application were suitability for desktop (for visual support during consultations) and online accessibility but it should also be printable as PDF (A4 format, to be used during house visits).

Operation and Data Type Abstraction

Content and data ordering for the CHILD-profile were based on the ICF-CY framework, resulting in 4 domains: "Body structures and functions," "Activities and participation," "Environment," and "Personal factors." The specific content of each domain was customized to the specific Dutch CHC practice and is in accordance with CHC's professional framework and "toolbox" [33,34]. During 2 review group meetings, the CHC professionals (2 nurses and 2 medical doctors) indicated that the clear overview, ordering of data, and the use of colors were an improvement on accessibility in comparison to the currently used EMD. They proposed even more emphasis on neutral (nuanced) and positive formulations. Second, as not all items are equally relevant during the continuum from age 0 to 18, the review group prioritized specific content for the different age groups (0-15 months, 15 months to 4 years, 4-9 years, 9-12 years, and 12-18 years). Consensus was reached on expert agreement and adaptations were made on prioritization per age category and more positive terminology of data.

Visual Encoding and Interaction Design

The visualization was designed while taking into account the CHC context, user experiences of prototypes, user's desires, formal and technical requirements, and the indicated options for improvement of this data visualization.

The qualitative tests of prototypes (on average 30 minute sessions) showed that both target groups could handle the prototype well and performed most of the given tasks correctly (CHC professionals: 7 tasks of 9; parents: 6 tasks of 9). Most participants could link different domains in which health facilitators and barriers are described. Stakeholders feedback on the prototypes included mostly positive remarks such as "nice to build up information during lifetime", "nice that not only risks factors but also protective factors are included in the overview" and "good to see coherence between health determinants". However, some parents mentioned the following remarks: "it is a lot of data, in the beginning it is hard to know where to start", "it is important that formulations are clear". Participants indicated that in some CHILD-profiles they missed specific information about the child and that it is important to know where the data come from. As participants mentioned the importance of showing a timeline and a separate conclusion section to highlight critical information regarding the last consultation, these elements were incorporated in the final version of the CHILD-profile. Gaze-tracker output showed that all participants explored the profile by starting at the center (child icon/image) and clearly distinguished the middle planes from outer columns. Almost all domain titles were noticed except for "Activities & Participation" and participating professionals often paid more attention to the "conclusion/advice" section than parents.

Algorithm Design

This algorithm design phase resulted in an application which automatically transfers CHC health data registered in the EMD. The application is built independently from the existing EMD and can be connected to any application programming interface that provides the related EMD data. The dashboard offers a

"front end" summary to be linked to the EMD systems and online parent portal. The final version of the visualization design is tested and operational in the browsers used in the specific context (the CHC organizations uses Chrome and Firefox).

Prototype and Downstream Validation

So far, the described procedure resulted in a comprehensible 360° CHILD-profile, usable on computer and mobile devices (laptop or tablet) and printable for home visits. This visualization of CHC data at a glance is validated on impact at the level of algorithm design and visual encoding and interaction design and is ready to be introduced to CHC practice. Field study with focus on downstream validation on the level of operation and data type abstraction is beyond the scope of this article. This field study will be separately presented in feasibility RCT's protocol and result papers on this study which includes quantitative and qualitative research.

Discussion

Overview

This paper describes the stepwise development of a new dashboard, which combines visualization and theoretical ordering of health data based on the ICF-CY framework, to offer guidance on how to use the nested design model to achieve visualization of a comprehensive overview at a glance.

In this example, the practical implementation of the ICF-CY framework to summarize electronic health records is intended to display coherence between different health domains. The goal is to facilitate analytic thought processes during shared decision making toward preventive, individualized health plans directed at promoting health [26,32].

The CHILD-profile is designed to optimally display a holistic overview of data from electronic health records in line with the ICF-CY framework and enables considering multiple perspectives on child's development and health. Within the ongoing project, the dashboard itself was evaluated while taking into account several perspectives.

Strengths and Limitations

This project shows us which opportunities can arise from bringing together expertise/experience from the medical and information visualization/human–computer interaction field of knowledge. This collaboration, not yet common within health care, leads to synergy and optimal ground for realizing meaningful visualization of complex health information and sufficient adoption rate and essential performance in practice.

Additionally, the choice for a user-centered design approach, with active involvement of relevant stakeholders in every design level, increases the likelihood of usability within CHC practice and reaching the intended goals [17].

The currently experienced problems with EMD concerning accessibility of health data are avoided in this new information technology by considering international standards of human–computer interaction for information representation (ISO 9241-12 [25]) as well as theoretical aspects of design based on prior research in this field [26,27].

The nested design model is especially suitable for the context of data visualization within health care as it offers a holistic perspective on the design process [15]. For each level of design, evaluation during development (upstream validation) and after finishing the data-visualization design (downstream validation) is included. By integrating these design and evaluation methods, knowledge is generated on how to deliver a solid visualization with performance as intended as well as on how to measure actual effectiveness in practice and interpret the findings during implementation. However, it is important to note that the nested design model offers researchers a framework for structuring the design process on a rather abstract level. For each specific visualization, the choice for design and evaluation methods and the operationalization should be customized to the content and aim of the visualization and the context in which it will be implemented.

As we can only understand how people use a new tool when it exists, we could only partly tackle downstream validation within this project. Early versions of the dashboard and prototype are technically tested and qualitative tests are performed with rather limited study populations. To complete downstream validation process, studies with higher numbers of participants must be performed to reach sufficient power to evaluate if the innovation contributes to experienced needs in practice and leads to the intended health outcomes.

Opportunities and Challenges

By utilizing the ICF-CY as a framework for ordering health data, professionals are provided with an interactional structure for aggregating details of an individual's unique health reality across several dimensions. This structure makes it not only possible to comprehensibly display the multidimensionality of health but also the coherence between different health domains. Therefore, we hypothesize that the use of this new dashboard in CHC practice can:

- support to identify strengths, challenges, needs, and goals and "entry points" for health management;
- automatically guide (mostly subconsciously) "thinking processes" toward a more predictive, personalized, and participative approach of health;
- improve health literacy and facilitate shared decision making.

The modern information technologies, used to deliver a functional profile, allow greater direct access to health information for parents and youth (during visits and at home via online portal). By providing parents/youth insight into health facilitators and barriers, we think they will be empowered to take a more proactive, leading role during decision-making processes and make preventive health plans fit their context.

To study usability, adoption rate, and performance (regarding the intended goals) in practice, a field study and other follow-up studies need to be performed with sufficient power. To complete the validation process, it is important to measure ordering effects, visual salience, and bias effects, considering variables such as educational background and others. It is, however, a challenge to perform effect studies with sufficient sample sizes within the multidisciplinary and heterogeneous context of the

preventive CHC. Therefore, the first study to be performed will be a pragmatic feasibility RCT, in which both CHILD-profile's feasibility and RCT's feasibility aims will be evaluated. The RCT protocol and results will be published in separate articles [31]. Results of this field study will offer underpinning of necessary requirements for successful follow-up effect studies with sufficient power.

After completion of downstream validation and effective implementation of this new tool in CHC, we anticipate that using the CHILD-profile within CHC will stimulate toward more complete and uniform data registrations. This would lead to availability of standardized and theoretically structured health data (in accordance with the ICF-CY framework), which are more fit for epidemiological research and future possibilities like automatic transformation toward internationally standardized ICF codes.

Conclusions

This work is an important step toward bridging the information asymmetry between electronic health data, physicians, and patients and clients in general.

We propose the nested design model as a method to structure the design process while considering validation cycles for each level of design, both immediately during the process and impact-oriented validation after implementation, considering the effects of individual aspects on performance in practice.

We provide guidance on how to utilize the design model in a health context based on a concrete example and specific guidelines on how to address heterogeneous capabilities within preventive CHC through visual means and interaction design.

In our design study we developed a working prototype of a comprehensible 360° CHILD-profile on which CHC data are visualized at a glance. The application automatically converts CHC health data, already registered in the EMD, into a visualization which represents the continuum-based context of children's health and development.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
An example of schematic description of a professional within CHC-context (an integration of empathy map and persona).
[PDF File (Adobe PDF File), 583 KB - formative_v5i2e24061_app1.pdf]

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Abbreviations

BPS: Bio-Psycho-Social model of health
CHC: preventive Child Health Care
CSS: Cascading Style Sheets
DSM-5: Diagnostic and Statistical Manual of Mental Disorders, 5th edition
EMD: electronic medical dossier
ICD-11: International Statistical Classification of Diseases and Related Health Problems, 11th revision
ICF-CY: International Classification of Functioning, Disability and Health: Children and Youth version
ISO: International Organization for Standardization
MD: medical doctor
PHC: personalized health care
RCT: randomized controlled trial

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Original Paper

Analyzing Digital Evidence From a Telemental Health Platform to Assess Complex Psychological Responses to the COVID-19 Pandemic: Content Analysis of Text Messages

Thomas D Hull[1,2], MS, MPhil; Jacob Levine[1], PhD; Niels Bantilan[1], MPH; Angel N Desai[3], MPH, MD; Maimuna S Majumder[4], PhD

[1]Talkspace, New York, NY, United States

[2]Department of Counseling and Clinical Psychology, Teachers College, Columbia University, New York, NY, United States

[3]Department of Internal Medicine, University of California at Davis, Davis, CA, United States

[4]Computational Health Informatics Program, Boston Children's Hospital, Harvard Medical School, Boston, MA, United States

Corresponding Author:
Thomas D Hull, MS, MPhil
Talkspace
2578 Broadway #607
New York, NY, 10025
United States
Phone: 1 4802548815
Email: tdh732@mail.harvard.edu

Abstract

Background: The novel COVID-19 disease has negatively impacted mortality, economic conditions, and mental health. These impacts are likely to continue after the COVID-19 pandemic ends. There are no methods for characterizing the mental health burden of the COVID-19 pandemic, and differentiating this burden from that of the prepandemic era. Accurate illness detection methods are critical for facilitating pandemic-related treatment and preventing the worsening of symptoms.

Objective: We aimed to identify major themes and symptom clusters in the SMS text messages that patients send to therapists. We assessed patients who were seeking treatment for pandemic-related distress on Talkspace, which is a popular telemental health platform.

Methods: We used a machine learning algorithm to identify patients' pandemic-related concerns, based on their SMS text messages in a large, digital mental health service platform (ie, Talkspace). This platform uses natural language processing methods to analyze unstructured therapy transcript data, in parallel with brief clinical assessment methods for analyzing depression and anxiety symptoms.

Results: Our results show a significant increase in the incidence of COVID-19–related intake anxiety symptoms (P<.001), but no significant differences in the incidence of intake depression symptoms (P=.79). During our transcript analyses, we identified terms that were related to 24 symptoms outside of those included in the diagnostic criteria for anxiety and depression.

Conclusions: Our findings for Talkspace suggest that people who seek treatment during the pandemic experience more severe intake anxiety than they did before the COVID-19 outbreak. It is important to monitor the symptoms that we identified in this study and the symptoms of anxiety and depression, to fully understand the effects of the COVID-19 pandemic on mental health.

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KEYWORDS

digital phenotyping; COVID-19; telehealth; digital mental health; natural language processing; machine learning; mental health; phenotyping; burden; treatment; symptom

Introduction

Since late 2019, the ongoing COVID-19 pandemic has proved to be extremely disruptive; the pandemic has resulted in high morbidity and mortality rates, as well as economic and mental health consequences. These issues pose a challenge for mental health services, as little is known about SARS-CoV-2 and the psychological impact that the COVID-19 crisis has on medical

professionals, essential workers, unemployed individuals, and other people who engage in physical distancing. Early reports have suggested that mental health professionals face considerable challenges due to the lack of information and established guidelines for assessing and treating patients with COVID-19 [1]. Psychological sequelae to major events like the COVID-19 pandemic vary greatly [2-4]. This makes it difficult to assess the full range of symptoms that are potentially related to the COVID-19 crisis, and to track the course of COVID-19–related reactions over time. The use of comprehensive symptom checklists and exhaustive clinical interviews poses a considerable burden to clinicians and respondents alike. However, this burden can be avoided if the most common symptoms are known ahead of time.

A major obstacle to identifying the most relevant symptoms for screening is the amount of time it takes to amass clinical observations for a suitably large patient population. Large patient populations are needed for determining the full scope of patients' reactions. It is difficult to differentiate peripheral symptoms from central and pathogenic symptoms [5]. It is also difficult to differentiate symptoms that are ordinarily reported by a diverse, treatment-seeking population from symptoms that are more closely associated with COVID-19–related concerns. However, there is a lack of this type of data for the ongoing COVID-19 crisis. Data that are generated by large telemental health services that remotely deliver care (ie, US and global telemental health services) may be helpful in describing the full complexity of patients' clinical presentations. Text messages between patients and therapists (ie, text messages that are a part of intake and treatment procedures) offer the most useful data. These data are relatively unstructured compared to standardized symptom measures, but they offer the advantage of capturing patients' experiences more comprehensively. This allows therapists to differentiate symptoms that are reported in conjunction with mentions of COVID-19, from symptoms that are reported by individuals who seek care for other reasons. Natural language processing (NLP) methods refer to a broad set of methods that have been designed to analyze unstructured textual data. These methods range from simple methods that search for specific words in a block of text, to more complex neural network models that extract the meaning of certain statements by analyzing the larger context of a text corpus.

The aim of this study was to identify major themes and symptom clusters in the text messages that patients send to therapists. We assessed patients who were seeking treatment for pandemic-related distress on Talkspace, which is a popular telemental health platform. To achieve our objective, we differentiated symptoms that were associated with the pandemic from symptoms that were only experienced by individuals who seek treatment, by investigating the relationships among words that were associated with mentions of COVID-19. This is impossible to do when only relying on structured symptom measures that do not specify whether symptoms relate to the pandemic or some other cause. Therefore, we used a multistep process that involved brief symptom measures to determine the relationship between the pandemic and common, self-reported anxiety and depression symptoms; identify patients with COVID-19-related concerns; and isolate words that highly correlate with mentions of SARS-CoV-2. We categorized these words by using a digital phenotyping process for determining the prevalence of clinical and nonclinical themes, to ultimately identify symptoms in diagnostic categories that are not reflected in structured measures for common anxiety and depression symptoms. Our study demonstrates that our method has strong face validity and high levels of clinical interpretability. Therefore, our method can potentially be used to inform decisions on structured measures for tracking responses to the pandemic over time.

Methods

Setting

Talkspace is a telemental health platform that enables licensed psychotherapists to deliver care through asynchronous, two-way messaging methods, including text messaging, audio messaging, and video messaging. Talkspace also allows psychotherapists to schedule live video sessions with patients within their regions of licensure. Studies have shown that Talkspace is acceptable and feasible for increasing patients' access to care [6]. Talkspace has been used by over 2000 therapists who each serve an average of 15-20 patients at any given time (ie, throughout the United States and worldwide). This platform allows for the seamless transfer of symptom and outcome measure data to therapists, and offers crisis and referral services to patients who need a higher level of care than what the messaging platform can offer.

Participants

To evaluate changes in patients' self-reported symptoms, we administered the 7-item Generalized Anxiety Disorder questionnaire (GAD-7) [7] and the 9-item Patient Health Questionnaire [8] to patients who started treatment for depression and anxiety between January 1, 2017 and June 9, 2020. This allowed us to compare pre–COVID-19 pandemic trends in self-reported symptoms against trends that are contemporaneous to the ongoing COVID-19 pandemic.

To evaluate symptoms that are not included in the standard measures for depression and anxiety, regular expressions that were related to the pandemic, including "corona," "virus," "covid," and "pandemic," were identified and assessed. We verified that all regular expressions had a near 0% incidence rate prior to February 2020 (see Table 1). We conducted computerized keyword matching to analyze and identify COVID-19–related terms from all patient messages in treatment transcripts that were generated between March 1, 2020 and June 9, 2020. In this study, we defined "transcript" as the set of all messages that were exchanged between a patient and a care provider. Therefore, each patient had exactly 1 transcript.

Table 1. Percentage of messages that contained pandemic-related seed words/regular expressions before and after the COVID-19 pandemic.

Month and year	% of messages that contained "corona"	% of messages that contained "virus"	% of messages that contained "covid"	% of messages that contained "pandemic"
January 2020	0.0182%	0.0683%	0%	0.0017%
February 2020	0.0785%	0.1604%	0.0045%	0.0074%
March 2020	1.1113%	2.2173%	0.9072%	0.6105%
April 2020	0.4743%	1.0913%	1.2988%	1.0372%
May 2020	0.2848%	0.5751%	1.1225%	0.9988%
June 2020	0.2688%	0.4727%	1.1481%	0.9735%

Statistical Analysis

We calculated and aggregated average summary scores for patients' anxiety and depression scale scores. Furthermore, we stratified these scores based on patients' days of admission to assess changes over time. Statistical analyses were conducted with statistical analysis packages that use the Python programming language. Pandas was used for data analysis [9,10], Matplotlib [11] and Seaborn [12] were used for visualization, and Scipy [13] and Pandera [14] were used for data validation and hypothesis testing.

In order to identify the words and phrases (ie, n-grams) that are the most likely to appear with COVID-19–related mentions, we used NLP methods to represent each text day (ie, the days that text messages were sent) as a vector of word counts. These vectors were then transformed into term frequency-inverse document frequency (TF-IDF) values. In this study, TF-IDF values were used to identify changes in word use frequency over time. We computed Pearson correlation coefficients between each word's TF-IDF trajectory and the proportion of messages that mentioned COVID-19–related words during the same text day. Only terms that fell below the false discovery rate threshold of 0.01 were selected. Analyses were conducted with packages that use the Python programming language. Spacy [15] and Textacy [16] were used for NLP analyses, and Scipy [13] and Statsmodels [17] were used for statistical analyses.

Since the selected words had no identifiable structure on their own, these words were assigned to empirically derived, human-validated topics by using Empath [18], which is a software program that assigns words to topical categories based on similarities in word use (ie, word embeddings). These categories were then validated by human curators. We calculated the percentage of words in each Empath-assigned topical category.

Empath category assignment is a nonarbitrary method for evaluating major topics that are associated with mentions of COVID-19, including positive and negative emotion states. However, this method does not categorize words based on diagnostic criteria. To determine the relationship between words that are associated with mentions of COVID-19 and words that are associated with diagnostic categories, words were converted into a dictionary, which was used to compare words with the publicly available International Classification of Diseases, Tenth Revision (ICD-10) symptom descriptions for the classification of mental and behavioral disorders [19]. Words and phrases that did not match existing diagnostic criteria were inspected for clinical relevance and reported as additional criteria.

All data were analyzed by using machine learning analytical methods. All data were deidentified prior to analysis. Patients who used the Talkspace service provided consent for using their aggregated and deidentified data for research purposes. Procedures for the collection of symptom questionnaires were approved by the Teachers College, Columbia University institutional review board (approval number: 15-426).

Results

Participants

We collected symptom data from 169,889 patients between January 1, 2017 and June 9, 2020. Most patients (88,444/160,807, 55%) were aged 26-35 years. Women accounted for 73.2% (124,358/167,559) of the included participants. A total of 60.3% (51,222/84,945) of participants identified as European American. There was a minimum of 2211 patients from every state. Most of the participants were from California (24,634/169,889, 14.5%) and New York (20,387/169,889, 12%). Furthermore, 44.6% (75,770/169,889) of participants reported that they were undergoing therapy for the first time (see Table 2).

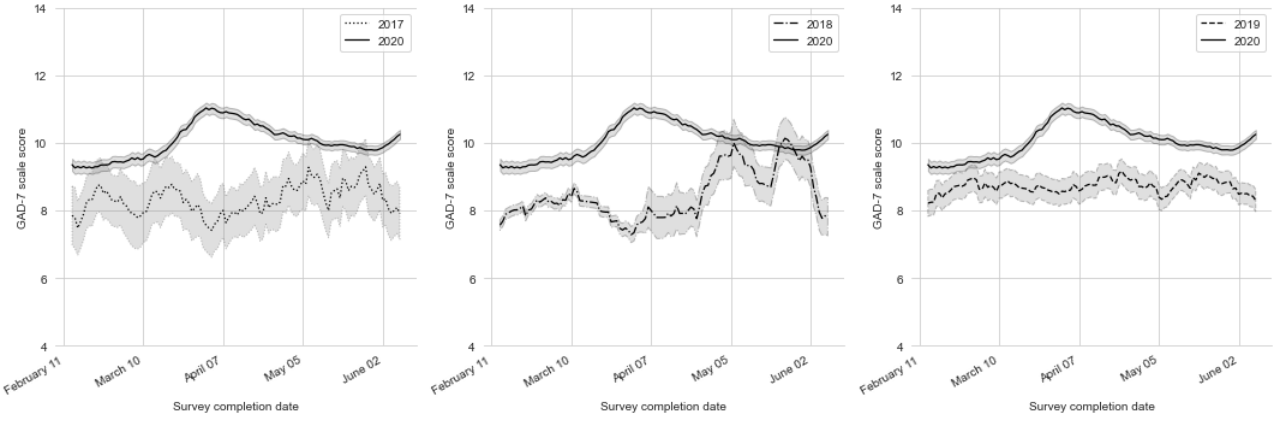
Table 2. Demographic characteristics of the full sample (N=169,889).

Variable	Value, n (%)	Number of participants with missing data, n
Age (years)		9082
18-25	38,594 (24)	
26-35	88,444 (55)	
36-49	23,960 (14.9)	
≥50	9809 (6.1)	
Education		24,552
Bachelor degree or higher	108,857 (74.9)	
High school diploma	36,480 (25.1)	
Race/ethnicity		84,944
European American	51,222 (60.3)	
African American	14,271 (16.8)	
Southeast/Asian American	8495 (10)	
Native American	425 (0.5)	
Other	10,533 (12.4)	
Hispanic/Latinx	12,997 (15.3)	
Gender		2330
Female	122,653 (73.2)	
Male	40,382 (24.1)	
Other	4524 (2.7)	
Patients' state of residence		0
California	24,634 (14.5)	
New York	20,387 (12)	
Texas	13,081 (7.7)	
Florida	9174 (5.4)	
Other US state	102,613 (60.4)	

Outcomes

Based on the intake averages of the GAD-7 scores, a 1.42 increase (95% CI 1.18-1.65) in the average intake severity of anxiety symptom scores was observed in the 10,645 patients who underwent depression or anxiety treatment between March 15, 2020 and April 1, 2020. This was the period when GAD-7 scores were at their highest peak. As of June 9, 2020, there has been an ongoing 0.33 increase (95% CI 0.11-0.54; P<.001) in GAD-7 scores (see Figure 1). No significant changes were observed in 9-item Patient Health Questionnaire scores for intake depression severity (P=.79).

Figure 1. The 2-week GAD-7 score rolling averages from February 1, 2020 to June 9, 2020. The rolling averages from 2017, 2018, and 2019 are also presented. GAD-7: 7-item Generalized Anxiety Disorder questionnaire.



A total of 219,156 transcripts were identified and included in this study. These transcripts accounted for the 169,889 patients with available outcome data. The remaining 49,267 patients chose not to complete an intake assessment or had incomplete responses. All transcripts were analyzed, and 18.5% (40,448/219,156) of transcripts were found to contain mentions of COVID-19. Of the 500,000 words and phrases in the transcripts with mentions of COVID-19, 2377 (0.5%) positively correlated with terms that were associated with mentions of COVID-19, and 661 (0.1%) negatively correlated with terms that were associated with mentions of COVID-19. The words that correlated the most with COVID-19–related mentions were categorized as a set of complex reaction categories via Empath. These Empath categories included confusion and negative emotions (assigned words: 713/2377, 30%); health and medical emergencies (assigned words: 499/2377, 21%); work, business, and economic concerns (assigned words: 428/2377, 18%); technology and internet (assigned words: 285/2377, 12%); cleaning and hygiene (assigned words: 190/2377, 8%); government and leadership (assigned words: 166/2377, 7%); and traveling and shopping (assigned words: 96/2377, 4%). The Empath categories that negatively correlated with mentions of COVID-19 were party and celebration (assigned words: 198/661, 30%); positive emotion and love (assigned words: 179/661, 27%); friends and children (assigned words: 178/661, 27%); and optimism (assigned words: 106/661, 16%). Although the words that were associated with parties, celebrations, love, friends, and children were far less likely to co-occur with mentions of COVID-19, the word stem “lone” (eg, words like “alone,” “lonely,” “loneliness,” etc) was not considerably related to pandemic concerns.

The words and phrases in these Empath categories exhibited similarities to existing ICD-10 diagnostic classifications, including those for acute stress reactions (ICD-10 F43.0), which meets the criteria for trauma reactions (ICD-10 F43.1) if acute stress reactions persist over time; paranoia symptoms (ICD-10 F22); grief symptoms (ICD-10 Z63.4; symptoms need to persist for over 6 months to meet the full grief criteria); insomnia symptoms (ICD-10 G47.00); panic symptoms (ICD-10 F41.0); agoraphobia symptoms (ICD-10 F40.00); nonsuicidal self-injuries (ICD-10 Z91.5); obsession-compulsion symptoms (ICD-10 F42.9); and hypochondriasis symptoms (ICD-10 F45.21). Additional clinically relevant content included confusion about one’s state and difficulties in controlling anger at others and institutions (see Textbox 1).

Textbox 1. Descriptions of International Classification of Diseases, Tenth Revision diagnostic categories and symptoms that were identified via digital phenotyping.

Hypochondriasis (F45.21)

- Worries of unexplained aches and pains (eg, head, back, joint, abdomen, and leg pain)
- Feeling that illnesses are not being taken seriously enough

Insomnia (G47.00)

- Problems with falling asleep, problems with staying asleep, and overall poor sleep quality

Obsession-compulsion (F42.9)

- Unpleasant thoughts, urges, or images that repeatedly enter the mind
- Feeling driven to perform certain behaviors or mental acts over and over again

Paranoia (F22)

- Feeling punished without cause
- Feeling sure one is being talked about
- Feeling that people are out to get you
- Feeling one must be on guard even with friends

Grief (Z63.4)

- Thoughts of a person who died make it hard do things one normally does
- Memories of a person who died are upsetting
- Feeling longing for the person who died
- Feeling angry about the death

Acute stress (F43.0) and posttraumatic stress disorder (F43.1)

- Experiencing an especially frightening, horrible, or traumatic event
- Having nightmares about the event(s) or thoughts about the event(s) when one did not want to
- Trying hard not to think about the event(s) or going out of the way to avoid situations that are reminders of the event(s)
- Feeling constantly on guard, watchful, or easily startled
- Feeling numb or detached from people, activities, or surroundings
- Feeling guilty or unable to stop blaming oneself or others for the event(s) or any problems the events may have caused

Nonsuicidal self-injury (Z91.5)

- Deliberately hurting oneself physically without intending to kill oneself or as a strategy for relief

Panic (F41.0)

- Experiencing panic episodes
- Worrying about having another episode

Agoraphobia (F40.00)

- Worrying about being in a public space in which escape might not be available should excessive anxiety or panic symptoms develop
- Obsessive, persistent, intense fear of open places

Anxiety (F41.9)

- Feeling afraid, as if something awful might happen
- Not being able to stop or control worry
- Worrying too much about different things
- Becoming easily annoyed or irritable

COVID-19–specific psychological criteria

- Feeling unsure about whether psychological reactions are normative or problematic
- Difficulty in controlling anger at others' actions or lack of actions

Discussion

In this study, we investigated the relationship between the COVID-19 pandemic and the intake anxiety and depression symptoms of treatment-seeking patients on a digital mental health platform. We identified a significant and noticeable increase in anxiety symptom severity, but not in depression symptom severity. We also applied machine learning methods to a large body of treatment transcripts via NLP methods, to identify additional symptoms that were associated with mentions of COVID-19, but would have been missed by symptom measures that assess anxiety or depression alone. These additional symptoms included those that were associated with other diagnostic categories, such as acute stress, posttraumatic stress disorder, grief, obsession-compulsion disorder, insomnia, hypochondriasis, nonsuicidal self-injury, and paranoia. In some ways, a more complex symptom profile can be generated via dimensional approaches to psychopathologic nosology [20,21], which focuses more on symptoms and functions rather than diagnostic categories. Our study suggests that tracking the lasting psychological impact of COVID-19 requires measures for a variety of symptoms from several disorders. To date, survey-based studies have accounted for a mix of depression, anxiety, insomnia, and stress-related conditions [22-24]. However, these studies have not reported data on the other symptoms that we identified in this study. Constructing an appropriate measure—whether by combining self-reported ratings with clinicians' ratings or ratings from other sources, using the advantages of ecological momentary assessments, or developing other strategies for mitigating recall bias—is beyond the scope of this study. However, our study highlights that constructing appropriate measures is an important next step in applying our findings to practice.

An assessment that is composed of symptom questions that are informed by the appropriate measures could ultimately identify subpopulations of patients with different symptom profiles. This would assist with individualizing treatments and tracking heterogeneous responses to clinical interventions. For example, social isolation and loneliness are distinct risk pathways for suicide. Therefore, these risk pathways should be assessed as distinct behaviors, to inform treatment planning [25]. This is also the case for individuals with comorbid psychiatric disorders. Comorbidity is common, yet without pandemic-specific, longitudinal assessments, true comorbidity could be conflated with changing symptom constellations for the same underlying pathology. This has been exemplified in cases that demonstrate the dynamic interplay of bipolar disorder and anxiety symptoms [26]. Selecting symptom questions based on the rapid digital phenotyping methods that we implemented in this study can help reduce the burden on respondents, and provide a broader dimensional approach to monitoring psychopathology (ie, an approach that focuses on symptoms rather than diagnostic categories) [20]. Indeed, one of the goals of the National Institute of Mental Health has been to analyze disorders via a dimensional approach that does not rely on disorder categories, but instead draws on big data (ie, large clinical datasets) to increase our understanding of the underlying mechanisms of health and illness [27,28]. The data reported in this study are an important first step in the efforts for understanding symptom clusters that are associated with the pandemic, guiding the discovery of pathogenic mechanisms, and informing personalized interventions that maximize treatment benefits [29-31]. A critical next step for research is continuing to evaluate COVID-19 symptoms after vaccination and other programs begin to lower SARS-CoV-2 infection rates and reduce the threat of COVID-19. Commonly identified behaviors, such as social withdrawal, extreme anger, and COVID-19–related paranoia, may diminish after the pandemic and reflect adaptive responses to the pandemic. If, on the other hand, these symptoms persist, the possibility that other pathology mechanisms are at play increases, and further research would be warranted.

In our study, the lack of terms with the word stem "lone" may be in line with studies that have reported that loneliness is unlikely to be a major factor in COVID-19 pandemic–related psychological distress [24]. The lack of these terms also suggest that people are in fact isolated from others, given the few mentions of social topics in the text messages of patients with COVID-19–related complaints. The patients in this study may not yet think that isolation is similar to loneliness. The 18.5% (40,448/219,156) of patients who mentioned the pandemic exhibited a substantial increase in disease burden over and above that of the prestudy patient population that was already undergoing treatment. This finding corresponds with the increased number of new COVID-19 cases that was reported on the Talkspace platform. An important feature of this study is that we distinguish and quantify patients who seek care for COVID-19–related concerns, instead of patients who would have sought care without the influence of pandemic-related stressors. In this study, although anxiety symptom severity started to return to pre–COVID-19 pandemic levels between May 5, 2020 and May 30, 2020, we observed the opposite trend on early June 2020. It is thus advisable to continue focusing on patients who experience psychological symptoms and require treatment as a result of the pandemic.

Although this study offers a novel method and dataset for rapidly phenotyping COVID-19–related symptoms, it is not without limitations. First, our results may not be generalizable beyond the population of individuals who seek treatment through digital platforms. Second, our analyses relied on the longitudinal data of a convenience sample that self-reported their symptoms. We did not assess referral sources or use random assignment methods. Of particular note is the large number of women in our sample. However, this is consistent with existing data on the use of telemedicine services for routine care [32]. Despite these limitations, our results demonstrate the utility of large,

unstructured data in rapid digital phenotyping methods for identifying psychological symptoms that are associated with patients' COVID-19–related concerns, but are missed by standard depression and anxiety screening methods. The symptoms we identified in this study can be used to inform standard symptom surveys. Our study demonstrates how digital phenotyping can assist in and accelerate the development of traditional monitoring tools that do not require the use of digital therapy platforms or large amounts of textual material, avoid the potential for unwanted monitoring among technology users, and ensure that monitoring is an overt process (ie, people who are monitored are aware of being monitored).

Conflicts of Interest

TDH, JL, and NB are employees of Talkspace. AND and MSM declare no conflicts of interest.

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Abbreviations

GAD-7: 7-item Generalized Anxiety Disorder questionnaire
ICD-10: International Classification of Diseases, Tenth Revision
NLP: natural language processing
TF-IDF: term frequency-inverse document frequency

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Original Paper

Recruitment of Participants for a 3D Virtual Supermarket: Cross-sectional Observational Study

Jody C Hoenink[1], BSc, MSc; Joreintje D Mackenbach[1], BSc, MSc, PhD; Laura Nynke van der Laan[2], BSc, MSc, PhD; Jeroen Lakerveld[1], BSc, MSc, PhD; Wilma Waterlander[3], BSc, MSc, PhD; Joline W J Beulens[1,4], BSc, MSc, PhD

[1]Department of Epidemiology and Data Science, Amsterdam UMC, Vrije Universiteit Amsterdam, Amsterdam Public Health Research Institute, Amsterdam, Netherlands

[2]Department of Communication and Cognition, Tilburg School of Humanities and Digital Sciences, Tilburg University, Tilburg, Netherlands

[3]Department of Public Health, Amsterdam UMC, University of Amsterdam, Amsterdam Public Health Research Institute, Amsterdam, Netherlands

[4]Julius Center for Health Sciences and Primary Care, University Medical Center Utrecht, Utrecht University, Utrecht, Netherlands

Corresponding Author:
Jody C Hoenink, BSc, MSc
Department of Epidemiology and Data Science
Amsterdam UMC, Vrije Universiteit Amsterdam
Amsterdam Public Health Research Institute
De Boelelaan 1117
Amsterdam
Netherlands
Phone: 31 204449681
Email: j.c.hoenink@amsterdamumc.nl

Abstract

Background: Virtual supermarkets offer a practical and affordable setting to test the efficacy of different pricing and nudging strategies before they are implemented in the real world. Despite the advantages of using virtual supermarkets for this purpose, conducting studies in online settings is challenging with regard to recruitment and retention of sufficient and suitable participants.

Objective: To describe cost, time, and retention with regard to participants recruited using various strategies and potential sociodemographic differences between participants recruited via different strategies.

Methods: This cross-sectional study used data from a randomized controlled trial in which 455 Dutch adults with low and high educational levels were invited to shop 5 times in a 3D virtual supermarket. Participants were recruited via social media and flyers. A log that tracked the costs of and time spent on the different recruitment strategies was kept by the study team. Outcome measures included the cost of recruitment strategies, the time investment by researchers, and recruitment and attrition rates of participants in the study.

Results: The median age of study completers was 31.0 (IQR 25.0) and 157 out of 346 study completers (45.4%) were highly educated. Out of the 455 included participants, 235 (51.6%) were recruited via social media campaigns, 131 (28.8%) via home-delivered flyers, 38 (8.4%) via flyers directly distributed by the study team, and 46 (10.1%) via word-of-mouth. Of all paid recruitment strategies, social media campaigns were the cheapest and least time-consuming, whereas the distribution of flyers by the study team was the most expensive and time-consuming recruitment strategy. Age, sex, overweight status, employment situation, and number of adults within the household varied by recruitment strategy.

Conclusions: Using different recruitment strategies resulted in the efficient recruitment of a representative study sample and retention of participants was relatively high. While “word-of-mouth” was the most cost- and time-effective recruitment strategy, using only one type of recruitment strategy could result in a demographically skewed study population.

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KEYWORDS

online study; nudges; pricing; recruitment strategies

Introduction

Supermarkets are an important point-of-purchase setting [1] particularly applicable in studies targeting diet as a risk factor for noncommunicable diseases. Examples of promising strategies to improve population diets in supermarket settings include pricing and nudging strategies. Studies have shown that pricing (eg, price promotions on healthier products) and nudging (eg, prominent placement of healthier products) strategies can be effective in increasing purchases of healthy foods [2-5]. While pricing strategies can be seen as "harder" approaches, nudges can be seen as "softer," as nudges are less intrusive and simply alter the choice environment to make the healthy choice the easier choice, without removing the unhealthy choice [3]. Despite their promise, investigating the effectiveness of pricing (especially increasing the price of unhealthy foods) and nudging strategies in real supermarkets is costly (eg, purchases of materials or compensation of the supermarket for loss of revenue) and time consuming for researchers (eg, recruitment of participants, collecting receipts, imputing purchasing data).

Virtual supermarket environments may offer a practical and affordable means of testing the efficacy of different pricing and nudging strategies *before* they are implemented in real-world settings. Virtual supermarket environments include online web shops for grocery shopping and 3D virtual supermarkets. The 3D virtual supermarket imitates a real-life supermarket by duplicating the layout and using 3D products. Once a virtual supermarket is constructed, researchers can easily manipulate the supermarket environment by adjusting prices, and adding nudges such as posters or frames around products. A number of 3D virtual supermarkets have been developed to date [6-9]. Overall, previous studies of 3D virtual supermarkets have indicated that they are a valid tool for investigating the effect of pricing strategies on food purchases [6], also when compared to real-life purchases [8]. As such, 3D virtual supermarkets appear to be a valid alternative to real-world supermarkets as an environment in which the efficacy of nudging and pricing strategies can be studied.

Recruitment of a sufficiently large sample that adequately represents the target population can be difficult [10]. Reporting on the effectiveness of recruitment strategies facilitates improvements in the design and methods of future studies. The effectiveness of recruitment strategies depends on several factors including the study design, setting, study population, and the use of incentives [11]. Despite the advantages of 3D virtual supermarkets, it may be more difficult to recruit participants for online studies compared to interventions in real-world settings, as participants need to be adept at using technology and need to have access to a smartphone or computer with internet access [12,13]. Difficulty with recruitment can lead to longer recruitment times, increased use of resources, and reduced sample size and power. Additionally, it may be more difficult to retain participants as compared to studies in real-world settings due to the lack of personal contact [11,13] for example, which may lead to selection bias and loss of statistical power [12]. Furthermore, particularly when using a within-subject study design where participants are asked to conduct multiple rounds of shopping over a specified period, long waits between these shopping trips might lead to diminished interest, as the novelty of the online intervention decreases, and increased frustration, resulting in additional attrition. While some degree of attrition is largely inevitable, excessive attrition reduces statistical power, increases bias, and leads to lower generalizability of results [13].

Evidence suggests that most intervention studies, that is, experimental studies online or in the real world in which investigators assign the exposure(s) to participants, use print advertising such as flyers, posters, and newspaper advertisements to recruit potential participants [14,15]. Challenges related to the recruitment and retention of participants in online studies have led to the use of alternative recruitment strategies that rely on internet advertising and social media [13]. These innovative recruitment strategies are attractive due to their potential to reach a larger number of people, apparent cost-effectiveness, and ability to reach populations that are considered hard-to-reach (eg, young adults and adults with a lower educational level) [13,15]. Despite the growing popularity of recruitment via social media, data on the effectiveness of this strategy in the context of online studies are limited [15].

Online studies have reported on the use of several recruitment strategies [6,11]. However, as far as we are aware, no studies investigating the effectiveness of social media as a recruitment strategy have been conducted in the Netherlands to date [13]. The aim of this study was to describe cost, time, and retention rates with regard to different recruitment strategies (including innovative and traditional recruitment strategies), and the sociodemographic characteristics of participants recruited via these different strategies.

Methods

Study Overview

This study is part of the "Sustainable Prevention of Cardiometabolic Risk through Nudging Health Behaviors" (Supreme Nudge) project [16]. Data presented in this paper describe the cost, time, and retention rates associated with different recruitment strategies from a larger study investigating the efficacy of nudging and pricing strategies on food purchasing behavior in a virtual supermarket and effect modification by socioeconomic position (SEP). Results of this trial are reported elsewhere [17] and additional details about the study aims and design are presented in Multimedia Appendix 1. The study design and procedures for this virtual supermarket study were approved by the Medical Ethics Review Committee of VU University Medical Centre (OHRP: IRB00002911), and all participants provided informed consent.

Inclusion Criteria

Inclusion criteria were that participants had to be 18 years or older, were able to communicate in Dutch, had access to a computer with internet, had a valid email address, and regularly did the grocery shopping for their household. This study aimed to include an approximately equal number of lower and higher SEP adults determined using the proxy educational level. Given the known difficulties associated with recruiting low SEP

individuals combined with the fact that only approximately 28% of the Dutch population is considered to have a low educational level [18], we included individuals with both low and medium educational level in the lower SEP group. Adults were considered low or medium SEP if their highest obtained educational level was primary education, intermediate vocational education, or higher secondary education. As shopping was done for the household, only 1 person per household was allowed to participate.

Recruitment of Participants

According to the sample size calculation, at least 300 participants were needed to find a statistically significant difference in one of the main outcomes of the trial (vegetable purchases) between the control condition and experimental conditions (not yet accounting for possible attrition). Details regarding the sample size calculation can be found in Multimedia Appendix 1. Both traditional and more novel recruitment strategies were used to recruit participants. The traditional recruitment methods included advertising via flyers. The more novel recruitment strategy included using social media advertising, which has become an increasingly popular approach [11]. Flyers were distributed directly to participants on the street, at local events, and in real-world supermarkets. The flyers contained information on the inclusion criteria, activities within the study, and the reward for completing the study (a guaranteed incentive of €25 [~US $30]). Distribution of the flyers took place in October 2018. Flyers were also distributed around the University campus in October 2018. Approximately 500 flyers were printed at €0.35 (US $0.42) per flyer. Flyers were also delivered to addresses in low-income neighborhoods via postal services and by the study team. Low-income neighborhoods (ie, those with an average household income per resident under the median Dutch household income) were selected in order to increase participation rates of lower SEP individuals [19,20]. The social media campaign consisted of pay-per-click Facebook and Instagram campaigns and ran from mid-September to mid-December 2018. A professional was hired to set up the Facebook and Instagram campaigns. Campaigns were separated for low and high SEP target groups. Using existing and nondisclosed Facebook algorithms, the campaigns were adapted automatically based on what worked best for each target group. The target groups of the 2 Facebook campaigns were adjusted according to the characteristics of participants included in the study at a particular point in time. For example, if too few men had been recruited for the study after a few weeks, the Facebook campaign was adjusted to only include men in order to increase the recruitment of men. In addition, a Twitter post was created using the Supreme Nudge account (with over 250 followers at that time). Participants recruited from Facebook, Instagram, and Twitter were considered to be recruited using "social media strategies." Although the researchers did not actively encourage participants to recruit others (eg, there was no incentive for participants to recruit others for the study), participants were also recruited by word-of-mouth at no cost to the researchers. A log to track the costs of the different recruitment strategies was kept by the study team. Furthermore, a log tracking the development of recruitment material (eg, posters and Facebook campaign) by the researchers and the distribution of posters by the researchers was kept. We intended to recruit participants between September and December 2018. If insufficient participants completed the study within this period (N≤300), recruitment would have continued in January 2019.

Study Procedure

The social media campaigns and the study flyers directed potential participants to a registration website where more information about the study was provided and visitors could be redirected to a Survalyzer questionnaire for informed consent by entering their email address. Potential participants received an email with a link to the baseline questionnaire, which included questions regarding their sociodemographic characteristics and shopping habits. Inclusion criteria were assessed using the baseline questionnaire. If participants met the inclusion criteria, they received a link to the virtual supermarket and were asked to download the virtual supermarket to their computer and conduct a trial shop in which they needed to find 5 specific products from a grocery shopping list. Participants that successfully retrieved at least four out of five products were included in the study (Multimedia Appendix 1). Participants were then asked to shop 5 times in the virtual supermarket over the course of 5 consecutive weeks. During the first virtual shopping trip, participants were asked the following: "Imagine that you only have herbs at home and you decide to do the shopping for the entire household (people for whom you normally do the grocery shopping for) for one week. You receive a budget from us. You buy all your daily meals, snacks and drinks for the entire week (toiletries and alcohol are not for sale in this supermarket). The budget is only a guideline; it is possible to spend a little less or a little more." For the subsequent 4 shopping trips, this prompt was updated to include the information that their usual supermarket was now closed and, as such, that they had to do their shopping in a new supermarket. Participants received guaranteed incentives for completing weekly shops: after participants completed their first shopping trip, they received a €5 (~US $6.05) gift voucher and after completing all 5 rounds, participants received an additional €20 (~US $24) gift voucher.

Participant Characteristics

When assessing the eligibility of participants through a questionnaire, participants also answered questions regarding their age (years), sex (male or female), height (meters), weight (kilograms), household size (number of children and adults in the household), household net monthly income (ranging from <€1700 [~US $1815] to >€5000 [~US $6053]), highest educational level attained (primary school, secondary school, vocational education, or higher education), employment status (full-time employed, part-time employed, housewife/man, receiving benefits, retired, student, and other), responsibility for household shopping (fully responsible, mostly responsible, partly responsible, and someone else is responsible), frequency of household shopping (less than once a week, once a week, twice a week, three times a week, and more often), weekly budget for food shopping (<€25 [~US $30], €26-€50 [~US $31-US $61], €51-€100 [~US $62-US $121], €101-€150 [~US $122-US $182], €201-€250 [~US $243-US $303], €251-€300 [~US $303-US $363], and >€300 [>US $363]), and location of

usual food shopping (at the market, in the supermarket, in small local shops, in organic food shops and other). After completing the final round of shopping, participants were also asked 8 questions regarding their experience of the virtual supermarket. Examples of prompts were "The program was easy to understand" and "The products I purchased in the virtual supermarket resemble my regular food purchases." These items have been used in previous studies to assess participants' experience of other virtual supermarkets [6,7]. Answering options were 5-point Likert scales ranging from "strongly disagree" to "strongly agree." Results regarding participants' experience of the virtual supermarket is presented in Multimedia Appendix 2.

Outcome Measures

We collected data on participant characteristics and recruitment method to describe the type of participants that were recruited and retained using the different recruitment strategies. Furthermore, data on the costs associated with the different recruitment strategies were collected.

Analyses

Overall Recruitment and Retention of Participants

We report descriptive statistics on the overall number of participants recruited and retained using the different recruitment strategies.

Recruitment Cost, Time, and Retention Rates According to Recruitment Strategy

Descriptive statistics on the number of participants recruited and retained using the different recruitment strategies and the costs associated with these strategies are reported. The cost per recruitment strategy was calculated by dividing the total amount spent on a recruitment strategy by the number of participants recruited via the corresponding strategy. This was also done for the time researchers spent on each recruitment strategy.

Participant Characteristics

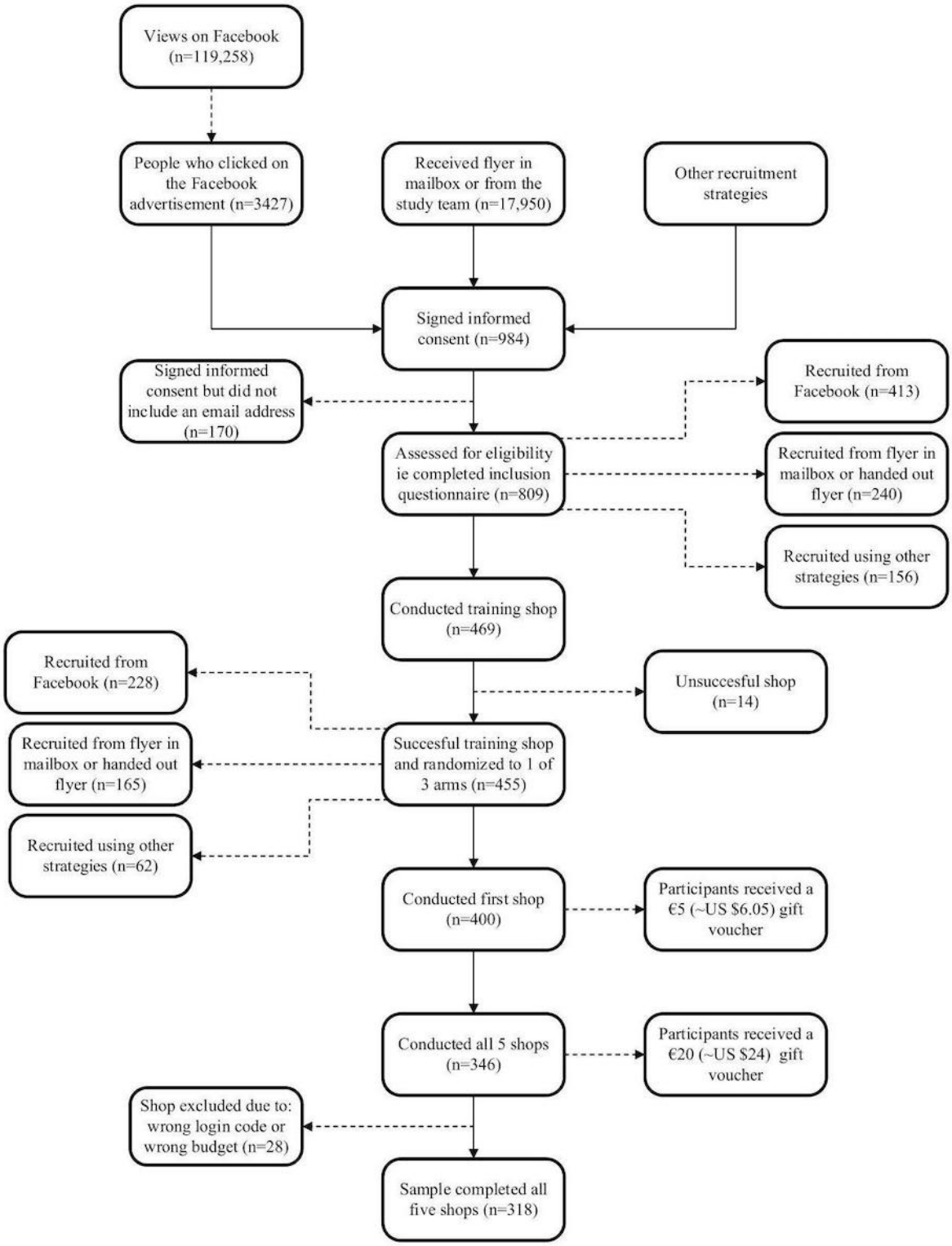
Differences in participant characteristics between those who signed up for the study and met the inclusion criteria, participants that successfully conducted a training shop, participants that completed the study (ie, carried out all 5 rounds of shopping), and study noncompleters were inspected visually and formally tested. Differences between completers and noncompleters and differences in population characteristics between the different recruitment strategies were assessed using a one-way ANOVA for continuous outcome variables (ie, BMI and age) and the Pearson chi-square test in the case of categorical outcome variables (eg, educational level and income). Non-normally distributed continuous outcome variables were log transformed. Analyses were conducted in STATA version 14.1 (StataCorp) and a *P*-value of .05 was used to indicate statistical significance.

Results

Overall Recruitment and Retention of Participants

Participants were recruited between September and December 2018. Figure 1 shows the flow of participants over the trial period. Regarding the recruitment campaigns, 3427 people clicked on the advertisement and were directed to the registration website. Initially, the campaign was much more likely to reach women (often aged 45 and older), after which the campaign was adapted to reach more men. This resulted in the campaign mostly reaching men under the age of 25. Around 17,500 people received a study flyer in their mailbox and 450 people received a study flyer directly from the study team. After being recruited by the different strategies and registering via the website, 809 people provided informed consent and were eligible for participation. Of those, 455 successfully conducted the training shop and were included in the study. A total of 346 participants completed the study and 318 participants generated usable data for all 5 rounds of shopping (ie, generated data that could be linked back to the participant and in which the login code corresponded to the participants' assigned budget). Of all participants who successfully conducted the training shop, 76.0% (346/455) completed the study.

Figure 1. Flow chart of participant recruitment and retention.



Recruitment Cost, Time, and Retention Rates According to Recruitment Strategy

In Table 1, the costs of various recruitment strategies and the number of participants recruited using the different recruitment strategies are displayed. Over half (n=426) of the 809 adults who signed up for the study were recruited using the social media campaigns (mostly Facebook) and 29.7% (n=240) were recruited using flyers distributed to home addresses. Social media campaigns resulted in the highest absolute registration, inclusion in the study, and study completion. Distribution of flyers by the research team was the most expensive strategy, while the social media campaigns were the least expensive paid strategy in terms of the cost per person after completion of the study. Regarding the Facebook campaign, the cost per click was estimated to be €0.14 (US $0.17). The unpaid recruitment strategy "word-of-mouth" required no time investment by the research team and involved no recruitment costs. Regarding

paid recruitment strategies, social media campaigns were the most time-efficient and flyers distributed directly by the study team were the least time-efficient for the researchers (8 minutes per study completer compared to 100 minutes per study completer, respectively). While the costs of flyers distributed by the team were similar to flyers distributed to home addresses (ie, €21 [US $25.52] and €20 [US $24.21], respectively), the time investment for flyers distributed directly by the study team was much higher compared to flyers distributed to home addresses (ie, 100 minutes and 25 minutes, respectively). The highest study completion rate was achieved with the "word-of-mouth" recruitment strategy (from 6.8% [55/809] of registered participants to 11.6% [40/346] of study completers). These results are also confirmed when calculating the percentage of participants that were included and completed the study compared to those that registered for each recruitment strategy (Table 2). In total, 72.7% (40/55) of participants recruited via word-of-mouth completed the study, compared to 39.9% (170/426), 44.2% (106/240), 54% (27/50), and 3.4% (3/38) of participants recruited via social media campaigns, flyers distributed to home addresses, flyers distributed directly by the study team, and unknown recruitment strategies, respectively (Table 2).

Table 1. The cost, time, and percentage of participants in each recruitment strategy during three phases of the study.

Recruitment type	Cost (€[a])	Time (min)	Registered			Included			Completed		
			n (%) (N=809)	Cost (€) per participant	Time (min) per participant	n (%) (N=455)	Cost (€) per participant	Time (min) per participant	n (%) (N=346)	Cost (€) per participant	Time (min) per participant
Social media campaigns	1.298	1440	426 (52.7)	3	3	235 (51.6)	6	6	170 (49.1)	8	8
Flyers distributed to home addresses	2.142	2700	240 (29.7)	9	11	131 (28.8)	16	21	106 (30.6)	20	25
Flyers distributed directly by the team	0.558	3000	50 (6.2)	11	60	38 (8.4)	16	71	27 (7.8)	21	100
Word-of-mouth	0	0	55 (6.8)	0	0	46 (10.1)	0	0	40 (11.6)	0	0
Unknown	N/A[b]	N/A	38 (4.7)	N/A	N/A	5 (1.1)	N/A	N/A	3 (0.9)	N/A	N/A

[a]€1 = Approximately US $1.2.

[b]N/A: not applicable.

Table 2. The percentage of participants that were included in the study and completed the study compared to those that registered in each recruitment strategy.

Recruitment type	Registered, N	Included, n (%)	Completed, n (%)
Social media campaigns	426	235 (55.2)	170 (39.9)
Flyers distributed to home addresses	240	131 (54.6)	106 (44.2)
Flyers distributed directly by the team	50	38 (76.0)	27 (54.0)
Word-of-mouth	55	46 (83.6)	40 (72.7)
Unknown	38	5 (13.2)	3 (7.9)

Participant Characteristics

Characteristics of participants who signed up for the study and met the inclusion criteria, participants that successfully conducted a training shop, participants that completed the study (ie, carried out all 5 rounds of shopping), and study noncompleters are presented in Table 3. The median age of participants included in the study was 31 (SD 25.0) and the majority of participants were female. Most participants included in the study had a medium educational level and a monthly household net income below €1700 (~US $2057). Study completers were somewhat younger than study noncompleters (median age of 31.0 compared to 37.0, respectively), but this difference was not statistically significant (P=.21). Study noncompleters were statistically significantly more often overweight (P=.01) and had older computers (P≤.001) compared to study completers. No other large observable differences in participant characteristics were found between study completers and noncompleters. For study completers, the average time in days between participants' first shop and last shop was 38.1 (SD 13.1).

Participant characteristics by recruitment strategy can be found in Table 4. The participant characteristics age, overweight status, employment situation, and the percentage of households with at least two adults differed statistically significantly by recruitment strategy (Table 4). For example, the average age of participants recruited via social media was lower, and a larger proportion of overweight or obese participants were recruited via flyers distributed to home addresses.

Table 3. Characteristics of the study population who completed and did not complete the study.

Characteristics	Total sample (N=809)	Sample included (N=455)	Completers (N=346)	Noncompleters (N=463)	*P* value
Median (IQR) age, years	35.0 (27.0)	31.0 (25.0)	31.0 (24.0)	37.0 (30.0)	.21
Female sex, n (%)	515 (63.7)	284 (62.4)	215 (62.1)	299 (64.6)	.53
Mean (SD) BMI[a]	25.3 (5.3)	24.9 (4.8)	24.9 (4.9)	25.6 (5.5)	.05
Overweight status, n (%): overweight or obese[a,b]	348 (43.8)	176 (39.9)	129 (38.9)	219 (48.8)	.01
Educational level[c], n (%)					.07
Low educational level	90 (11.1)	43 (9.5)	31 (9.0)	59 (12.7)	
Medium educational level	379 (46.8)	212 (46.6)	158 (45.7)	221 (47.7)	
High educational level	337 (41.7)	200 (44.0)	157 (45.4)	180 (38.9)	
Monthly household net income[d], n (%)					.32
€0-€1700[e]	306 (38.3)	172 (38.6)	123 (36.5)	183 (40.3)	
€1701-€2500	195 (24.4)	105 (23.5)	81 (24.0)	114 (25.1)	
€2501-€3500	140 (17.5)	84 (18.8)	69 (20.5)	71 (15.6)	
More than €3501	159 (19.9)	90 (20.2)	70 (20.8)	89 (19.6)	
Employment situation, n (%)					.12
Full time job	183 (22.6)	108 (23.7)	90 (26.0)	93 (20.5)	
Part time job	206 (25.5)	112 (24.6)	84 (24.3)	122 (26.9)	
Student	187 (23.1)	118 (25.9)	85 (24.6)	78 (17.2)	
Unemployed[f]	204 (25.2)	101 (22.2)	78 (22.5)	126 (27.8)	
Entrepreneur or other	29 (3.6)	16 (3.5)	9 (2.6)	20 (4.4)	
Household composition, n (%)					
At least two adults	547 (67.6)	312 (68.6)	243 (70.2)	314 (69.2)	.40
At least one child	263 (32.5)	141 (31.0)	109 (31.5)	154 (33.9)	.60
Type of computer, n (%)					.56
Apple-based	106 (13.1)	54 (11.9)	44 (12.7)	62 (13.7)	
Windows-based	495 (61.2)	293 (64.4)	213 (61.6)	291 (64.1)	
Other or unknown	93 (11.5)	42 (9.2)	33 (9.5)	51 (11.2)	
Two or more computers/laptops	115 (14.2)	66 (14.5)	56 (16.2)	59 (13.0)	
Computer age in years, n (%)					<.001
Less than 3 years	411 (50.8)	245 (53.8)	183 (52.9)	228 (49.2)	
Between 3 and 6 years	310 (38.3)	175 (38.5)	140 (40.5)	170 (36.7)	
Older than 6 years	70 (8.7)	30 (6.6)	20 (5.8)	50 (10.8)	
Unknown	18 (2.2)	5 (1.1)	3 (0.9)	15 (3.2)	

[a]14 missing values.

[b]Participants with a BMI higher than 25.0 were considered overweight or obese.

[c]Low educational level included participants with primary education, medium educational level included participants with lower or higher secondary education and high educational level included participants with tertiary education.

[d]Nine missing values.

[e]€1 = Approximately US $1.2.

[f]Includes those who are retired, unemployed, unable to work and/or receiving social benefits and housewives/husbands.

Table 4. Characteristics of the study population for the entire sample and stratified by recruitment strategy.[a]

Characteristics	Total sample (N=455)	Social media (N=235)	Flyers to home addresses (N=131)	Flyers from study team (N=38)	Word-of-mouth (N=46)	*P* value
Median (IQR) age, years	31.0 (25.0)	25.0 (18.0)	46.0 (26.0)	39.0 (25.0)	27.0 (25.0)	.02
Female sex, n (%)	284 (62.4)	131 (55.7)	92 (70.2)	26 (68.4)	32 (69.6)	.03
Mean (SD) BMI[b]	24.9 (4.8)	24.7 (4.9)	25.4 (4.4)	24.7 (5.4)	24.3 (5.4)	.63
Overweight status: overweight or obese status[b,c], n (%)	176 (39.5)	87 (38.5)	65 (50.0)	10 (27.0)	11 (24.4)	.01
Educational level[d], n (%)						.22
Low educational level	43 (9.5)	19 (8.1)	19 (14.5)	1 (2.6)	3 (6.5)	
Medium educational level	212 (46.6)	111 (47.2)	63 (48.1)	16 (42.1)	22 (47.8)	
High educational level	200 (44.0)	105 (44.7)	49 (37.4)	21 (55.3)	21 (45.7)	
Monthly household net income[e], n (%)						.34
€0-€1700[f]	172 (38.1)	100 (42.7)	38 (29.0)	15 (39.5)	17 (37.0)	
€1701-€2500	105 (23.3)	45 (19.5)	39 (29.8)	11 (28.9)	8 (17.4)	
€2501-€3500	84 (18.6)	41 (17.7)	26 (19.8)	5 (13.2)	11 (23.9)	
More than €3501	90 (20.0)	45 (19.5)	28 (21.4)	7 (18.4)	10 (21.7)	
Employment situation, n (%)						.02
Full-time job	108 (23.7)	50 (21.3)	35 (26.7)	9 (23.7)	13 (28.3)	
Part-time job	112 (24.6)	48 (20.4)	31 (23.7)	14 (36.8)	18 (39.1)	
Student	118 (25.9)	89 (37.9)	9 (6.9)	6 (15.8)	13 (28.3)	
Unemployed[g]	101 (22.2)	42 (17.9)	50 (38.2)	5 (13.2)	2 (4.3)	
Entrepreneur or other	16 (3.5)	6 (2.6)	6 (4.6)	4 (10.5)	0 (0.0)	
Household composition, n (%)						
At least two adults	312 (68.6)	152 (64.7)	97 (74.0)	22 (57.9)	38 (82.6)	.01
At least one child	141 (31.0)	74 (31.5)	43 (32.8)	12 (31.6)	12 (26.1)	.93

[a]Unknown recruitment strategy was not included in the analyses.

[b]Nine missing values; 6 missing values for social media and 1 missing value for the other strategies.

[c]Participants with a BMI higher than 25.0 were considered overweight or obese.

[d]Low educational level included participants with primary education, medium educational level included participants with lower or higher secondary education and high educational level included participants with tertiary education.

[e]Four missing values for social media.

[f]€1 = Approximately US $1.2.

[g]Includes those who are retired, unemployed, unable to work and/or receiving social benefits and housewives/husbands.

Discussion

Principal Findings

This study found that the recruitment strategy word-of-mouth involved zero costs, required no time effort on the part of the researchers, and yielded the highest study-completion rate. Of all paid recruitment strategies, the least expensive strategy was social media campaigns. Social media campaigns also yielded the highest absolute registration and completion rates. Sociodemographic characteristics such as age, sex, and overweight status varied with the recruitment strategy.

Effective recruitment approaches are those that lead to the creation of a representative and large enough sample of study participants [21]. The combination of different recruitment strategies resulted in the recruitment of a relatively diverse study population in the space of 3 months. Social media campaigns were the most cost-efficient paid recruitment strategy employed and word-of-mouth was free, required no time effort on the part of researchers, and yielded in the highest retention rates. These results are comparable to previous studies carried out among the general population that report on the effectiveness and costs of recruitment via social media campaigns and other more traditional recruitment strategies [11,15,22]. For example, a study by Frandsen et al [15] found that social media drew more

interest and was more cost effective than traditional methods such as flyering at baseline. Also, a systematic review investigating the effectiveness of Facebook as a recruitment strategy found reduced costs, shorter recruitment periods, better representation, and improved participant selection compared to traditional recruitment methods [22]. Surprisingly, a comparable study investigating the effectiveness of online methods to recruit participants for a virtual supermarket study found Facebook advertisements to be less successful as a recruitment strategy than was anticipated [6]. The use of a guaranteed incentive in this study and other studies that have successfully used Facebook to recruit participants (eg, [13]) may provide an explanation for the difference in findings between this study and the aforementioned study. A guaranteed incentive is likely to attract more people than no incentive or a prize lottery, for example. Future studies investigating the efficacy of social media campaigns for the recruitment of participants could investigate the role of incentives alongside this strategy.

Participants recruited via social media were less likely to complete the study compared to those recruited by flyers and word-of-mouth. In this study, word-of-mouth was found to be surprisingly effective; 10.1% (46/455) of the study population was recruited via word-of-mouth without the researchers actively encouraging participants to recruit peers. A disadvantage associated with recruitment via word-of-mouth, or via the exclusive use of a single recruitment strategy in general, is that it may yield a demographically skewed study population [15]. Contrary to the previous research finding that only age varied by recruitment strategy [11], we found that other demographic variables such as household composition, overweight status, sex, age, and employment situation all varied by recruitment strategy. Overall, our results suggest that it is important to use several different recruitment strategies if the aim is to include a diverse population (eg, younger and older adults with low and high SEP) in a study. Similarly, a systematic review investigating strategies for the successful recruitment of young adults to healthy lifestyle programs found that single recruitment strategies are less effective than mixed strategies, as fewer participants were recruited and higher attrition rates were reported when using a single recruitment strategy exclusively [14]. Nevertheless, despite using several recruitment strategies and targeting the social media campaigns to people with specific characteristics (eg, SEP, age, and sex), the recruitment strategies did not result in a sample that perfectly represented the target population. Instead, the study included a slightly younger population with more females and more highly educated participants. Differences in sociodemographic characteristics between this study sample and the average Dutch population may have been caused by the inclusion criteria of the study such as being the primary shopper for the household (leading to inclusion of more female participants) and the type of recruitment strategy used (eg, younger people may be more likely to be recruited via Facebook).

The current study results also suggest that recruitment strategies directly involving people (ie, active recruitment strategies using word-of-mouth or flyers distributed by the study team) lead to higher retention rates compared to recruitment strategies that do not involve personal contact (ie, passive recruitment strategies using social media campaigns and flyers distributed to homes). By contrast, the reach of social media campaigns and flyers sent to homes was much larger compared to the other recruitment strategies used. Moreover, social media campaigns can be used to target certain groups that are underrepresented in the study sample [22]. As such, neither active nor passive recruitment strategies are necessarily superior to the other [14]. Rather, it appears to be important to use a combination of *both* strategies, as active recruitment methods enhance recruitment and retention rates, but also require the most resources. However, despite the higher attrition rates associated with recruitment by means of passive strategies, these strategies do seem to have a wider reach and require only limited resources (especially when using social media) as compared to active recruitment strategies.

Strengths and limitations

A strength of this study is the use of different recruitment strategies (eg, Facebook and flyers), which led to the creation of a diverse study population in a relatively short period. Furthermore, a relatively high completion rate of 76.0% (346/455) was found; this is particularly interesting in light of the fact that participants were asked to conduct 5 rounds of shopping over the course of 5 consecutive weeks. A limitation of this study is the limited generalizability of the results. While this study successfully recruited a relatively representative sample using traditional and novel recruitment strategies within the specified timeframe, the same might not apply to different studies in different settings. For example, we do not know whether our recruitment efforts were successful because of the methods used, because of the type of study (virtual supermarket study) that participants signed up for, or because of the guaranteed incentive of €25 (US $30). Another limitation of this study is that the study population was self-selecting, which could have led to the creation of a nonrepresentative study population (eg, due to the inclusion of more highly motivated adults). This type of bias may be inherent to this type of research in a community-based setting in which participants, by definition, need to sign up for a study themselves rather than be recruited by a physician, for example. This self-selection bias could, for example, be quantified by comparing the sociodemographic characteristics of the study sample with the sociodemographic characteristics of adults who received the study flyers.

Conclusion

Regarding paid recruitment strategies, social media campaigns, particularly via Facebook, were more cost-effective than other more traditional methods. The unpaid recruitment strategy "word-of-mouth" yielded the highest study completion rate and required the least amount of time and effort on the part of the researchers. Employing only 1 recruitment strategy may lead to the creation of a demographically skewed sample.

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Authors' Contributions

JH, JM, JL, WW, and JB helped design the study. NvdL constructed the virtual supermarket software. JH conducted analyses and interpreted the results. JH and JM drafted the paper. All authors reviewed and edited the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Details regarding the SN VirtuMart trial.
[DOCX File , 23 KB - formative_v5i2e19234_app1.docx]

Multimedia Appendix 2
Participant experience of the SN VirtuMart trial.
[DOCX File , 18 KB - formative_v5i2e19234_app2.docx]

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Abbreviations

SEP: socioeconomic position

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Original Paper

Development and Feasibility of a Digital Acceptance and Commitment Therapy–Based Intervention for Generalized Anxiety Disorder: Pilot Acceptability Study

Nicola R Hemmings[1,2], BSc, MSc; Jamie M Kawadler[2], BA, MSc, PhD; Rachel Whatmough[3,4], BSc, DClinPsy; Sonia Ponzo[2], BSc, MSc, PhD; Alessio Rossi[5], BSc, MD, PhD; Davide Morelli[2,6], BSc, MSc, PhD, DPhil; Geoffrey Bird[2,7,8], BSc, MA, PhD; David Plans[2,7,9], BA, MSc, PhD

[1]Department of Organizational Psychology, Birkbeck University of London, London, United Kingdom

[2]BioBeats Group Ltd, London, United Kingdom

[3]Work With Wellbeing, London, United Kingdom

[4]Salomons Institute for Applied Psychology, Canterbury Christ Church University, Kent, United Kingdom

[5]Department of Computer Science, University of Pisa, Pisa, Italy

[6]Department of Engineering Science, Institute of Biomedical Engineering, University of Oxford, Oxford, United Kingdom

[7]Department of Experimental Psychology, University of Oxford, Oxford, United Kingdom

[8]Social, Genetic and Developmental Psychiatry Centre, Institute of Psychiatry, Psychology and Neuroscience, King's College London, London, United Kingdom

[9]Initiative in the Digital Economy, Department of Science, Innovation, Technology, and Entrepreneurship, University of Exeter, Exeter, United Kingdom

Corresponding Author:
Nicola R Hemmings, BSc, MSc
Department of Organizational Psychology
Birkbeck University of London
Malet St
London, WC1E 7HX
United Kingdom
Phone: 44 7716362200
Email: nhemmi01@mail.bbk.ac.uk

Abstract

Background: Generalized anxiety disorder (GAD) is characterized by excessive worry that is difficult to control and has high comorbidity with mood disorders including depression. Individuals experience long wait times for diagnosis and often face accessibility barriers to treatment. There is a need for a digital solution that is accessible and acceptable to those with GAD.

Objective: This paper aims to describe the development of a digital intervention prototype of acceptance and commitment therapy (ACT) for GAD that sits within an existing well-being app platform, BioBase. A pilot feasibility study evaluating acceptability and usability is conducted in a sample of adults with a diagnosis of GAD, self-referred to the study.

Methods: Phase 1 applied the person-based approach (creation of guiding principles, intervention design objectives, and the key intervention features). In Phase 2 participants received the app-based therapeutic and paired wearable for 2 weeks. Self-report questionnaires were obtained at baseline and posttreatment. The primary outcome was psychological flexibility (Acceptance and Action Questionnaire-II [AAQ-II]) as this is the aim of ACT. Mental well-being (Warwick-Edinburgh Mental Well-being Scale [WEMWBS]) and symptoms of anxiety (7-item Generalized Anxiety Disorder Assessment [GAD-7]) and depression (9-item Patient Health Questionnaire [PHQ-9]) were also assessed. Posttreatment usability was assessed via self-report measures (System Usability Scale [SUS]) in addition to interviews that further explored feasibility of the digital intervention in this sample.

Results: The app-based therapeutic was well received. Of 13 participants, 10 (77%) completed the treatment. Results show a high usability rating (83.5). Participants found the digital intervention to be relevant, useful, and helpful in managing their anxiety. Participants had lower anxiety (d=0.69) and depression (d=0.84) scores at exit, and these differences were significantly different from baseline (P=.03 and .008 for GAD-7 and PHQ-9, respectively). Participants had higher psychological flexibility and well-being scores at exit, although these were not significantly different from baseline (P=.11 and .55 for AAQ-II and WEMWBS, respectively).

Conclusions: This ACT prototype within BioBase is an acceptable and feasible digital intervention in reducing symptoms of anxiety and depression. This study suggests that this intervention warrants a larger feasibility study in adults with GAD.

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KEYWORDS

anxiety; depression; acceptance and commitment therapy; person-based approach; mHealth; mental health; digital; remote; smartphone; mobile phone

Introduction

Background

Generalized anxiety disorder (GAD) is diagnosed if an individual has excessive worry that is difficult to control for more days than not over a period of 6 months [1]. GAD is associated with an increased reactivity to, and avoidance of, internal experiences [2]. There is high comorbidity of GAD with other anxiety (51.7%) and mood (63%) disorders [3], especially with depression (r=.62) [4].

Just under half of individuals with GAD suffer for 2 years before correctly being diagnosed [5], and even after diagnosis, waiting times for treatment are up to 18 weeks [6].

A digital therapeutic tool has the potential to increase accessibility and availability of treatment for those suffering with GAD by reducing barriers such as waiting times before treatment [7], perceived stigma [8,9], geographical distance, financial costs, and lack of time due to, for example, work commitments or caring responsibilities [10]. Digital interventions, whether therapist-guided or self-guided, have been shown to be as effective as face-to-face interventions [11,12] when based on the same core processes of face-to-face treatment with only the mode of delivery changing [13].

Acceptance and Commitment Therapy as a Treatment for GAD

Acceptance and commitment therapy (ACT) is a form of cognitive behavioral therapy, rooted in functional contextualism [14,15] and relational frame theory [16].

ACT aims to increase psychological flexibility, or the ability to deal with challenging experiences in a flexible way while continuing to act based on one's values [17]. Psychological flexibility reduces experiential avoidance and the unwillingness to experience difficult emotions, thoughts, or sensations [17].

The aforesaid reduction of experiential avoidance and increase in psychological flexibility are achieved via 6 core processes of change that are closely interlinked. *Contact with the present moment* is the nonjudgmental present moment awareness of one's internal and external environment. *Self-as-context* is noticing that one is not just ones' thoughts, emotions, and self-image, but they are also the observer of them. *Cognitive defusion* includes techniques aiming to treat thoughts and feelings for what they are (mental imagery, streams of words, sensations), not as truths that must be reacted to or get caught up in. *Acceptance* means allowing unpleasant feelings, rather than trying to change them. *Values* are knowing what matters in life to provide meaning and direction. *Committed action* is taking targeting value-based action and doing what it takes, even when difficult [17-19].

Psychological flexibility is proposed to be a fundamental aspect of health and well-being [20]; even though ACT does not aim to specifically eliminate symptoms of anxiety, the ACT model has a transdiagnostic approach and has been consistently shown to reduce symptoms of anxiety [21] and depression [22] among other mood disorders via its 6 core processes. This effect could be due to the reduction of "experiential avoidance," a proposed concept of anxiety [2]. Experiential avoidance is the attempt to avoid or control internal experiences, rather than accepting them. This fear of losing control over one's emotional responses (in particular anxiety) is seen as the opposite of being psychologically flexible; therefore, increasing psychological flexibility can reduce experiential avoidance, and thus increase psychological flexibility.

ACT has been used in digital interventions and has shown to be an efficacious and acceptable treatment for adults with anxiety disorders [23], and there is early support for therapist-guided and self-guided digital ACT-based effectiveness reducing anxiety in populations with anxiety disorders [24-26] and the general population [27-29].

However, poor engagement rates are a well-documented and an ongoing concern in the design, development, and evaluation of digital interventions [30-34]. Self-guided interventions suffer from even greater dropout than therapist-guided interventions [35], potentially due to the increased support that these can offer [36]. However, reasons for poor engagement and dropout are not consistently reported in the literature; a systematic review from 2010 reported a wide range of adherence rates (2%-83% [37]) in 16 studies using internet-based interventions and specifically called for analysis of variables associated with dropout. Consistent reporting of these variables remains an issue in the literature [38-40]. To increase engagement, which is linked to efficacy [41], more research is needed to determine whether adopting an accepted framework, such as the person-based approach (PBA), could serve as a potential first step in designing interventions with greater engagement rates.

Person-Based Approach

The PBA is a systematic framework for designing interventions that addresses and accommodates perspectives of the people who will use them. Adopting a PBA addresses the ongoing concern of a lack of engagement in digital interventions [42,43], with the aim of increasing the likelihood of achieving the desired therapeutic outcome. It goes beyond the traditional system of collecting user feedback as it addresses a person's experience of the intended behavior change techniques [43].

The approach is conducted over 2 stages to create a persuasive, feasible, and relevant digital intervention [43]. First, the development stage creates a *persona*, a summary representation of qualitative research conducted with a wide range of people from the target user's population, showcasing a deep understanding of their psychosocial context alongside their views on the proposed intervention. The second stage identifies *guiding principles* that inform the intervention development in addressing the persona's key context-specific behavioral issues [43]. Understanding the user's views and psychosocial context enables the ability to address barriers to engagement and therefore, increase acceptability, feasibility, and efficacy of the digital intervention [44].

The PBA is a useful methodology in designing digital interventions; however, to our knowledge, there has been no published research on using the PBA for the development of a suitable self-guided digital intervention for GAD.

Aim

This paper describes the development of a digital intervention via a mobile app for GAD, based on ACT using the PBA. Furthermore, it reports the results of a pilot study evaluating the prototype digital intervention in a sample of adults with self-referred GAD. The pilot study is designed to (1) evaluate the acceptability and usability of ACT-based content in a digital format derived using the PBA, and (2) provide a possible trend of the efficacy of this intervention with respect to psychological flexibility, mental well-being, and symptoms of anxiety and depression.

Methods

Phase 1: Development

Technical Platform

The technical platform used in this study was a pre-existing multidimensional well-being app, BioBase (BioBeats Ltd). BioBase is a smartphone app that contains several features that cover the core processes of ACT (aware, open, and active).

The ACT-based modules that provided psychoeducational information and activities on the core processes were shown via an in-app course named "Find Your Way." The course was complemented by in-app BioBase tools (screenshots can be found in Multimedia Appendix 1).

To support the ACT pillars of "Aware," "Open," and "Active," mood tracking is available through an Ecological Momentary Assessment (EMA; [45]), which allows individuals to increase their awareness of their emotional state by choosing a mood from a list of options and specify any ecological component surrounding the moment they chose to declare their mood (ie, where they were, whether they were alone or with somebody, and what activities they were engaged in). EMAs have been shown to be a valuable mood-tracking tool in the context of digital therapeutics aiming to reduce levels of anxiety and depression [46].

In addition to the mood tracking tool, an in-the-moment breathing exercise for stress reduction and a mindfulness-based progressive relaxation tool (Body Scan) were used to reduce symptoms of anxiety and depression through either heart rate variability biofeedback [47,48] or awareness of body sensations [49].

Finally, passive data collection on physical activity (ie, the number of steps performed every 20 seconds) and sleep continuity (eg, hours slept, number of awakenings) was achieved via the paired wearable device, BioBeam, and data on sleep and physical activity history were displayed on in-app dashboards. Awareness of and insight into one's own sleep and activity patterns have been shown to affect anxiety and well-being [50,51].

All tools provided in-app feedback and recommendations to encourage positive behavior change.

The BioBase app, previously containing content for workplace stressors, has been shown to increase well-being and decrease anxiety after 4 weeks of use [52,53].

Intervention

Stage 1: Development of a GAD Persona

A persona defines the guiding principles of the intervention: a collection of symptoms, desired health behaviors, barriers to treatment, and desired impact of the intervention. Such a persona was created to understand the current psychosocial context of the target population (individuals with GAD).

The Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM-5) [50] was consulted to clarify the current diagnostic criteria. Clinically recommended therapies, and their critiques, were investigated alongside models of GAD, self-help strategies, and confounding factors to their effectiveness [19,21,23,54-57]. This review of the literature highlighted behavioral issues specific to GAD, centered around explicit or voluntary cognitive avoidance strategies, and avoidance of internal experiences.

To create relevant scenarios in which to base an intervention, a persona narrative was created by a psychologist (NH) which was centered around everyday life for a person with GAD. These narratives were based on the psychologist's experience of user feedback from previous BioBase studies with individuals with high anxiety [52,53] in conjunction with the aforementioned review of the literature. Examples include:

> *I enjoy my job but struggle to concentrate and feel guilty for taking time off when my anxiety is overwhelming*
>
> *I just feel like I am always on edge and it is affecting my work and relationships*
>
> *I don't know what to do, I am just always anxious and can't stop it*
>
> *I am always tired and can never concentrate*
>
> *I feel like there is this looming dread - but I'm not sure where it is coming from*
>
> *My whole body is exhausted, I feel constantly tense, all my muscles ache*
>
> *I can't remember when I last slept well*

In addition to the narratives, clear user journeys were created highlighting how a person would receive and interact with the digital intervention. A list of desired outcome behaviors was also collated to inform the intervention design.

Stage 2: Intervention Design and Creation

A prototype digital intervention was constructed that targeted the desired outcome behaviors and integrated into the existing National Institute for Health and Care Excellence's (NICE) stepped treatment pathways for GAD [58]. The NICE stepped treatment pathway organizes the provision of service based on the severity of an individual's symptoms. Initial steps involve monitoring and provision of relevant information. This escalates to self-help or therapist-guided interventions and then to medication and combined interventions [59].

The *intervention design objectives* were to reduce symptoms of GAD (ie, excessive worry and anxiety, linked to increased reactivity to and avoidance of internal experiences) by means of increasing psychological flexibility.

The *key features* that could address these aims are provision of education and guidance on anxiety, specific therapeutics to help the users to be open to and aware of their internal experiences, guidance on defusing and accepting difficult internal sensations, and advice as to how to clarify personal values and reduce barriers to life goals.

The content was curated by a psychologist experienced in creating engaging digital interventions (NH), based on the targeting of key behaviors, efficacy of ACT processes [60], exercises in a digital format [27,61], and use of visual metaphors for engagement with the program.

The treatment aimed to increase the concept of psychological flexibility through psychoeducation and exercises based on the 3 pillars of ACT: Aware, Open, and Action. Across these 3 pillars, the treatment program is structured around the 6 core processes of ACT: present moment, self-as-context, cognitive defusion, acceptance, values, and committed action (Table 1). This feasibility study investigated a prototype of an initial 6 modules (of 30 total modules designed)—1 module for each core ACT process. Each module contained the same structure: a brief overview of a metaphor that describes a core ACT process, a description of the metaphor (that can be accessed via text or audio file), and an activity to complete with a free text box in which the users can apply the therapeutic concept to their current scenario.

The 6 modules, each taking less than 5 minutes to read/listen, could be accessed and completed in any order, as previous research has shown no consistent user preference for guided or unstructured user journey [62]. The user was free to spend as long as necessary on the activities as in other digital interventions [28,62]. A schedule of 1 module per day was recommended to participants. Each module contained a follow-up notification on completion, which reminded the users to be cognizant of the concept that they had worked through.

Table 1. The structure of the digital intervention prototype. The outline evidences the 3 core pillars of ACT[a] alongside the 6 ACT processes and links the intervention design objectives with the intervention key features (module name and exercise).

Module number	Pillar	Process	Intervention design objective	Key feature (Exercise)	Module name
1	Aware	Present moment	The users have increased awareness of what is driving their decisions in life (thoughts, feelings, emotions, and urges).	Passengers on the bus. Notice what thoughts, emotions, feelings, and sensations you are carrying with you.	In your driving seat
2	Aware	Self-as-context	The users have a greater awareness of their internal narrative directed by their thoughts and its effect on their behavior and decisions throughout the day. They check that they are basing decisions and behavior on reality, not the story their thoughts are telling them.	Noticing if the story your thoughts are telling you is different from reality.	The storyteller
3	Open	Cognitive defusion	The users are better able to notice and distinguish between thoughts that are either helping them or preventing them from reaching their goals and then build a positive mindset by attending to helpful thoughts.	Labeling thoughts as helpful or unhelpful.	Is this helpful?
4	Open	Acceptance	The users are aware of difficult emotions, thoughts, or urges they are experiencing, and the short-term gains and long-term costs of their avoidance behaviors.	Journaling the short- and long-term impact of current avoidance behaviors.	What are you avoiding?
5	Active	Values	The users connect with their values and what really matters to them to live a meaningful, valued life.	Journaling what a loved one says about you during an anniversary speech.	Your attention, please
6	Active	Committed Action	The users state that they are willing to experience initial discomfort in order to achieve meaningful goals for them.	Acknowledging barriers and creating an action plan.	ACTion plan

[a]ACT: acceptance and commitment therapy.

To safely address readability and clarity of the modules, iterative testing was conducted with 10 paid user testers with no pre-existing anxiety. Modifications were made to simplify the language and to improve the clarity of what is addressed by the activity. The app was then further reviewed by a clinical psychologist (RW), who has experience using ACT-based approaches in GAD, whose feedback was fed into the program design via the PBA framework.

To meet the specific behavioral context of GAD (such as excessive worry) the overall design of the app was intended to be relaxing and calming. The home screen changes color based on the time of day to anchor the persons to their present environment. The tone and style of the language used were accessible, nonjudgmental, friendly, and supportive and avoided explicitly mentioning any specific medical conditions or diagnosis (unless necessary within therapeutic Step 1: "Information on anxiety"). All modules had a Flesch Kincaid reading ease score [63] of 71.5 or above suggesting it should be easily understood by individuals aged 13 and above.

Phase 2: Feasibility Testing

Overview

A feasibility test of the initial prototype app–based therapeutic (testing acceptability, usability, and efficacy) was conducted in a sample of individuals who have reported a diagnosis of GAD from a mental health professional as the first step in an iterative cycle of development and evaluation. The study took place in February-March 2020.

Participants

Participants were recruited from a pool of subjects excluded from a previous study in student mental health [52], because of a declaration of diagnosed mental health disorder. Based on similar feasibility studies [25], up to 20 participants were contacted. Participants were paid £20 (~US $27) for their time to take part.

Inclusion criteria were age over 18, self-reported clinical diagnosis of GAD from a general practitioner (GP) or mental health professional, able to read and understand English, and access to an iPhone (6 or above). All participants were given a participant information sheet and provided consent via the

consent form. Ethical approval was obtained from the University of Exeter Research Ethics Committee (eUEBS003011).

Procedure

At baseline, demographic information and the baseline questionnaire data were collected. Participants were then given a unique activation code and sent a video and study information pack to provide a clear overview of what they would be required to do (interact with the app every day for at least 5 minutes a day, using whichever tools they feel comfortable with, and complete all 6 ACT modules in the 2-week period), as well as relevant contacts for research-related questions and mental health emergencies. At 2 weeks after app download, exit questionnaire data were collected and access to the app ceased.

Treatment dosage was defined as completion of all 6 ACT modules and participants were excluded if they did not complete all modules. Participants were given the option to take part in semistructured interviews with an experienced psychologist (JK) after the exit questionnaire was completed.

Duty of Care

As this population is at risk of severe mental health issues, a duty of care protocol was implemented if the research team felt there was a significant concern for the participant's welfare. In the demographics section, each participant was required to input details of an emergency contact and his/her GP; participants were excluded from the study if they failed to provide this information. If on either the baseline or exit questionnaire participants stated they had thoughts of self-harm or suicide or both over the past 2 weeks, the research team would contact the at-risk participant via email with relevant helpline information, the participant's emergency contact by email with relevant information on how to support someone during a mental health crisis, and also the participant's GP via a letter with information on the study and questionnaire results.

Outcome Measures

Psychological flexibility, or the ability to be aware of and deal with difficult emotions while acting in accordance with one's values, was measured by the 7-item Acceptance and Action Questionnaire-II (AAQ-II), which utilizes a 7-point Likert response scale (scores range 10-70 with lower scores indicating greater psychological flexibility) [64].

Mental well-being was assessed using the 14-item Warwick-Edinburgh Mental Well-being Scale (WEMWBS), which utilizes a 5-point Likert scale for responses (scores range from 14 to 70, with higher scores indicating greater mental well-being) [65].

The 7-item Generalized Anxiety Disorder Assessment (GAD-7) [66] and the 9-item Patient Health Questionnaire (PHQ-9) [67] are clinical assessment tools for measuring anxiety and depression, respectively, over the previous 2 weeks. GAD-7 scores range from 0 to 21 and PHQ-9 scores from 0 to 27; both have a cutoff of 10, indicating moderate symptoms which warrant referral to a mental health professional.

Feedback questions were asked as part of the exit questionnaire, regarding learned concepts, any behavior change, and any benefits received as a result of the intervention. The System Usability Scale (SUS) was included as part of the exit questionnaire to assess usability of the app; it assesses the ability of the participant to effectively and efficiently complete tasks using the system, as well as the participant's satisfaction in using the app. The scale provides a single number and corresponding grade [68].

Optional semistructured interviews were conducted to further explore feasibility of the intervention in the participant's own words, in terms of usability of the app and acceptability of the ACT-based content (ie, if the participants felt the content was relevant to the anxiety they struggle with). Questions were based around downloading the app and setting up the paired wearable, accessing the modules, experience using the tools and features (ie, usability), and experience during and after completion of the modules and if any aspect of the content triggered anxiety (ie, acceptability).

Statistical Analysis

To explore Aim 1 (evaluate the acceptability and usability), the SUS was reported, and a thematic analysis of the feedback questionnaires and semistructured interviews were conducted.

To explore Aim 2 (exploratory analysis to evaluate the preliminary efficacy of this intervention), differences between baseline and exit scores of the AAQ-II, WEMWBS, GAD-7, and PHQ-9 were analyzed. Because of small sample size, nonparametric paired-sample Wilcoxon signed-rank tests were carried out using R [69]. Differences were considered significant if $P<.05$. Effect sizes were calculated as $Z/\sqrt{N}$ and interpreted in accordance with Cohen's classification of effect sizes (ie, 0.2 [small effect], 0.5 [moderate effect], 0.8 [large effect]) [70].

Results

Participants

A total of 13 participants met inclusion criteria, were eligible to take part in the study, and agreed to do so. Seven participants failed to meet inclusion criteria, as they ceased communication before the study could begin (n=3) or did not download the app (n=4). Three participants were excluded from the analysis because they did not complete all 6 modules (1 participant completed no modules and 2 participants completed 1 module). The final sample consisted of 10 participants; of these 10, 7 participated in the semistructured interview after the exit questionnaire. CONSORT flow chart is presented in Figure 1. Demographics are presented in Table 2.

Figure 1. Study flow chart.

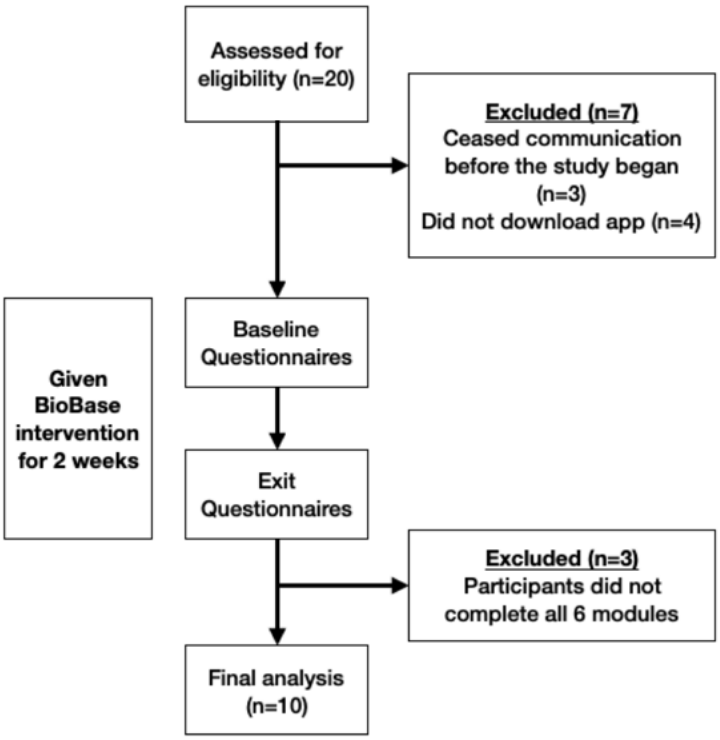


Table 2. Baseline characteristics of the study sample (N=10).

Variable	Value
Age (years), mean (range)	25.2 (19-48)
Gender, n	
Female	10
Male	0
Education, n (%)	
School to age 16	2 (20)
College/A-levels to age 18	7 (70)
Undergraduate degree	1 (10)
Undertaking therapy/counseling, n (%)	
Yes	2 (20)
No	8 (80)
On medication for anxiety, n (%)	
Yes	8 (80)
No	2 (20)

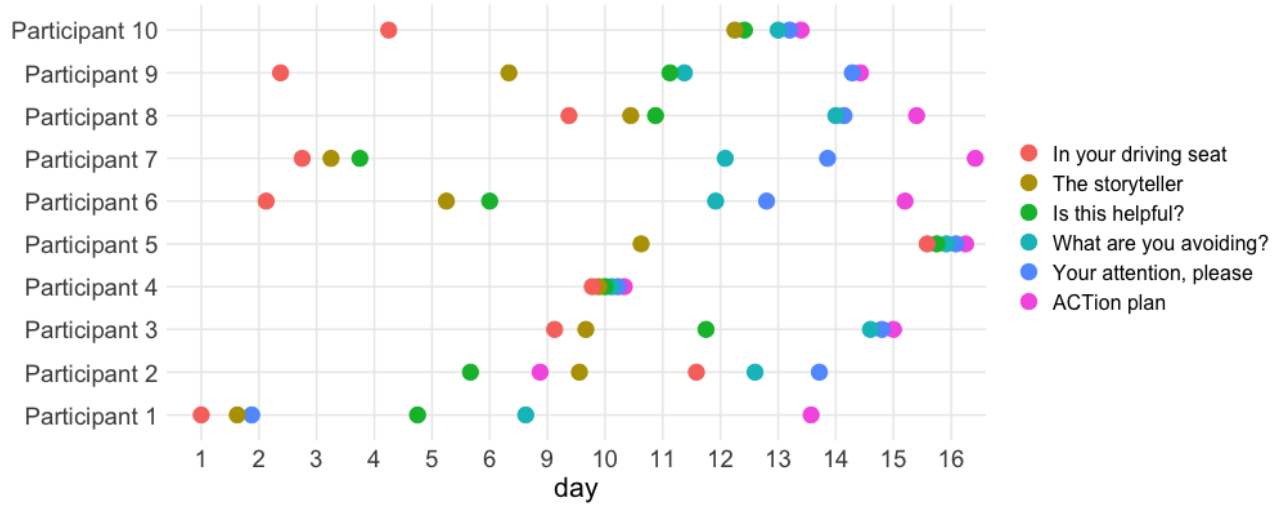
Duty of Care

Seven participants responded to item 9 of the baseline or exit PHQ-9, indicating they had thoughts of self-harm/suicide in the previous 2 weeks; the participant, the participant's emergency contact, and the participant's GP were then contacted as per the duty of care protocol.

Engagement

All participants onboarded on to the app over 2 days and engaged with the app on average 5.8 minutes per day (median 6.0, IQR 4.9-7.4 minutes). The instructions to participants were to complete all 6 modules within 2 weeks, and there was considerable variability in the spacing between module completion (Figure 2); some participants completing 1 or 2 modules per day (n=6), some completed up to 3 in 1 day (n=2), and some completed all 6 modules in 1 day (n=2).

Figure 2. Completion order of ACT-based modules by participant. Participants onboarded onto the app over 2 days and had access to the app for 14 days.



The most-used tool was the mood declaration (EMA); every participant completed at least seven declarations over the study (mean 13.1, median 13, IQR 9.3-14). As much as 9/10 participants (90%) also completed the deep breathing exercise (mean 2.4, median 2, IQR 1.3-2.8) and 6/10 participants (60%) completed the body scan exercise (mean 1.4, median 1, IQR 0-1.8).

Usability

Results from the SUS indicate an average A rating (mean 83.4, median 88.7, IQR 75-96.9). All 7 participants that had an exit interview stated downloading the app and going through the app onboarding process including pairing the wearable were simple and none reported problems. Three participants stated they felt they needed to wear the wearable a bit too tight or that it was uncomfortable at times.

Acceptability

All 7 participants that engaged in exit interviews stated that the ACT modules were relevant to the anxiety they currently struggled with. Two participants stated they had engaged in therapy before and, therefore, the ACT modules were not new concepts. All others stated the modules were relevant to, helpful, and useful for their anxiety. One participant noted the ease of use with each module being “quite short and didn’t take long to complete.” Two participants stated addressing overthinking and challenging thoughts (“The storyteller” and “Is this helpful?”) were particularly useful. Another 2 participants mentioned “What are you avoiding?” as the most useful module. One participant preferred the journaling activities on paper, rather than in the app.

Participants stated the tools were also relevant, useful, and helpful to their anxiety. Three participants stated the deep breathing exercise was therapeutic, especially before bed. Two participants specifically found the mood tracker helpful for their anxiety, stating “it made me stop and think a bit more about how I’m feeling.” One participant mentioned the body scan as the most useful tool as she preferred body awareness mindfulness techniques over breathing-related relaxation exercises.

Overall, 2 participants stated that by “using an app every day to check in with myself, it’s much easier to control my anxiety” and that “having goals set by the app and a module to complete each day was helping my mental state ... makes me look at [a feeling], acknowledge it and move on from it easier.”

Preliminary Efficacy

Outcome Measures

Table 3 shows the descriptive statistics for baseline and exit for scores on psychological flexibility (AAQ-II), mental well-being (WEMWBS), and symptoms of anxiety (GAD-7) and depression (PHQ-9).

On average, participants had lower median scores for GAD-7 and PHQ-9 at exit than at baseline, indicating fewer anxious and depressive symptoms, respectively, and these differences were statistically significant (P=.03 and .008, respectively, for GAD-7 and PHQ-9; Table 3). For the GAD-7, the median exit score (9.8) fell below the threshold for moderate anxiety (score of 10) from a median baseline score of 12.8 (Figure 3).

Participants had lower median AAQ-II scores at exit than at baseline, indicating more psychological flexibility and better functioning, and higher median mental well-being scores, although this difference was not statistically significant (P=.11 and .55 for AAQ-II and WEMWBS, respectively; Table 3).

An additional analysis was conducted on 13 participants, which included 3 participants that did not complete all 6 modules, to determine if excluding these participants had a significant impact on the results. However, these results remain significant for change in GAD-7 (n=13; baseline median 12, exit median 8, Wilcoxon W=53, P=.011, d=0.81) and PHQ-9 (n=13; baseline median 10, exit median 8, Wilcoxon W=45, P=.008, d=0.84).

Table 3. Preliminary efficacy in participants (N=10) of the digital intervention. The clinical cutoff for GAD-7 and PHQ-9 for moderate anxiety or depression, respectively, is 10.

Measure	Baseline	Exit	Statistical significance
AAQ-II[a], median (range)	30.5 (23.0-48.0)	29.0 (17.0-47.0)	W[e]=30; *P*=.11; ES[f]=0.512
WEMWBS[b], median (range)	36.5 (17.0-58.0)	38.0 (22.0-56.0)	W=41.5; *P*=.55; ES=0.630
GAD-7[c], median (range)	14.0 (0-20)	9.0 (1-19)	W=34.0; *P*=.03[g]; ES=0.691
PHQ-9[d], median (range)	11.5 (1.0-26.0)	9.5 (0-25.0)	W=45; *P*=.008[h]; ES=0.840

[a]AAQ-II: Acceptance and Action Questionnaire-II.

[b]WEMWBS: Warwick-Edinburgh Mental Well-being Scale.

[c]GAD-7: 7-item Generalized Anxiety Disorder Assessment.

[d]PHQ-9: 9-item Patient Health Questionnaire.

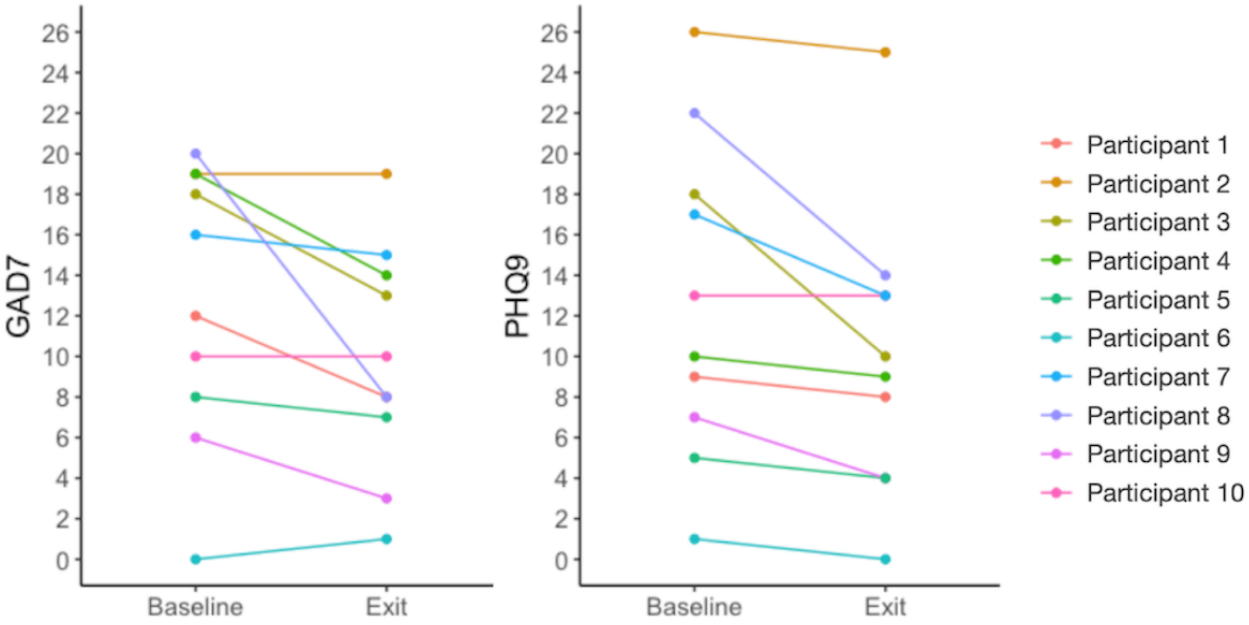
[e]W: paired-sample Wilcoxon signed-rank tests.

[f]ES: effect size.

[g]*P*<.05.

[h]*P*<.01.

Figure 3. GAD-7 and PHQ-9 results in participants (N=10) of the digital intervention. The clinical cutoff for moderate anxiety or depression, respectively, is 10.



Interviews

Using the exit questionnaires, participants reported that the primary learned concept was that mental health consists of a number of factors; 3 participants specifically mentioned learning how much their sleep patterns play an important role. This was investigated further in interviews with participants.

Two participants mentioned they learned the most from the "Is this helpful?" module; 1 participant said, "how to divide your thoughts into those that are helpful and not helpful ... a way I haven't looked at it before… even now, since I've stopped using it, if I have a thought, I think 'what have you just gained from that thought?' and if it's not a productive thought, I need to either eradicate it or turn it into one. And I just found that really useful for a positive mindset".

In terms of behavior change after the intervention, participants mentioned being more aware of their sleep patterns, consistently doing deep breathing and body scan exercises (without the guide on the app), checking in more with how they are feeling, and trying to make their goals more specific to avoid being overwhelmed.

Discussion

Principal Findings

This pilot study aimed to describe the development of a self-guided ACT-based digital prototype for individuals with GAD and to provide a feasibility analysis (ie, evaluate the acceptability, usability and preliminary efficacy) of the digital intervention. The study found that the content was acceptable to this population, and highly regarded due to its relevance for the participants' struggle with anxiety. The intervention was

judged to be usable in a digital format, with an "A" rating on the SUS scale. Additionally, preliminary evidence suggests that this intervention may reduce symptoms of anxiety and depression.

Acceptability

Participants stated that they found the app and ACT-based content useful, easy to complete, and relevant to the anxiety they struggle with. Modules from all 3 pillars of ACT (Aware, Open, Active) were also mentioned as being useful. The therapeutic tools for mood tracking, deep breathing, and mindfulness alongside the novel ACT content were also mentioned as being helpful for managing symptoms. Additionally, using the app daily made it easier for participants to control their anxiety, acknowledge their mental state, and take actions that move them closer to achieving their goals. It is important to note the participants had been diagnosed with GAD and were not treatment naïve; 2 participants did not find the concepts novel. However, being reminded of these concepts was found to be helpful, thereby demonstrating the utility of the intervention.

Usability

This study found the app-based therapeutic to have an SUS rating of 83.5, which equates to an A rating, representing programs that people are likely to recommend to their friends [68]. This is comparable to web-based ACT programs [27,29,62]. Three participants commented that the wrist-worn wearable was uncomfortable at times, but this did not affect their judgment of the intervention as simple and easy to use.

Engagement

Of the 13 initial participants, 10 (77%) were included in the final analysis (3 participants did not complete all modules). This was comparable to another self-guided study using a 9-module, 2-week online program (75%; [27]) with similar financial incentives for the participants to take part, and on the higher end of other guided internet-based treatment programs (average adherence rates of 31%, range of 2%-83%) [37]. The dropout rate of this self-guided digital intervention (23%) is slightly higher than those of face-to-face, therapist-led ACT programs (15.8% [71] and 17.35% [72]).

Adherences rates in self-guided app-based ACT interventions are not consistently reported, therefore putting engagement results within the context of the wider literature is difficult. Across internet-based ACT treatments, 1 review found the average attrition rate was 19.2% [23], but made no separate analysis between guided (n=13) and unguided (n=5) interventions. Where higher dropout rates are observed [30,32], these could be explained by a lack of technical knowledge, lower motivation to engage with treatment, and poor usability of the system [25]. While this study found 65% (13/20) uptake rate, encouragingly, this pilot study indicates system usability was high and the adherence rate was on the higher end of the expected range.

Analysis of Initial Efficacy

Although only a pilot acceptability study, the results provide preliminary evidence that this app-based therapeutic may be efficacious in reducing clinical symptoms in GAD. In this small sample, the results show trends of increasing psychological flexibility and well-being and decreasing symptoms of anxiety and depression. The large effect sizes found in this study are comparable to similar studies investigating digital ACT-based interventions on anxiety and depression [27,29,73], but due to the low sample size these results are in need of replication with larger sample sizes.

Symptoms of anxiety and depression were significantly decreased after 2 weeks (P=.03 and .008 for GAD-7 and PHQ-9, respectively). Mean GAD-7 scores decreased by 3 points (median 5 points) and mean PHQ-9 scores decreased by 2.8 points (median 2 points), but this may not represent a clinically significant change, as participants on average are at the cusp of the cutoff of 10, indicating moderate symptoms and a recommendation of a referral to a mental health professional. However, the reduction in anxiety and depression scores allude to the transdiagnostic effect of the treatment on comorbid symptoms [74] and highlights that a therapeutic solution for GAD should address the high comorbidity of anxiety and depression.

This study did not find a statistically significant increase in psychological flexibility (AAQ-II, P=.11), which is the primary objective of ACT-based interventions; however, given the small sample size, it is likely the study was underpowered to detect this effect. Future research with an increased sample size could investigate the mediating effect of psychological flexibility on anxiety and depression scores.

Limitations

The feasibility phase of this study was limited by its small sample size and relatively short intervention period, and so conclusions are made with caution. Even though GAD is more common in females [3], the study was limited by a sample composed only of females. Future research should include measures of ethnicity [75] and aim for a sample more representative of the population with GAD. Compared with other PBA studies [44,76,77], the small sample size used in this study to represent the target population means that study may not have covered all context-specific behaviors that users with GAD may experience. In addition, the intervention was a prototype (6 modules) of a larger intervention (30 modules), and therefore only investigates the initial feasibility of the intervention concept. The intervention also comprises features that are known to decrease symptoms of anxiety, and these effects cannot be interpreted separately. Further research with a larger feasibility study on the 30-module intervention, that is more generalizable to a wider population of individuals with GAD, is warranted.

In addition, participants were paid to take part, meaning that engagement rates with the ACT modules in uncompensated participants are unknown. In a previous study using BioBase content related to workplace stressors, paid participants showed higher engagement in the program. However, there were no differences seen in the effect on outcome measures of well-being and anxiety. Future research on engagement should aim to use a similar incentive scheme to particular usage cases.

Although the prototype design process listed desired outcome behaviors of the intervention, the approach lacked clearly stated behavior change techniques for each of the desired behaviors [78]. Future iterations of the program will need to address this to increase engagement and efficacy of the intervention. In addition, barriers to use need to be further investigated, including the restrictions of using a technology-based solution as a therapeutic. For example, individuals with GAD may find technology useful to help soothe anxiety symptoms; however, technology can also be a tool to provide unhelpful distraction from difficult thoughts and feelings. In addition, technology can be used to connect with supportive social networks; however, feelings of being overwhelmed due to social media use can also increase symptoms of anxiety.

Conclusions

The PBA approach is designed to complement and enrich the evidence-based approach to intervention design. This paper shows that the design and development of a persona and incorporation of intervention design objectives and key features alongside the app of an ACT-based model can be a feasible solution within in an app-based therapeutic. However, in keeping with the PBA approach, more research is needed to further define the engagement criteria for an efficacious product and further develop and tailor the ACT intervention to the target GAD population in keeping with the iterative development–evaluation–development cycles of the PBA.

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Conflicts of Interest

DP and DM were the CEO and CTO, respectively, and cofounders of BioBeats, the provider of the BioBase program. Both DP and DM contributed to interpretation of the data and revising the manuscript, but were not involved in study design, recruitment, analysis, or initial drafting of the manuscript. SP, NH, JK, and GB were employees of BioBeats. The analysis was conducted by NH, JK, and SP. Manuscript was drafted by NH and JK. GB contributed to revision of the manuscript and interpretation of data. RW was a paid consultant for BioBeats, the provider of the BioBase program, and contributed to program design and revision of the manuscript.

Multimedia Appendix 1
Screenshots of the app.
[PDF File (Adobe PDF File), 227 KB - formative_v5i2e21737_app1.pdf]

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Abbreviations

AAQ-II: Acceptance and Action Questionnaire-II
ACT: acceptance and commitment therapy
DSM-5: Diagnostic and Statistical Manual of Mental Disorders, 5th edition
EMA: Ecological Momentary Assessment
GAD: generalized anxiety disorder
GAD-7: 7-item Generalized Anxiety Disorder Assessment
NICE: National Institute for Health and Care Excellence
PBA: person-based approach
PHQ-9: 9-item Patient Health Questionnaire
SUS: System Usability Scale
WEMWBS: Warwick-Edinburgh Mental Well-being Scale

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Original Paper

A Web-Based Self-Management Support Prototype for Adults With Chronic Kidney Disease (My Kidneys My Health): Co-Design and Usability Testing

Maoliosa Donald[1], PhD; Heather Beanlands[2], PhD; Sharon E Straus[3], MSc, MD; Michelle Smekal[1], MSc; Sarah Gil[1], BSc; Meghan J Elliott[1], MSc, MD; Gwen Herrington[4], MSc; Lori Harwood[5], PhD; Blair Waldvogel[4], MBA; Maria Delgado[4], BBus; Dwight Sparkes[4], BSc; Allison Tong[6], PhD; Allan Grill[3], MD; Marta Novak[3], PhD, MD; Matthew Thomas James[1], PhD, MD; K Scott Brimble[7], MSc, MD; Susan Samuel[1], MSc, MD; Karen Tu[3], MSc, MD; Janine Farragher[1], PhD; Brenda R Hemmelgarn[8], PhD, MD

[1]Department of Community Health Sciences, University of Calgary, Calgary, AB, Canada

[2]Daphne Cockwell School of Nursing, Ryerson University, Toronto, ON, Canada

[3]Department of Family & Community Medicine, University of Toronto, Toronto, ON, Canada

[4]Can-SOLVE CKD Network, Vancouver, BC, Canada

[5]London Health Sciences Centre, London, ON, Canada

[6]Sydney School of Public Health, The University of Sydney, Sydney, Australia

[7]Department of Medicine, McMaster University, Hamilton, ON, Canada

[8]Faculty of Medicine and Dentistry, University of Alberta, Edmonton, AB, Canada

Corresponding Author:
Brenda R Hemmelgarn, PhD, MD
Faculty of Medicine and Dentistry
University of Alberta
2J2.01 Walter C MacKenzie Health Sciences Centre
Edmonton, AB, T6G 2B7
Canada
Phone: 1 780 492 9728
Email: Brenda.Hemmelgarn@albertahealthservices.ca

Abstract

Background: Supporting patients to self-manage their chronic kidney disease (CKD) has been identified as a research priority by patients with CKD and those who care for them. Self-management has been shown to slow CKD progression and improve the quality of life of individuals living with the disease. Previous work has identified a need for a person-centered, theory-informed, web-based tool for CKD self-management that can be individualized to a patient's unique situation, priorities, and preferences. We addressed this gap using an integrated knowledge translation method and patient engagement principles.

Objective: The aim of this study is to conduct systematic co-design and usability testing of a web-based self-management prototype for adults with CKD (nondialysis and nontransplant) and their caregivers to enhance self-management support.

Methods: A multistep, iterative system development cycle was used to co-design and test the *My Kidneys My Health* prototype. The 3-step process included creating website features and content using 2 sequential focus groups with patients with CKD and caregivers, heuristic testing using the 10 heuristic principles by Nielsen, and usability testing through in-person 60-minute interviews with patients with CKD and their caregivers. Patients with CKD, caregivers, clinicians, researchers, software developers, graphic designers, and policy makers were involved in all steps of this study.

Results: In step 1, 18 participants (14 patients and 4 caregivers) attended one of the 2 sequential focus groups. The participants provided specific suggestions for simplifying navigation as well as suggestions to incorporate video, text, audio, interactive components, and visuals to convey information. A total of 5 reviewers completed the heuristic analysis (step 2), identifying items mainly related to navigation and functionality. Furthermore, 5 participants completed usability testing (step 3) and provided feedback on video production, navigation, features and functionality, and branding. Participants reported visiting the website repeatedly for the following features: personalized food tool, my health care provider question list, symptom guidance based on CKD severity, and medication advice. Usability was high, with a mean system usability score of 90 out of 100.

Conclusions: The *My Kidneys My Health* prototype is a systematically developed, multifaceted, web-based CKD self-management support tool guided by the theory and preferences of patients with CKD and their caregivers. The website is user friendly and provides features that improve user experience by tailoring the content and resources to their needs. A feasibility study will provide insights into the acceptability of and engagement with the prototype and identify preliminary patient-reported outcomes (eg, self-efficacy) as well as potential factors related to implementation. This work is relevant given the shift to virtual care during the current pandemic times and provides patients with support when in-person care is restricted.

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KEYWORDS

chronic kidney disease; knowledge-to-action framework; integrated knowledge translation; patient engagement; patient-oriented research; self-management; web-based intervention

Introduction

Background

Chronic kidney disease (CKD) affects approximately 9% of Canadians [1], with 90% to 95% of the individuals being cared for in the community by primary care [2]. CKD self-management support can slow the progression of the disease and improve the quality of life of those with CKD [3]. International studies of CKD research priority setting involving patients and those who care for them has identified the need for strategies to help patients self-manage their CKD as a top-10 research priority [4-6].

Many individuals with CKD receive self-management education and support through face-to-face interactions in the clinic setting [7]. However, with increasing access to the internet [8] and the nature of pandemics, the potential for an eHealth platform to provide easy access and timely, tailored information and support could be a sustainable way to enhance self-management strategies. eHealth applications can be designed to improve knowledge and self-management behaviors and actively involve individuals in their care [9]. Numerous websites are readily available to support CKD self-management, providing educational programs and support [10-12]. However, patients are infrequently involved in their development, and the websites lack features that combine health information with decision support and/or assist with behavior change [13,14].

Individuals with CKD (nondialysis and nontransplant) have multiple needs that can differ based on the complexity of their illness, health-related knowledge, and confidence in managing the disease. An eHealth CKD self-management support intervention that can be individualized to a patient's unique situation, priorities, and preferences holds promise for improving their health outcomes and enhancing their quality of life.

Previous Work

This study is informed by our previous work using a collaborative and systematic approach to determine the best practices for CKD adult self-management support interventions [7,13,15-17]. Specifically, our work is guided by the integrated knowledge translation (IKT) method [18] and the Canadian Institutes of Health Research (CIHR) Strategy for Patient-Oriented Research (SPOR) patient engagement principles [19]. Our knowledge users from the CKD community include patients, caregivers, clinicians, researchers, and policy makers from across Canada. Throughout this work, 4 to 6 patients and caregivers (patient partners) were active members of our research team. The patient partners represent diversity in age, gender, ethnicity, and attitudes toward technology.

Objectives

The aim of this study is to conduct systematic co-design and usability testing of a web-based, self-management prototype for adults with CKD (nondialysis and nontransplant) and their caregivers to enhance self-management support.

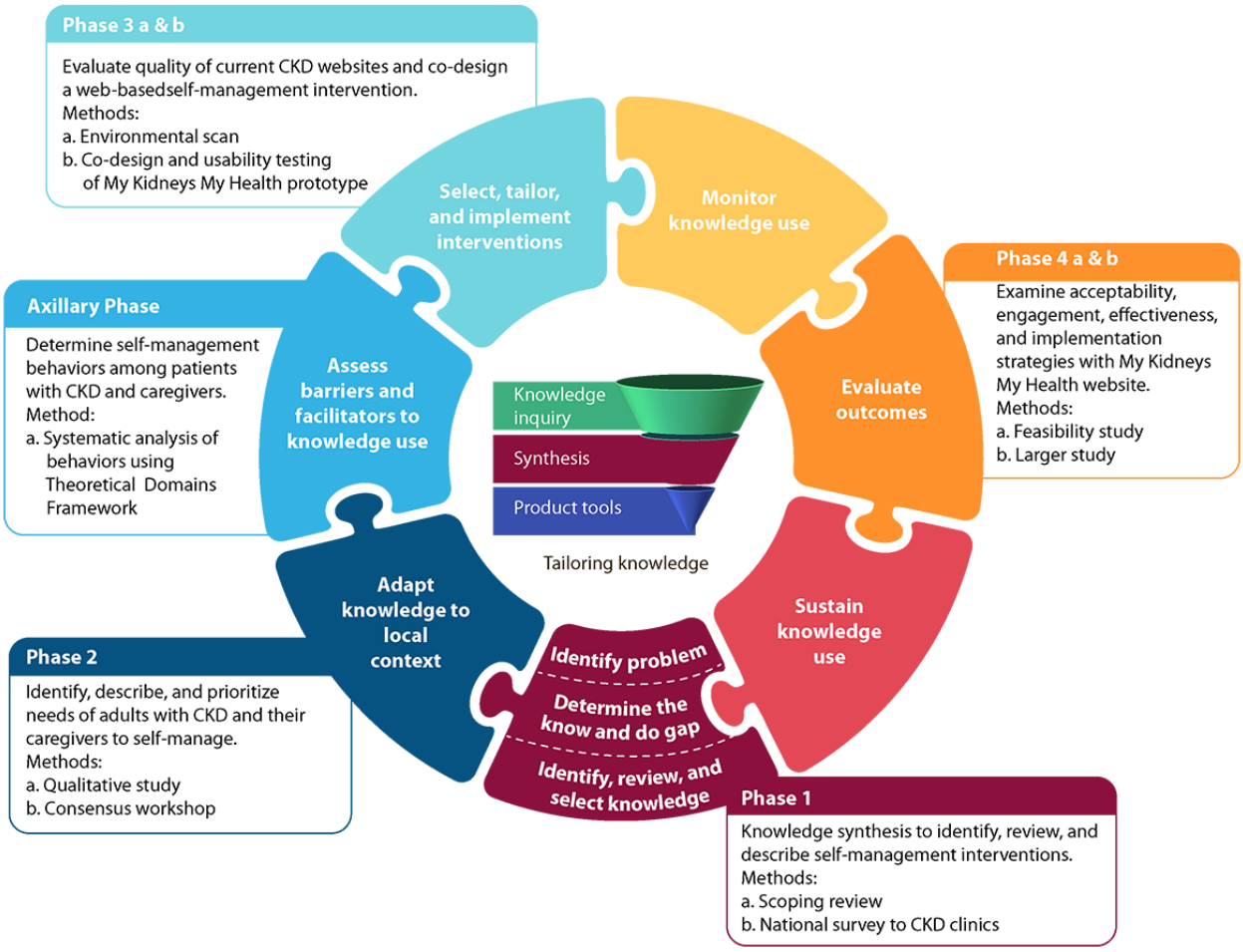
Methods

Applying IKT and Patient Engagement to the Broader Program of Work

The knowledge-to-action (KTA) framework guided multiphase activities for determining the self-management support intervention for patients with CKD [20]. The KTA framework consists of 2 components: the *knowledge creation* funnel and the *action cycle*. We mapped our activities to the KTA framework (Figure 1). In phase 1, our patient partners contributed to the conceptualization of the research problem and the identification of relevant literature (including gray literature and patient education resources) for our scoping review [13] and national survey for CKD clinics [7]. Patient engagement with our patient partners and linkages with patients and caregivers in the community helped us identify knowledge gaps within the current literature and care to support CKD self-management. In phase 2, through 6 focus groups and 11 interviews (33 patients and 15 caregivers), we identified the perceived self-management needs (eg, empowerment through knowledge and tangible supports), including the potential for an eHealth tool (ie, activation through information sharing by the way of accessible, relevant, timely, and appropriate amount of advice) [16]. Our sample included participants with a diverse range of demographic and clinical characteristics, recruited through purposive sampling. We prioritized these needs during a consensus workshop with key stakeholders and identified the features and content for a web-based eHealth tool [15]. The stakeholders included 24 participants from across Canada: 11 patients, 6 caregivers, 2 nurses, 1 dietitian, 1 pharmacist, 1 policy maker, 1 primary care physician, and 1 nephrologist. The preferred features included visuals, the ability to enter and track health information and interact with health care providers, *on-the-go* access, links to resources, and access to personal health information. An axillary study was conducted to assess patient and caregiver barriers and facilitators for the

self-management of CKD [17]. In phase 3a, an environmental scan of CKD self-management websites [14] identified a gap between web-based applications and our population's self-management support needs, necessitating the co-design of a website. This study (phase 3b) involved the co-design (involving patient partners, patient and caregiver study participants, clinicians, researchers, software developers, graphic designers, and policy makers) and usability testing of the *My Kidneys My Health* web-based prototype that is compatible with mobile devices to support self-management.

Figure 1. Knowledge-to-action framework and chronic kidney disease self-management project multiphase activities. CKD: chronic kidney disease.



The *My Kidneys My Health* prototype was co-designed and tested using a 3-step system development cycle [21] and agile methodologies [22]. These approaches emphasize collaboration with our system users (patients and caregivers) and the flexibility to respond to the changes and needs of users throughout the process. The 3 steps included the creation of website features and content, heuristic testing, and usability testing. Ethics approval was obtained from the University of Calgary Conjoint Health Research Ethics Board (REB19-0002). All participants provided written consent before their participation.

Step 1: Creation of Website Features and Content

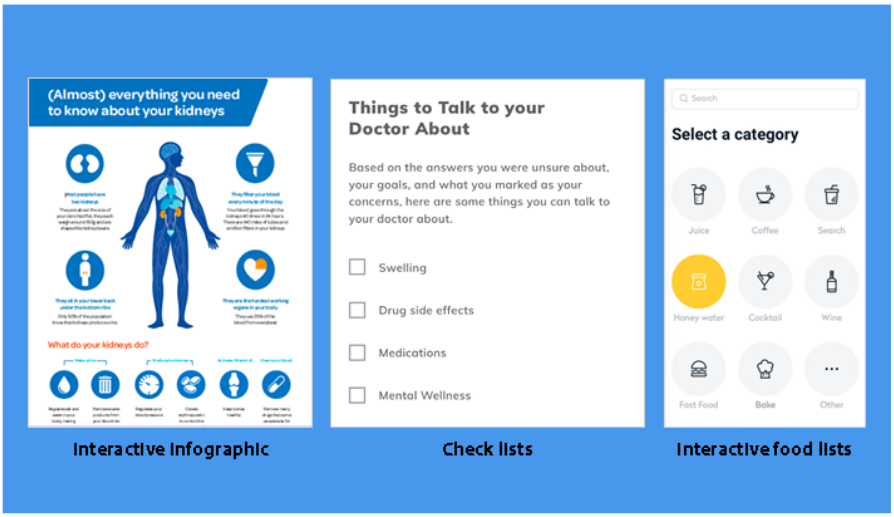
The purpose of step 1 was to evaluate the website features identified during the consensus workshop [15] and present the website components that may deliver the 4 behavior-change strategies we identified in our axillary study (ie, education, modeling, persuasion, and environmental restructuring) [17]. In creating the website features and content, we considered mobile device compatibility. In this step, we built relevant content based on the 8 topic areas identified by patients and caregivers in our previous work (ie, understanding CKD, diet, symptoms, medication and alternate treatments, finances, mental and physical health, travel, and work and school considerations) [16]. We included relevant, credible, and nonproprietary content identified in our environmental scan of CKD websites [14]. Content was also acquired from the Kidney Disease: Improving Global Outcomes CKD guidelines [23] and other relevant agencies (eg, Diabetes Canada, Canadian Cardiovascular Society), along with content expert input from clinicians specializing in CKD care (ie, dietitians, pharmacists, social workers, nurses, nephrologists, and occupational therapists). To ensure reliable, objective, and valid information, we followed the Health on the Net guidelines [24]. The Web Content Accessibility Guidelines were followed to deliver content accessible for individuals with low vision or other accessibility needs [25]. Efforts were made using the Microsoft Office software to ensure that the readability level met that of the general population (ie, grade 7 or less).

Wireframes and mood boards were developed based on previously constructed personas [15] to aid developers by providing detailed descriptions of user goals, motivations, and behaviors (Figure 2). Research team members reviewed iterations of wireframes and mood boards (ie, color palettes and

typography) to inform visual feature conceptualizations (Figure 3).

Figure 2. Website wireframes.

Figure 3. Website visual conceptualizations.



Using purposive sampling, individuals from CKD and general nephrology clinics in Calgary, Alberta, were invited to participate if they met the following eligibility criteria: were English speaking, were aged 18 years or above, were able to provide informed consent, and were aware of their diagnosis of CKD (stages 1-5, not currently on dialysis, and not a previous kidney transplant recipient) regardless of the cause or duration of CKD. Informal caregivers (eg, family members and friends) of individuals with CKD were also eligible. Participants completed 2 questionnaires: (1) a demographic form and (2) the eHealth Literacy Scale (eHEALS). The eHEALS is an 8-item self-report tool measuring individuals' perceived ability to find, evaluate, and apply eHealth information [26]. The overall scores range from 8 to 40, with a higher score indicating higher self-perceived eHealth literacy [26].

A total of 2 sequential focus groups were facilitated by MD (primary author) to obtain participant feedback and preferences regarding the proposed features. The initial focus group reviewed the visual feature conceptualizations and the prioritized features (ie, voting technique using Monopoly Money to determine the value of the individual features) to be developed in further detail for the initial click-through website prototype. The focus group questions addressed accessibility, adoption, sustainability, and overall strengths/weaknesses of the key features (Multimedia Appendix 1). The second focus group

reviewed the initial prototype, and participants were instructed to provide their input on the proposed website pages and functional elements. Questions focused on individual webpage presentation (eg, clarity and missing items) and functional elements (eg, drag and drop, check boxes, and tailored features; Multimedia Appendix 2). Research team members, software developers, and graphic designers developed the semistructured interview guides.

The focus groups were audio recorded and transcribed verbatim by a transcriptionist with experience in qualitative research. A total of 2 research members (MD and MS) completed a descriptive synthesis of the voting results and focus group transcripts. The research team members reviewed the findings from both sessions, and appropriate refinements were made to the prototype.

Step 2: Heuristic Testing

Heuristic testing based on the 10 heuristic principles by Nielsen [27] was undertaken independently by 5 reviewers (3 research team members [MS, SG, and SA], 1 human factor specialist [JH], and 1 software developer [MP]) to identify system and design issues with the prototype viewed on computer and mobile devices. The areas of focus included navigation, information architecture, search, forms and data entry, trust and credibility, writing and content quality, page layout, and visual design. The reviewers were asked to rate each website page using the following scoring: −1 (does not comply), +1 (complies), or 0 (partially complies). If an item within the focus area was not relevant, the reviewers were instructed to leave the rating blank. Reviewers provided comments to explain their ratings. The reviewers met to discuss the ratings, and consensus was reached through discussion regarding the items to be addressed before usability testing.

Step 3: Usability Testing

Purposive sampling, using the same recruitment strategy, inclusion criteria, and questionnaires (ie, demographic and eHEALS), was used as previously described in step 1. Potential participants had to have no previous exposure to the development of the tool. Acknowledging that usability testing with 3 to 5 participants can identify 85% of usability issues, we aimed to recruit this number of participants [28].

In-person 60-minute interviews were conducted by MD (primary author) to identify issues with the prototype interface and strategies and paths that participants use, including the time spent in completing tasks. Participants were interviewed in their own natural environment (ie, where they would likely use the *My Kidneys My Health* website), using their preferred devices (ie, desktop, laptop, tablet, and mobile phone).

Participants worked through 5 scenarios (Multimedia Appendix 3) while engaging in a think-aloud protocol (ie, participants communicated their thought processes verbally while performing prespecified tasks) and responded to a series of open-ended questions about the features, format, interface, and content [29]. The System Usability Scale (SUS) was completed by each participant to access the perceived usability [30].

Interviews were audio recorded and transcribed verbatim by a transcriptionist with experience in qualitative research. The interview transcripts were independently analyzed using directed content analysis by 2 research team members (MD and MS) applying a deductive approach to categorize what was useful and the areas to enhance [31]. This list was used by software developers to refine the *My Kidneys My Health* website prototype.

Results

Step 1: Creation of Website Features and Content

A total of 18 participants (14 patients and 4 caregivers) attended one of the 2 sequential focus groups. Tables 1 and 2 provide the participant characteristics. Among the participants, 72% (13/18) were male, 67% (12/18) were over the age of 65 years, 61% (11/18) had a secondary or postsecondary education, and 67% (12/18) used the internet for more than 10 hours per week. Overall, 86% (12/14) of the patient participants had at least one comorbidity, 79% (11/14) were diagnosed with CKD in the past 10 years, 72% (10/14) had less severe CKD, and 72% (10/14) perceived their health status as *good*. A total of 16 participants completed the eHEALS, with a mean score of 26.7 (range 15-32), demonstrating a variety of perceived ability to use information technology for health.

Table 1. Focus group participant characteristics (N=18).

Patient and caregiver characteristics	Participants, n (%)
Role	
Patient	14 (78)
Caregiver	4 (22)
Gender	
Male	13 (72)
Female	5 (28)
Age (years)	
Under 50	2 (11)
50-64	4 (22)
65-74	5 (28)
≥75	7 (39)
Marital status	
Common law	1 (6)
Married	13 (72)
Single or widowed	4 (22)
Geographical location (population)	
<500,000 (rural)	5 (28)
≥500,000 (urban)	13 (72)
Level of education	
Primary (≤grade 12)	7 (39)
Secondary (college, university, or trade school)	9 (50)
Postsecondary graduate	2 (11)
Level of employment	
Full-time	4 (22)
Other (home duties, unemployed, student, or retired)	14 (78)
Ethnicity	
White	18 (100)
Electronic devices commonly used (can use multiple devices)	
Mobile phone	10 (56)
Tablet	11 (61)
Laptop	9 (50)
Desktop	8 (40)
Electronic devices used (mobile phone, tablet, laptop, and desktop)	
1	4 (22)
2	9 (50)
3	4 (22)
4	1(6)
Internet use (hours per week)	
<4	4 (22)
4-9	2 (11)
10-15	8 (45)
>15	4 (22)

Table 2. Self-reported patient clinical characteristics (N=14).

Self-reported patient clinical characteristics	Participants, n (%)
Duration of CKD[a] diagnosis (years)	
≤5	9 (65)
6-10	2 (14)
≥11	3 (21)
Cause of CKD	
Diabetes and/or high blood pressure	5 (36)
Glomerulonephritis (eg, Immunoglobulin A nephropathy, lupus)	4 (29)
Other (eg, sepsis, hereditary, obstruction)	2 (14)
Unknown	3 (21)
Comorbidities (can have multiple comorbidities)	
Diabetes	2 (14)
High blood pressure	11 (79)
Cardiovascular disease	1 (7)
None	2 (14)
Number of comorbidities	
0	2 (14)
1	10 (72)
2	2 (14)
Stage of CKD (eGFR[b], mL/min/1.73 m^2)	
30-60	5 (36)
15-29	5 (36)
<15	1 (7)
Unknown	3 (21)
Perceived health status	
Excellent	0 (0)
Very good	1 (7)
Good	10 (72)
Fair	2 (14)
Poor	1 (7)

[a]CKD: chronic kidney disease.

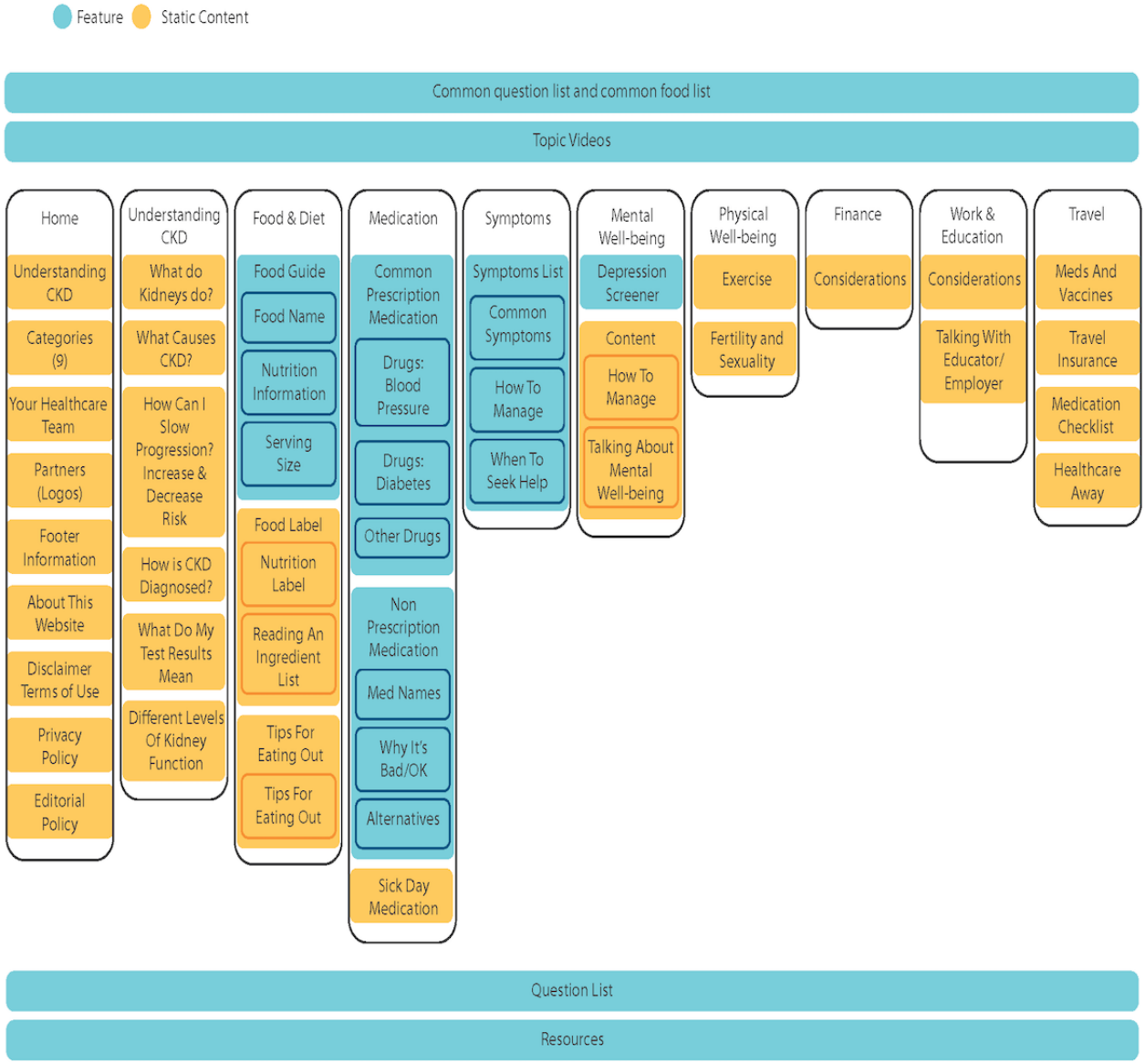
[b]eGFR: estimated glomerular filtration rate.

Participants from the first focus group endorsed the following features: interactive infographics about CKD, interactive food list and food label, customizable symptom list based on CKD severity, searchable medication list, and a screening tool for depression. Participants also suggested that the diet information should be customizable using food and nutrient filters to provide an individualized list of food items they could eat. They also recommended a personal list of questions for their health care provider based on their current information needs. The second focus group identified items on page layouts that were confusing or missing and provided suggestions for making them appropriate for users. They also provided visual and navigation suggestions as well as suggestions to incorporate video, text, audio, and visuals to convey information.

Further modifications were made to the *My Kidneys My Health* prototype and are represented on the website sitemap (Figure 4). The prototype consisted of 3 main components: videos, static content, and 4 interactive features. The first interactive feature included a *food guide/tool* that could be tailored to filter foods by nutrient content and a searchable database of over 400 common foods to create a personalized CKD-friendly food list that could be saved or emailed. The second feature was a search function specific to symptoms by CKD severity and medications by categories (ie, prescription, nonprescription, and sick day). The third feature was a validated screening tool for depression (ie, Patient Health Questionnaire-2) [32], and the fourth feature was a personalized list of questions to enhance communication

with health care providers. The personalized question list could also be saved or emailed.

Figure 4. Website sitemap.



Step 2: Heuristic Testing

Items that scored −1 (does not comply) and 0 (partially complies) were categorized by reviewers into *must* (ie, need to be addressed), *should* (ie, would like to be addressed), and *could* (ie, not necessary at this stage of development), with most items related to navigation and functionality; for example, the inclusion of a website navigation bar to move between website pages and the use of filters to personalize food choices for diet restrictions. Further modifications were made to the prototype before usability testing.

Step 3: Usability Testing

A total of 5 participant interviews (4 patients and 1 caregiver) were conducted; the participant characteristics are presented in Tables 3 and 4. After completing 5 interviews, we noted similar responses among participants with regard to the design, content, and navigation of the prototype. Among the participants, 60% (3/5) were male and were aged 65 years or above. A total of 80% (4/5) of the participants had postsecondary education and spent more than 15 hours a week on the internet. Furthermore, 75% (3/4) of the patients had less severe CKD. The mean total score for eHEALS was 29.6 (range 23-40).

Table 3. Usability testing participant characteristics (N=5).

Characteristic	Participants, n (%)
Role	
Patient	4 (80)
Caregiver	1 (20)
Gender	
Male	3 (60)
Female	2 (40)
Age (years)	
Under 50	2 (40)
50-64	0 (0)
65-74	3 (60)
≥75	0 (0)
Marital status	
Common law	1 (20)
Divorced	1 (20)
Married	1 (20)
Single	2 (40)
Geographical location (population)	
<500,000 (rural)	1 (20)
≥500,000 (urban)	4 (80)
Level of education	
Primary (≤grade 12)	1 (20)
Postsecondary (college, university, and trade school)	4 (80)
Graduate	0 (0)
Level of employment	
Full-time	1 (20)
Part-time	1 (20)
Retired	3 (60)
Ethnicity	
White	4 (80)
Visible minority	1 (20)
Electronic devices used (mobile phone, tablet, laptop, and desktop)	
1	1 (20)
2	1 (20)
3	2 (40)
4	1 (20)
Internet use (hours per week)	
<4	0 (0)
4-9	1 (20)
10-15	0 (0)
>15	4 (80)

Table 4. Self-reported patient clinical characteristics (N=4).

Characteristics	Participants, n (%)
Duration of CKD[a] diagnosis (years)	
≤5	2 (40)
6-10	1 (20)
≥11	1 (20)
Perceived level of health	
Excellent	0 (0)
Very good	2 (40)
Good	1 (20)
Fair	1 (20)
Poor	0 (0)
Stage of CKD (eGFR[b], mL/min/1.73 m^2)	
30-60	3 (75)
15-29	1 (25)
<15	0 (0)
Cause of CKD	
Diabetes	1 (20)
Diabetes and hypertension	1 (20)
Hypertension	1 (20)
Alport syndrome	1 (20)

[a]CKD: chronic kidney disease.

[b]eGFR: estimated glomerular filtration rate.

The usability categories reported on included video production, navigation, features and functionality, and branding. Participants reported that the following features were important for them to return to the website: personalized food tool, my health care provider question list, symptom guidance based on CKD severity, and medication advice. Usability was high, with a mean SUS score of 90 out of 100. Participants identified future considerations, including linking the website with a patient portal to upload personal health information and addressing other medical conditions such as diabetes (eg, add fat and sugar nutrient values to each of the food items).

Discussion

Principal Findings

Using an iterative 3-step system development cycle, we engaged patients and caregivers in the co-design and usability testing of the *My Kidneys My Health* website prototype. The application of the KTA framework enabled us to co-create a patient-facing CKD, self-management intervention grounded in evidence, patient preferences, and theoretical frameworks.

On the basis of patient and caregiver preferences, our website has the ability to inform through text, visuals, audio, and video (eg, CKD-related information); guide through interactive tools to make personalized recommendations to manage CKD and enhance quality of life (eg, food tool, screen for depression); and engage in communication with health care providers (eg, personalized list of questions for health care providers that can be emailed or saved) and peers (eg, links to nationwide support).

CKD self-management support interventions may consist of a variety of components, including education and management of the condition, information about resources, provision of action plans and equipment, monitoring of the condition, training, social support, and lifestyle advice [33]. A recent systematic review by Shen et al [34] evaluated the implementation and effectiveness of eHealth self-management interventions for patients with CKD. They identified 23 studies, with 9 studies using more than 1 eHealth technology (eg, telemedicine and wearable device). Only 3 studies reported using a computerized system (internet-based system where data are entered by a patient or provided by the system) with multiple functionality components (ie, record, communicate, alert, educate, and display) and a variety of intervention components (eg, education, plan/goals, and self-monitoring). The authors reported that overall eHealth self-management interventions were highly feasible, usable, and acceptable for patients with CKD; however, the 3 computer interventions were not developed using theory or in partnership with patients.

Although eHealth CKD self-management support interventions are burgeoning, interventions rarely consider a behavioral theoretical framework to investigate individual behavior change [7,34]. Our previous work explored the self-management behaviors of patients with CKD and their caregivers using the

theoretical domains framework [17]. The *My Kidneys My Health* prototype considers some of these behavior-change strategies (ie, education, modeling, persuasion, and environmental restructuring) [17]. Incorporating multiple behavior-change techniques can improve the effectiveness of eHealth interventions [35]. In terms of education, our website includes information on CKD-related information (topics identified by patients and caregivers), in addition to the consequences of certain health behaviors (eg, explaining *why* it is important to follow medication and diet advice). Although the website does not directly address modeling (ie, providing examples of others living with CKD), the website directs users to the Kidney Foundation of Canada (KFOC) website where there are stories and peer support opportunities. The *My Kidneys My Health* prototype provides an element of persuasion by providing credible information and resources. Finally, we address environmental restructuring by providing individuals with a web-based option where information and resources are accessible from any place users choose to engage in self-management support.

Meaningful patient involvement in our co-design process led to an intuitive and functional prototype. Our website architecture was logical to patients and caregivers and allowed users to follow their own personal journey, where they could have different paths depending on their needs. Participants indicated that they wanted information using a variety of formats (text, visuals, audio, and video) to address sensory needs (eg, vision and hearing deficits) and to be culturally sensitive. The system features can be tailored for each individual's context and changing life circumstances. For example, the interactive food tool can be used to create a personal list of foods based on restrictions at various times in the patient's health journey. Another unique feature of the *My Kidneys My Health* website is the personalized list of questions for their health care providers. Many patients with CKD, especially in the early stages, have difficulty comprehending the impact the illness can have on their lives. Involving patients in conversations with health care providers can increase their knowledge and develop confidence in managing their CKD [36]. An effective strategy is to use a question prompt sheet (prepared list of questions that the patients can review before their health care visit) [37]. Preliminary testing of question prompt sheets in nephrology has been undertaken [37,38] and shown to be feasible. However, they are limited in their current form, as they include preprescribed questions for selecting topic areas. The *My Kidneys My Health* prototype allows users to select relevant questions, save, and email questions at any time to themselves, family, and/or health care providers. Preloaded questions created by patients and caregivers are available under each topic area, and users can add or delete questions to create their own unique health-related question list. This list can prepare patients to initiate or enhance conversation with a variety of health care providers and empower them to take an active role in their care.

Strengths and Limitations

This study has several strengths. These include a person-centered, theory-informed, IKT approach where stakeholders were engaged throughout the process to build a multicomponent web-based self-management support for patients with CKD. However, this study also has limitations. The patient participants were from local CKD and general nephrology clinics, and the majority were older (aged >65 years) with less severe CKD. The website appears to be useful and accessible to older adults; however, the participants do not represent younger adults with CKD. Most of our participants were male, had high educational attainment, and indicated that they used the internet frequently (>10 hours a week). Selection bias is possible and may have favored individuals who had a relatively high education levels, were motivated to engage in self-management, and/or had an interest in technology-based interventions to manage their health. We also recognize the limited number of caregivers included, although the primary focus was on patients with CKD. Overall, other populations with CKD may identify different preferences for the website features based on their needs.

Conclusions

eHealth interventions show promise to support self-management for patients with CKD and to aid in slowing down or preventing the progression of the disease to kidney failure. We successfully co-designed and tested the usability of a multifaceted, self-management, web-based prototype for patients with CKD. It was guided by the preferences of patients with CKD and their caregivers using a systematic iterative process. Our eHealth tool informs, activates, and promotes communication with the intent to empower patients in their health care. Although many individuals may be willing and capable of using a web-based resource such as *My Kidneys My Health*, it is one of many strategies to enhance CKD self-management. The next phase of our work is to complete a feasibility study to determine the acceptability of and engagement with the prototype and identify preliminary patient-reported outcomes (eg, self-efficacy) and potential factors related to implementation. Our work is relevant given the shift to virtual care during the current pandemic and can support patients in managing their CKD.

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Authors' Contributions

All authors contributed to the research idea and study design. Data acquisition was done by MD, MS, and SG. The data analysis and interpretation were performed by MD, BH, MS, and SG. Each author contributed important intellectual content during manuscript drafting and revisions and accepts accountability for the overall work by ensuring that questions on the accuracy or integrity of any portion of the work are appropriately investigated and resolved. All authors read and approved the manuscript and agreed to act as guarantors of the work.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Interview Guide 1.
[DOCX File , 23 KB - formative_v5i2e22220_app1.docx]

Multimedia Appendix 2
Interview Guide 2.
[DOCX File , 23 KB - formative_v5i2e22220_app2.docx]

Multimedia Appendix 3
Usability scenarios.
[DOC File , 45 KB - formative_v5i2e22220_app3.doc]

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Abbreviations

CKD: chronic kidney disease
eHEALS: eHealth Literacy Scale
IKT: integrated knowledge translation
KTA: Knowledge-To-Action

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Original Paper

Evaluation of a Blended Relapse Prevention Program for Anxiety and Depression in General Practice: Qualitative Study

Esther Krijnen-de Bruin[1,2,3*], MSc; Jasmijn A Geerlings[2*], MSc; Anna DT Muntingh[1,2], PhD; Willemijn D Scholten[1,2], PhD; Otto R Maarsingh[4], MD, PhD; Annemieke van Straten[5], PhD; Neeltje M Batelaan[1,2], MD, PhD; Berno van Meijel[1,3,6], PhD

[1]Amsterdam UMC, Vrije Universiteit, Psychiatry, Amsterdam Public Health research institute, Amsterdam, Netherlands

[2]GGZ inGeest Specialized Mental Health Care, Amsterdam, Netherlands

[3]Health, Sports & Welfare, Cluster Nursing, Inholland University of Applied Sciences, Amsterdam, Netherlands

[4]Amsterdam UMC, Vrije Universiteit, General Practice & Elderly Care Medicine, Amsterdam Public Health research institute, Amsterdam, Netherlands

[5]Amsterdam UMC, Vrije Universiteit, Clinical Psychology, Amsterdam Public Health research institute, Amsterdam, Netherlands

[6]Parnassia Psychiatric Institute, Parnassia Academy, The Hague, Netherlands

[*]these authors contributed equally

Corresponding Author:
Esther Krijnen-de Bruin, MSc
Amsterdam UMC, Vrije Universiteit
Psychiatry
Amsterdam Public Health research institute
De Boelelaan 1117
Amsterdam
Netherlands
Phone: 31 884662683
Email: esther.krijnendebruin@inholland.nl

Abstract

Background: Existing studies have yet to investigate the perspectives of patients and professionals concerning relapse prevention programs for patients with remitted anxiety or depressive disorders in primary care. User opinions should be considered when optimizing the use and implementation of interventions.

Objective: This study aimed to evaluate the GET READY relapse prevention programs for patients with remitted anxiety or depressive disorders in general practice.

Methods: Semistructured interviews (N=26) and focus group interviews (N=2) with patients and mental health professionals (MHPs) in the Netherlands were performed. Patients with remitted anxiety or depressive disorders and their MHPs who participated in the GET READY study were interviewed individually. Findings from the interviews were tested in focus group interviews with patients and MHPs. Data were analyzed using thematic analysis.

Results: Participants were positive about the program because it created awareness of relapse risks. Lack of motivation, lack of recognizability, lack of support from the MHP, and symptom severity (too low or too high) appeared to be limiting factors in the use of the program. MHPs play a crucial role in motivating and supporting patients in relapse prevention. The perspectives of patients and MHPs were largely in accordance, although they had different perspectives concerning responsibilities for taking initiative.

Conclusions: The implementation of the GET READY program was challenging. Guidance from MHPs should be offered for relapse prevention programs based on eHealth. Both MHPs and patients should align their expectations concerning responsibilities in advance to ensure optimal usage. Usage of blended relapse prevention programs may be further enhanced by diagnosis-specific programs and easily accessible support from MHPs.

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KEYWORDS

relapse prevention; anxiety disorder; depressive disorder; eHealth; general practice; qualitative research

Introduction

The high prevalence of anxiety and depressive disorders is a major public health problem, affecting 615 million people globally [1]. Although effective treatment interventions (psychological as well as pharmacological) are available [2-5], 57% of patients in remission from anxiety disorders or depression experience a relapse within 4 years [6]. Effective relapse prevention provided in general practice could increase quality of life, decrease the high burden of disease for patients with anxiety and depressive disorders, and prevent the need for treatment in a (more costly) specialized mental health care setting [7].

Existing knowledge about effective components of relapse prevention programs and effective ways of implementation remains limited. Several effective relapse prevention programs for patients with remitted depressive disorders were examined in a meta-analysis by Biesheuvel-Leliefeld et al [8], although few studies on relapse prevention concern patients with anxiety disorders [9-12]. A limited number of relapse prevention programs use eHealth, even though it offers improved access to evidence-based treatments [13]. Results concerning effectiveness in these guided eHealth studies for patients with remitted depressive disorders are conflicting: One reports a lower relapse rate after 2 years, while another does not [14,15]. Two other studies, both guided [16] and unguided [17], report a decrease in residual depressive symptoms after participating in an online relapse prevention intervention [16,17]. Variations in type of treatment, guidance, and the duration of the intervention might explain the conflicting results of these studies.

Knowledge concerning how patients and professionals value these programs is lacking. Also, knowledge regarding the appreciation of specific program components is missing. Additional insight into the valuation, feasibility, and usability of relapse prevention programs could allow optimization of such programs, as well as their implementation and use.

To our knowledge, no previous studies have investigated the perspectives of users concerning relapse prevention programs in general practice, although some do focus on users' perspectives regarding blended interventions (eHealth combined with face-to-face contact) for depression treatment. In a study on the perspectives of patients concerning a blended cognitive behavioral therapy program for depression, Urech et al [18] reported that patients appreciate the constant availability of the online program and the possibility of reflecting on their progress. At the same time, however, patients feel pressure to complete modules, experience a lack of flexibility, and have difficulty finding motivation to complete the online modules.

In addition to the patients' perspectives on relapse prevention interventions, it is important to consider the perspectives of the professionals providing the program: If professionals do not support the intervention, patients are less likely to use it [19]. According to professionals, advantages of blended interventions include access to online content between face-to-face sessions for patients and the fact that the structure of the online format provides focus in the treatment. At the same time, however, professionals note that technical issues could be burdensome to patients, and they do not appreciate the limited possibility of customization for online programs [20].

This article describes findings from a qualitative study conducted as part of the GET READY (Guided E-healTh for RElapse prevention in Anxiety and Depression) study [21], in which a blended relapse prevention program tailored to the patients' preferences [22] was developed and tested. The overall aims of the GET READY study were to implement and evaluate the GET READY relapse prevention program. This program is offered by mental health professionals (MHPs) in general practices in the Netherlands to patients who are in remission from anxiety or depressive disorders.

The aim of the current study was to provide insight into the perspectives of users (both patients and MHPs) on the GET READY relapse prevention program, specifically regarding expectations of the program, attractiveness of the program, collaboration and communication between patients and MHPs, usability (especially in case of an increase of symptoms), and subjective effectiveness. In addition, the aim was to provide insight into factors that influence the use and implementation of the GET READY program in general practice.

Methods

Study Design

We conducted a qualitative study as part of the GET READY study. First, semistructured individual interviews were conducted with pairs of patients and MHPs. We then conducted 2 focus group interviews—one with patients and one with MHPs—to reflect on the findings from the individual qualitative interviews. The COnsolidated criteria for REporting Qualitative studies guideline [23] was followed in reporting on this study. The completed checklist can be found in Multimedia Appendix 1.

Sampling and Recruitment for the Qualitative Study

For the individual interviews, purposive sampling was performed (based on sex, age, clinical variables, and place of residence) among all 113 patients participating in the GET READY intervention program, with the aim of including 12-15 patients and 12-15 of their MHPs. All patients enrolled in the GET READY study were at least in partial remission from an anxiety or depressive disorder and had completed treatment in specialized mental health care within the past 2 years. The researchers invited patients to participate in the individual interviews by telephone or email. The MHPs of patients agreeing to participate were invited to participate as well. In the Netherlands, most general practices employ MHPs—with professional backgrounds in community mental health, social work, or psychology—to provide mental health services [24]. Besides screening, diagnostics, providing psychoeducation, and

supporting self-management, one of their tasks is to support relapse prevention [25]. Patients whose MHPs declined to participate were not interviewed. By interviewing both the patient and their MHP, we aimed to gain insight into similarities and differences in perspectives within and between these groups.

For the 2 focus groups, patients and MHPs received invitations by email. Patients and MHPs participating in the individual interview could also participate in the focus group interviews.

All participants gave written informed consent and were offered a €25 (US $30.34) gift voucher for participating in the individual or the focus group interviews. The Medical Ethical Committee of the VU University Medical Center Amsterdam judged that ethical approval was not required according to Dutch legislation. The methods of the full GET READY study are described in detail in the study protocol [21]. The GET READY program consists of 3 core components: (1) relapse psychoeducation module, (2) relapse prevention plan, and (3) weekly diary in which patients can monitor their symptoms. Furthermore, 12 optional eHealth modules are offered. All modules are focused on promoting self-management skills, by providing information, exercises, videos, and examples of fictive patients. As described, this program is offered to patients by MHPs. Patients had at least one face-to-face contact with their MHP during the GET READY study and were encouraged to visit their MHP once every 3 months, for a period of 9 months. Further details about the GET READY intervention can be found in Multimedia Appendix 2.

Data Collection

The interviews were conducted individually with patients and MHPs by JG, EKB, and two Master's students in medicine. All researchers had prior experience with qualitative research. Separate topic lists were developed for patients and MHPs (see Multimedia Appendix 3 and Multimedia Appendix 4), based on the aims of the study, the content of the GET READY intervention, the Consolidated Framework for Implementation Research [26], and literature on qualitative research [27,28]. In short, the topic lists contained questions regarding expectations of the program, attractiveness of the program, collaboration and communication between patients and MHPs, usability (especially in case of an increase of symptoms), and subjective effectiveness of the relapse prevention program. The interviewers did not know the patients in advance. Although they were familiar with the researchers, the MHPs were encouraged to express all comments and criticism they might have.

The interviews were conducted in the patients' homes or the general practice location between February 2018 and February 2019. Each interview lasted about 45 minutes. Data collection and analysis occurred in an iterative process, with intermediate analyses guiding subsequent data collection [29]. Data were collected until data saturation was reached (ie, when no new themes emerged from the interviews).

After completing the individual interviews, 2 focus group interviews were conducted in June 2019 and September 2019 at the research clinic, one with patients and one with MHPs. These interviews were moderated by BM, an experienced researcher in the field of qualitative methodology. In the focus group interviews, preliminary findings from the individual interviews were presented, and input from participants was collected about their perceptions on remarkable findings in the data. Each focus group interview lasted about 90 minutes.

Individual interviews and focus group interviews were audio recorded, transcribed verbatim, and summarized. The transcripts were checked for accuracy (by reading and listening) and corrected as needed by EKB. Participants were anonymized from transcription to the reporting of the data, with only the interviewers having access to the identification key.

Data Analysis

Data from the first sequence of individual interviews were analyzed according to the 6 steps of thematic analysis suggested by Braun and Clarke [29]. All interviews were read and re-read carefully, and initial ideas about the content of the data were recorded in the field notes (Step 1). All interviews were coded independently by 2 researchers using MAXQDA 12 [30] (EKB and JG or Master's student). This was followed by comparing the codes and resolving disagreements through discussion. After 3 interviews, a first draft of the coding tree was prepared, and it was supplemented or adjusted regularly, based on the intermediate analyses of data (Step 2). We searched the coded data for themes, which we subsequently reviewed and defined. Preliminary themes and subthemes were discussed within the project group. Coded segments were divided among the themes and read carefully, and relevant segments were selected. A summary was prepared for each theme (Steps 3, 4, and 5). The final step consisted of producing a comprehensive and detailed report of relevant segments for each theme and selecting the most compelling ones.

Results

Demographic and Clinical Characteristics

Demographic and clinical variables of the patients and MHPs are presented in Table 1. Our sample contained 13 pairs of patients and their MHPs, resulting in 26 individual interviews. One MHP was interviewed twice about 2 different patients. Seven patients participated in the focus group interview. None of the patients participated in both the individual and focus group interviews. Six MHPs participated in the other focus group interview, 2 of whom had also participated in an individual interview. Reasons for nonparticipation are provided in Multimedia Appendix 5.

Table 1. Demographic and clinical characteristics of patients and mental health professionals (MHPs).

Characteristics	Individual interviews		Focus group interviews	
	Patients (n=13)	MHPs (n=12)	Patients (n=7)	MHPs (n=6)
Age range (years)	21-63	27-58	31-70	41-60
Age (years), n				
20-39	6	4	2	0
40-59	5	8	3	5
≥60	2	0	2	1
Sex, n				
Female	9	11	4	5
Male	4	1	3	1
Diagnosis (in remission), n				
Anxiety disorder	4	N/A[a]	2	N/A
Depressive disorder	4	N/A	0	N/A
Anxiety and depressive disorder	5	N/A	5	N/A

[a]N/A: not applicable.

Overview of the Themes

Three central themes emerged from the data: "perceived value of the relapse prevention program," "usability of the relapse prevention program," and "need for guidance." Each theme is considered in detail in the following paragraphs, and an overview of the themes can be found in Table 2.

Table 2. Overview of the main themes and subthemes and a description of their content.

Main and subthemes	Content
Perceived value of the relapse prevention program	
Prior expectations	Positive expectations of patients and MHPs[a] before using the program increased motivation for use
Evaluation of the program	Attitudes towards the program and its (subjective) effects (eg, increased awareness of relapse risks)
Factors inhibiting use of the program	Specific factors that reduce motivation to use the program (eg, absence of current symptoms)
Usability of the relapse prevention program	Technical aspects, attractiveness, and reflection on choices in the design of the program (eg, positive or negative views about reminders)
Need for guidance	
Personal contact is essential	Added value of personal contact with MHP, prerequisite for active use of the program
Initiating contact	Belief that the other party (ie, patient or MHP) is responsible for taking initiative

[a]MHPs: mental health professionals.

Perceived Value of the Relapse Prevention Program

The first theme emerging from the data was the "perceived value of the relapse prevention program." This theme was defined using 3 subthemes: (1) prior expectations, (2) evaluation of the program, and (3) factors inhibiting use of the program.

Prior Expectations

Prior expectations of the relapse prevention program and, by extension, motivation for its use were related to several factors, starting with the current level of symptoms experienced by patients, along with the perceived risk of relapse and the expectation that the relapse prevention program could relieve symptoms. MHPs mentioned that they noticed these factors in their patients, and patients also mentioned these factors. Patients who had current symptoms, a high perceived risk of relapse, and a belief that the program could help prevent relapse appeared to have a high motivation for active use of the program.

Evaluation of the Program

Many patients mentioned the importance of the relapse prevention program following recovery from anxiety or depressive disorders. They particularly appreciated the active

role assigned to the patients themselves within the program, thereby encouraging them to be active participants in their process to remain well. According to the patients, the program raised awareness of relapse risks:

> *I find it very useful to raise my own awareness, so that I become more aware of the impact I can have, and therefore be more active in my own recovery.* [34003, female, 42 years old]

The focus group with patients showed that, given the diversity of modules, the relapse prevention program had relevant components for all patients. Several patients explicitly mentioned that the program provided a sense of security and stability at times when they showed signs of impending relapse.

Factors Inhibiting Use of the Program

Patients with few or very few symptoms believed that they would experience few, if any, benefits from participating in the program, thereby reducing their motivation to use or continue to use the program. Patients in this relatively stable situation found it more difficult to imagine the possibility of a future relapse, and they saw no immediate need to engage in active relapse prevention. On the other hand, having many symptoms could also hinder the use of the program, as a perceived lack of concentration and energy was a reason for decreased use.

According to MHPs, some patients feared that the use of the relapse prevention program could actually lead to dysregulation:

> *But at times I got the impression that people thought "yes, I'm doing well now" and that they were frightened that if they were to do something about their condition, they would feel less well.* [MHP 39, female]

Usability of the Relapse Prevention Program

Many patients and MHPs considered the online modules inviting, due to their appealing layout and normalizing effect. They indicated that the program normalized vulnerability to relapse: Completing mental health care treatment does not mean that all the symptoms and problems have been overcome nor that aggravation of symptoms can be ruled out in the future. Several patients and MHPs found the program easy to use:

> *Thought it was really good. I thought it was well structured. Clear, simple to use for both the MHP and the patient.* [MHP 39, female]

The relapse prevention program provided MHPs with practical tools for cooperating with patients in relapse prevention. The patients were motivated by the targeted suggestions for choosing relevant modules, given their problems and needs at that time. Moreover, they felt that the content of the eHealth modules corresponded to previous treatment in specialized mental health care. Some patients appreciated receiving this information again, especially as they had forgotten some of the content.

In contrast, some patients were annoyed by the repetition of information from previous treatment. Some patients found the program's focus on anxiety *and* depression restrictive. In their opinion, this did not enhance recognizability, particularly for those who had experienced only 1 of the 2 disorders.

One adverse aspect of the practical usability was that patients had to log on to a computer to work with the online modules. The patients suggested that it would have been easier to use an app. Patients participating in the focus group regarded the pressure caused by the program (by reminders and mandatory fields) as unpleasant and often irritating. On the other hand, the reminders in the program were sometimes also seen as a necessary "stick," which actually helped patients to continue with the program.

Patients did not always agree with each other. While some appreciated the clarity of the eHealth program, others found navigating the online platform confusing, as they had no clear overview of the available modules. They would have preferred a more intuitive program:

> *I sometimes found the navigation on the site rather complicated. It wasn't very logical.* [25002, female, 40 years old]

This was confirmed by patients and MHPs participating in the focus groups.

Need for Guidance

The third theme relates to the "Need for guidance." Both patients and MHPs considered the quality of the contact between patients and MHPs essential for effectiveness in preventing relapse.

Personal Contact is Essential

After patients started using the eHealth modules, patients and MHPs were encouraged to have personal contact with each other once every 3 months. Patients indicated that contact with their MHPs was particularly vital to helping them use or continue to use the eHealth modules in times of reduced stability.

Several patients reported having become aware of their current symptoms when preparing for their contact with their MHPs, because they knew that symptom levels would be discussed. The very prospect of the meeting seemed to increase awareness, which benefitted the focus of the conversation.

Both groups identified the combination of the eHealth program and the personal contact between patients and MHPs as a factor facilitating the use of the program. They noted that these elements complement and reinforce each other and that they would be of less value separately:

> *I don't think it's possible to do it just with eHealth. And only seeing an MHP wouldn't work either as this is just a snapshot in time and it's difficult to provide all the background information during that session. eHealth provides more background information, while the MHP gives practical tips.* [54001, female, 30 years old]

MHPs reported being happy to get patients started with eHealth modules, as this meant that the patients would have an active role in their own recovery:

> *It is good to be able to work with the relapse prevention program, in whatever form, in between the sessions and not just let it come down to those 30 or 40 minutes a month.* [MHP 25, male]

The combination of reminders from the eHealth program and the MHP provided an incentive for active use of the program. In the focus group interview with patients, it became apparent that patients receiving more support from an MHP appreciated the relapse prevention program more than patients who had received less or minimal support. The latter group indicated that they would have preferred to receive more support from the MHP in using the eHealth program.

The focus groups with patients and MHPs clearly indicated the importance of tailoring the level of support to individual patients, taking into account their coping styles and current symptom levels. The data further suggest the need to establish who will take primary responsibility when symptoms increase: Is the patient able to do this, or is active support by the MHP needed?

Initiating Contact

During the focus group interviews, MHPs clearly differed from patients in their task interpretations. The MHPs strongly emphasized the patient's self-management skills, while patients expected MHPs to play a more active role if and when symptoms were to get worse. The capacity of MHPs was an impeding factor, placing limits on the active approach and support of patients. As a result, patients requiring more support were not always reached successfully:

> *Our consultation hour is busy enough, so if, for instance, someone doesn't show up twice in a row for an appointment, and you have called them, then that's it. After all, we have so many patients who can't wait to get an appointment, so that also plays a role.* [MHP 34, female]

Discussion

Principal Findings

Both the patients and MHPs in our study were predominantly positive about the blended relapse prevention program. It created awareness of relapse risks, and users appreciated its usability and accessibility. Lack of motivation, lack of recognizability, lack of support from the MHP, and symptom severity (too low or too high) appeared to be limiting factors in the use of the program. The implementation of the program was thus challenging. Several patients and MHPs regarded the program as easy to use and clearly structured, although others referred to a lack of intuitive design and overview of modules. Patients and MHPs agreed that the combination of eHealth modules and face-to-face contact is essential. According to the respondents, the MHP plays a crucial role in motivating and supporting patients in the use of the relapse prevention program. Surprisingly, the level of agreement between MHPs and their patients was high. The paired interviews revealed no striking discrepancies within the pairs of patients and MHPs. However, the focus group interviews did reveal significant discrepancies, as MHPs assumed a certain level of self-management skills in patients, while patients articulated their limitations in this respect, expressing a desire for more direct and personalized support from their MHPs.

Limitations

This study has several limitations. One limitation of this study is the possibility of response bias, as patients knew the objectives of the study and might have given socially desirable answers. At the start of the interviews, we emphasized our openness to all feedback, including critical comments on the program. There was also a risk of selection bias, with participants who agreed to participate in the interviews possibly having been more positive towards the program than those who did not participate. Nonetheless, both positive and negative perspectives were explicitly discussed during the interviews. Furthermore, recall bias might have occurred, given the time elapsed between completing the program and the individual interview or focus group interview for some patients (range: 0-6 months for the individual interviews and 0-12 months for the focus group interviews). We noticed that some patients tended to forget which eHealth modules they had completed and whether they had received online feedback. To reduce this bias, patients could request an overview of their completed modules and number of feedback messages to and from the MHP during the interview. In addition, patients could remain engaged after the intervention period, as they received monthly newsletters about the study and still had access to the program. The longer duration between completion of the program and the focus group interviews was caused by the fact that the focus group interviews could be prepared and conducted only after all individual interviews were conducted and analyzed.

Comparison With Prior Work

The positive attitudes of MHPs and patients towards the program and the perceived increase in awareness of relapse risks are consistent with findings from previous research on relapse prevention for depression [31-33].

Our study revealed several factors influencing implementation, including motivation, recognizability, support received from the MHP, and symptom severity. Program use and implementation are facilitated by motivation and the perceived effectiveness of the program, as well as by the presence of current symptoms and the perceived high risk of future relapse. These findings are consistent with previous findings [34,35] demonstrating that motivation and perceived effectiveness increase adherence. On the contrary, lack of motivation impeded the use of the program, specifically in patients with few symptoms. A similar finding was suggested by Biesheuvel-Leliefeld et al [36], who may have found an indication of motivation issues among remitted patients, as they had major difficulties recruiting participants for their relapse prevention study. Another factor influencing use and implementation in our study was recognizability. This seems to correspond to findings reported by Gerhards et al [34] that patient perceptions that a program is not applicable to them act as a barrier to program usage. Our results further indicate that program implementation is determined by whether patients received support from their MHPs. This finding has also been reported in previous studies [31,33,34,37,38]. Accessible personal contact with and an active approach by the MHP appears to be the key to successful implementation of a program.

No unambiguous confirmation regarding the influence of symptom level on implementation and usage of relapse prevention programs was found in the literature. Interestingly, we found that both excessively low and excessively high perceived symptom levels hindered program use and implementation. According to a literature review on dropout from internet-based treatment, adult patients with few symptoms of any psychological disorder *and* those with more severe depressive symptoms were more likely to dropout from these treatments [39]. These findings might be generalizable to relapse prevention programs for anxiety and depressive disorders, as the setup of such internet-based treatments is similar to that of existing relapse prevention programs.

We identified different perspectives regarding responsibilities, with MHPs perceiving patients to be remitted and therefore relying on their self-management skills, while patients expected support and monitoring from their MHPs, particularly when symptoms worsened. A parallel finding is described in previous literature [40], with patients feeling that general practitioners should initiate contact, while general practitioners expect patients to contact them if needed. We found that these different expectations also exist between MHPs and patients, which has not been described before in the scientific literature.

Implications for Practice and Research

The present study highlights the importance of guidance in eHealth-based relapse prevention for anxiety and depression. The level of guidance from and engagement of the MHP emerged as crucial factors in the success of the relapse prevention program. The self-management skills of patients and desired level of support should thus be aligned in advance, particularly in case of worsening symptoms.

Because self-management skills might differ over time, among other things depending on symptoms, it is essential to discuss and align needs over the course of the contacts, possibly enhancing implementation of relapse prevention programs based on eHealth.

Given the lack of studies specifically addressing associations between symptom levels and adherence to relapse prevention programs, further quantitative studies on this association are needed. One appropriate design could involve using Ecological Momentary Assessment [41] to assess symptom levels and log data from an eHealth platform to assess adherence.

When developing new relapse prevention interventions, attention should be paid to accessible guidance by professionals, accessibility through an app, along with a clear and intuitive, flexible structure for the eHealth component. Also, specific interventions for specific diagnoses might increase recognizability.

Conclusions

Our findings suggest that personalized guidance from MHPs should be offered for eHealth-based relapse prevention programs, taking into account the preferences of patients and their level of self-management competencies. Both MHPs and patients should align expectations and needs in advance, as well as during the intervention, in order to increase implementation and enable optimal usage.

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Authors' Contributions

EKB, AM, OM, AVS, NB, and BM designed the study. EKB and JG recruited participants for the interviews and focus group interviews. EKB and JG conducted interviews and were primary analysts of the data. BM moderated the focus group interviews. AM and BM consulted on the data analysis. EKB and JG wrote the first draft of the manuscript. All authors discussed interpretation of results and contributed to and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
COREQ checklist.
[DOCX File , 19 KB - formative_v5i2e23200_app1.docx]

Multimedia Appendix 2
GET READY intervention.
[DOCX File , 66 KB - formative_v5i2e23200_app2.docx]

Multimedia Appendix 3
Topic guide interview patient.

[DOCX File , 18 KB - formative_v5i2e23200_app3.docx]

Multimedia Appendix 4
Topic guide interview MHP.
[DOCX File , 18 KB - formative_v5i2e23200_app4.docx]

Multimedia Appendix 5
Reasons for nonparticipation.
[DOCX File , 17 KB - formative_v5i2e23200_app5.docx]

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Abbreviations

GET READY: Guided E-healTh for RElapse prevention in Anxiety and Depression
MHP: mental health professional

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Original Paper

A Novel Food Record App for Dietary Assessments Among Older Adults With Type 2 Diabetes: Development and Usability Study

Hyunggu Jung[1,2], PhD; George Demiris[3], PhD, FACMI; Peter Tarczy-Hornoch[4,5,6], MD, FACMI; Mark Zachry[7], PhD

[1]Department of Computer Science and Engineering, University of Seoul, Seoul, Republic of Korea

[2]Department of Artificial Intelligence, University of Seoul, Seoul, Republic of Korea

[3]Department of Biobehavioral and Health Sciences, University of Pennsylvania, Philadelphia, PA, United States

[4]Department of Biomedical Informatics and Medical Education, University of Washington, Seattle, WA, United States

[5]Division of Neonatology, Department of Pediatrics, University of Washington, Seattle, WA, United States

[6]Department of Computer Science and Engineering, University of Washington, Seattle, WA, United States

[7]Department of Human Centered Design and Engineering, University of Washington, Seattle, WA, United States

Corresponding Author:
Hyunggu Jung, PhD
Department of Computer Science and Engineering
University of Seoul
Information and Technology Building
163 Seoulsiripdae-ro, Dongdaemun-gu
Seoul, 02504
Republic of Korea
Phone: 82 2 6490 2455
Email: hjung@uos.ac.kr

Abstract

Background: More than 1 in 4 people in the United States aged 65 years and older have type 2 diabetes. For diabetes care, medical nutrition therapy is recommended as a clinically effective intervention. Previous researchers have developed and validated dietary assessment methods using images of food items to improve the accuracy of self-reporting over traditional methods. Nevertheless, little is known about the usability of image-assisted dietary assessment methods for older adults with diabetes.

Objective: The aims of this study were (1) to create a food record app for dietary assessments (FRADA) that would support image-assisted dietary assessments, and (2) to evaluate the usability of FRADA for older adults with diabetes.

Methods: For the development of FRADA, we identified design principles that address the needs of older adults and implemented three fundamental tasks required for image-assisted dietary assessments: capturing, viewing, and transmitting images of food based on the design principles. For the usability assessment of FRADA, older adults aged 65 to 80 years (11 females and 3 males) were assigned to interact with FRADA in a lab-based setting. Participants' opinions of FRADA and its usability were determined by a follow-up survey and interview. As an evaluation indicator of usability, the responses to the survey, including an after-scenario questionnaire, were analyzed. Qualitative data from the interviews confirmed the responses to the survey.

Results: We developed a smartphone app that enables older adults with diabetes to capture, view, and transmit images of food items they consumed. The findings of this study showed that FRADA and its instructions for capturing, viewing, and transmitting images of food items were usable for older adults with diabetes. The survey showed that participants found FRADA easy to use and would consider using FRADA daily. The analysis of the qualitative data from interviews revealed multiple categories, such as the usability of FRADA, potential benefits of using FRADA, potential features to be added to FRADA, and concerns of older adults with diabetes regarding interactions with FRADA.

Conclusions: This study demonstrates in a lab-based setting not only the usability of FRADA by older adults with diabetes but also potential opportunities using FRADA in real-world settings. The findings suggest implications for creating a smartphone app for an image-assisted dietary assessment. Future work still remains to evaluate the feasibility and validity of FRADA with multiple stakeholders, including older adults with diabetes and dietitians.

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KEYWORDS

mobile health; older adults; diabetes; dietary assessment; smartphone app; usability test

Introduction

Older Adults with Type 2 Diabetes

Approximately 1 in 10 people in the United States has type 2 diabetes. More than 1 in 4 Americans aged 65 years and older have type 2 diabetes [1]. As the population of individuals aged 65 or over is anticipated to reach approximately 74 million by 2030 [2], it is expected that the population of older adults with diabetes will increase accordingly. Diabetes has a tremendous impact on the health of the US population. In 2013, it was reported that diabetes was the seventh leading cause of death [3]. Also, it is known that diabetes increases the risk of heart attack and stroke [1], as well as the risk of cancer, especially colorectal cancer [4-6]. Diabetes has a disproportionate impact on the health of older adults. Diabetes is known as the leading cause of blindness and kidney failure in older adults. Older adults with diabetes are two times more likely to develop dementia than older adults without diabetes [7]. Furthermore, 1 in 5 people aged 65 years and older has vision problems [7], and 1 in 3 adults with diabetes may have chronic kidney disease. Moreover, it is known that people over 75 years of age with diabetes are two times more likely to visit the emergency room for low blood glucose than younger patients with diabetes [7]. Diabetes also takes a financial toll. The estimated total costs of diagnosed diabetes in the United States rose to $327 billion in 2017 from $245 billion in 2012, which was a 41% increase in a 5-year period [8,9]. The total costs in 2017 included $237 billion for direct medical costs and $90 billion for indirect costs, such as inability to work as a result of disease-related disability, reduced productivity for those not in the labor force, and lost productive capacity due to early mortality [8,9]. The estimated costs imply that diabetes produces explicit and inexplicit burdens to both individual patients and society as a whole.

Medical Nutrition Therapy (MNT)

To improve diabetes care, the American Diabetes Association suggests a multipronged strategy to support the patients' behavior change efforts including healthy lifestyle changes (eg, physical activity, healthy eating, tobacco cessation, weight management, and effective coping), disease self-management, and prevention of diabetes complications [10]. MNT is recommended for individuals with diabetes as part of their overall treatment plan [3] to achieve the goals of nutritional therapy [11]. In particular, MNT is recommended as a clinically effective model to take care of individuals with diabetes [12-15], including older adults [16]. In order to meet treatment goals, individuals with diabetes are required to receive personalized MNT from registered dietitians and nutrition professionals [3].

Traditional Dietary Assessment Methods

For dietary advice, it is essential for dietitians to assess the nutritional status of patients with a variety of dietary data, such as meal patterns, food choices, and overall dietary balance. To collect such dietary data from each patient, dietitians use methods such as food records and 24-hour dietary recall (24HR). The food records method is an approach in which the patient is asked to write down all food items and the amounts consumed over one or more days. The objective of this method is to obtain a detailed description of food intake, including types and amounts of foods and beverages they have consumed. Since this method allows respondents to record their food intake right after they have consumed it, they do not have to rely on recalled memories of their meals. On the other hand, the 24HR method is an approach to get retrospective information about food consumption patterns through interviews with the patient. While the food records method needs some level of literacy to produce the records, the 24HR method does not require knowing how to describe food items to dietitians because a dietitian speaks with the respondent directly during the interview.

However, it is difficult to obtain accurate nutritional information using these methods because they are based on self-reported data. For instance, respondents would need to have strong motivation and literacy to keep recording their food intake using the food records method. Individuals tend not to maintain regular performance on such tasks over long periods [17]. Instead, they might prefer recording the food items for three meals at the same time based on memory instead of documenting the information every single time. In addition, the 24HR method requires individuals to recall the food items they consumed and the specific amounts they consumed [18]. Individuals might forget to mention all of the food items. Additionally, they might have trouble identifying the contents of the food items and estimating portion sizes. It might be particularly difficult to collect reliable data from older adults using traditional methods for dietary assessment because they have special considerations (eg, dietary restrictions) and diminished functional statuses. For example, the 24HR method might be inappropriate because memories among older adults are more likely to be impaired than those of younger adults [19,20]. In one study, older adults did not report energy intake adequately during the 24HR assessment [21].

Dietary Assessment Methods Using Food Images

To overcome the limitations of self-reporting by traditional methods for a dietary assessment, researchers have developed and validated dietary assessment methods using images of food items to improve the accuracy of self-reporting over traditional methods. Prior studies demonstrated the benefits of using images of food items. For example, they revealed that the use of images of food items led to identifying unreported foods and misreporting errors [22-24]. The dietary information from the images enabled researchers to identify additional energy intake of the given food items [22-24].

In other studies, researchers evaluated image-assisted 24HR methods using a variety of devices (Table 1). Prior studies not only showed how image-assisted dietary assessment methods reduced errors in self-reported data but also validated the use of an image-assisted dietary assessment method with general populations. Four studies recruited healthy adults [22,25-27] and the maximum mean age of the participants across the studies was 35 years [22,25,27-29]. One study included adults with

intellectual and developmental disabilities [30], but no studies recruited participants with any chronic diseases nor had participants aged 65 years or older to evaluate the image-assisted dietary assessment methods. The sample sizes of prior studies were small: four studies had between 20 and 54 participants [26-29] and two studies had fewer than 20 participants [22,25]. In regard to the approach used to capture images, three studies used passive image capture with wearable cameras [22,25,28], while three studies used active image capture with a handheld digital camera [27], iPad 2 (Apple Inc) [29], or smartphone [26].

Table 1. Characteristics of image-assisted 24-hour dietary recall methods.

Study	Participants	Age of participants (years), mean (SD)	Device for image collection	Capture	View	Transmit
[25]	14 healthy adults	35 (12)	Mobile phones with camera	✓	✓	✓
[27]	43 healthy adult women	35 (9)	Digital camera	✓	✓	Not reported
[22]	10 healthy adults	33 (11)	SenseCam	✓	✓	✓
[29]	23 adults with intellectual and developmental disabilities	26.4 (9.7)	iPad 2 (Apple Inc)	✓	✓	Not reported
[26]	54 healthy adults	Range: 19-28	Smartphone	✓	✓	✓
[28]	40 adults (20 females, 20 males)	Females: 28 (7); males: 35 (17)	SenseCam	✓	✓	✓

We found two gaps after reviewing those studies. First, no studies have evaluated the usability of image-assisted dietary assessment methods with older adults with diabetes. Second, little is still known about the usability of the image-assisted dietary assessment methods using smartphone apps, although a smartphone is the type of device that could perform the following three fundamental tasks required for image-assisted dietary assessments: (1) capturing images of food and beverages, (2) viewing images of food and beverages, and (3) transmitting images of food and beverages. Table 1 shows the characteristics of image-assisted 24HR methods.

To address those gaps, we aimed to answer multiple research questions through surveys and interviews (see Textbox 1). The specific aims of our study were (1) to develop a smartphone app for image-assisted dietary assessments, and (2) to evaluate the usability of the app by older adults with diabetes. Specifically, no data on the accuracy of identifying foods and estimating portion sizes were reported in this study.

Textbox 1. Research questions we aimed to answer through surveys and interviews.

- RQ1: How likely is it that older adults with diabetes will be satisfied with the ease of completing each task (ie, capturing, viewing, and transmitting images)?
- RQ2: How likely is it that older adults with diabetes will be satisfied with the amount of time it took to complete each task by using a food record app for dietary assessments (FRADA)?
- RQ3: What is the usability of FRADA with older adults with diabetes?
- RQ4: Would older adults with diabetes use a tablet as an alternative device?
- RQ5: Would it be easy for older adults with diabetes to follow the instructions, such as including all the food items in one single photograph and holding the phone at a 45-degree angle when taking pictures of food items?
- RQ6: Would older adults with diabetes want to use FRADA in the future?
- RQ7: What are the potential benefits for older adults with diabetes of using FRADA?
- RQ8: What are the potential features to be added to FRADA?
- RQ9: What are the concerns of older adults with diabetes when interacting with FRADA?
- RQ10: What are the potential target populations of FRADA?

Methods

Development of a Food Record App for Dietary Assessments

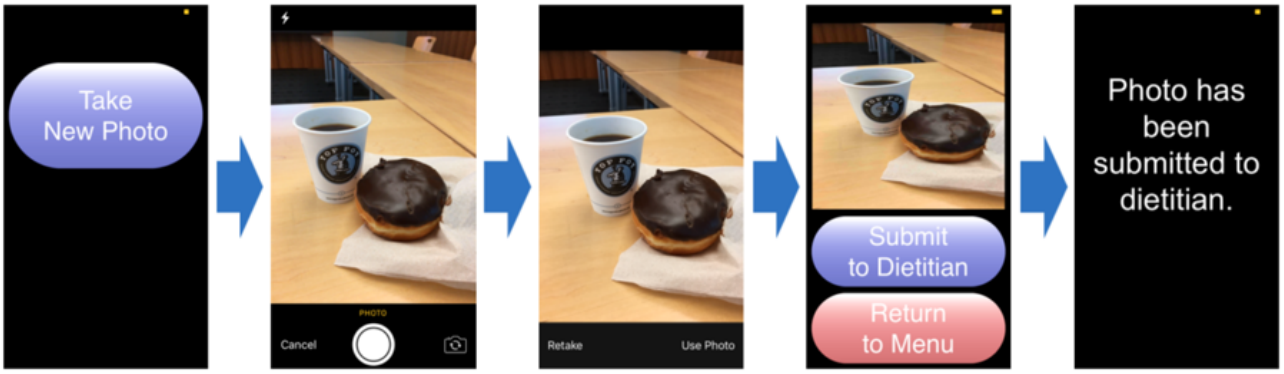
The first goal of this study was to create a food record app for dietary assessments (FRADA) to enable older adults with diabetes to collect images of their meals and snacks. Since collected images will be reviewed by dietitians in real-life scenarios, we developed two subapps of FRADA for older adults with diabetes: a client app and a server app to view collected images. Also, we developed an app that enables dietitians to view images of food items transmitted by smartphones of older adults with diabetes during 24HR interviews.

Development of Client and Server Apps for Older Adults With Diabetes

The role of the client app is for older adults with diabetes to transmit collected images of food items to a server from their smartphone; therefore, this app was embedded in their

smartphones. On the other hand, we implemented another subapp on the server, which receives transmitted images of food items, stores them, and manages any requests from the client side in the server. We used HTML and JavaScript languages to develop the client app using Apache Cordova [31] and a PHP language [32] to implement the app on the server. To reflect the special needs of older adults, we used large font sizes and big buttons based on the design principles [33] to design the user interface for the smartphone app. We built the app using Apache Cordova [31], an open-source framework on the Mac OS X 10.11 (Apple Inc) machine. To facilitate communication between smartphones and the server, we used open-source libraries provided by Apache Cordova [31]. Figure 1 illustrates the screenshots of the user interface on smartphones when study participants captured, reviewed, and transmitted images of food items.

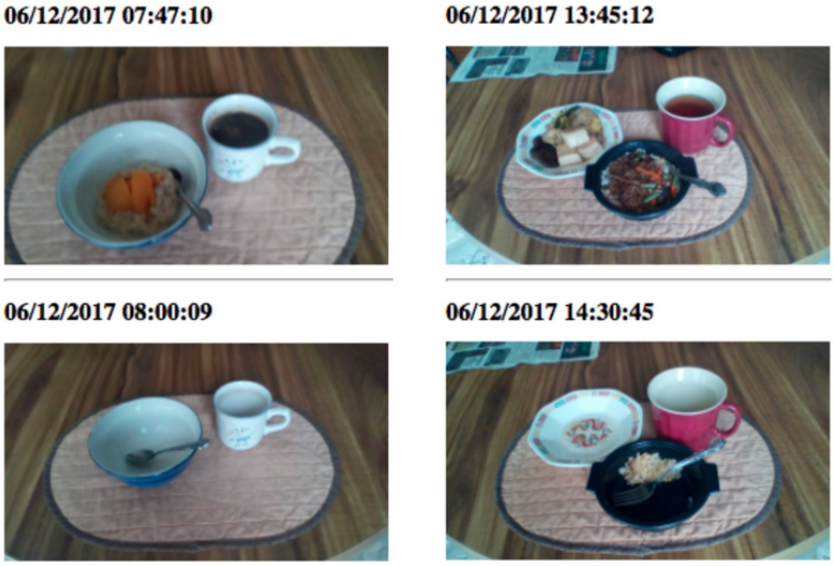
Figure 1. Screenshots of the user interface in the smartphone app.



Development of a Viewer App for Dietitians

A viewer app was designed to enable dietitians to view images of food items transmitted by smartphones of older adults with diabetes during 24HR interviews. We used HTML and JavaScript languages to develop the web-based app. The app was designed to perform two tasks: (1) gather images being stored in the database [30], and (2) display images to both dietitians and older adults with diabetes through devices (eg, laptops, tablets, or smartphones) during 24HR interviews. As Figure 2 illustrates, the app displays a series of images transmitted by each older adult participant with diabetes. The date and time information were added to the top of each image as metadata for the images. In particular, the app allowed users to navigate the images taken more recently by scrolling down the page, as images were organized in chronological order.

Figure 2. Screenshots of the user interface of the viewer app for reviewing images of food items during 24-hour dietary recall interviews.



Participants in Evaluation of Usability of FRADA

The inclusion criteria for participants were as follows: (1) 65 years or older; (2) diagnosed with type 2 diabetes or prediabetes for at least 6 months; (3) understand spoken English; (4) have their own smartphones with cameras; (5) live in independent living facilities, such as retirement communities, retirement homes, senior centers, or senior housing; and (6) have experience with smartphone usage for at least 6 months. We excluded any participants who were legally blind or had severe auditory impairments to avoid any potential sample biases that might influence the study. All procedures were approved by the Institutional Review Board at the University of Washington (IRB ID: STUDY00000432).

Recruitment Process

We recruited 14 participants to discover usability issues of FRADA. Twelve participants were recruited from three senior

centers, two senior housing locations, and one community center located in the metropolitan area of Seattle, Washington, while two were recruited by our personal network through a mailing list of the Greater Seattle Dietetic Association and in person. Although the sample size was small (N=14), it was comparable to similar published studies designed to discover usability issues using a qualitative approach [34-36].

Study Procedure

We collected data from older adults with diabetes via a lab-based usability session that consisted of a pretest survey, a posttask survey, and a posttest interview. Before each test, we provided a smartphone (ie, iPhone 6; Apple Inc), a plate of food and beverages (see Figure 3), and instructions that included a list of rules that each participant should keep in mind when interacting with FRADA. The rules were as follows: (1) you should include all of the food items in one single photograph, and (2) to get the best images, you should hold the phone at a 45-degree angle when taking pictures of the food and beverages. After that, we asked each study participant to fill out the pretest questionnaire with demographic questions to get information about him or her, including age, gender, education level, and years of experience using a smartphone. We then proceeded with the lab-based usability session.

Figure 3. Food items used in the study.

During the test in the lab, each participant was asked to accomplish the tasks (ie, capturing, viewing, and transmitting images of food items) by interacting with FRADA (see Textbox 2). In order to answer RQ1 and RQ2, once participants completed the tasks, they were asked to fill out an after-scenario questionnaire (ASQ; see Figure 4), which is known to be a valid and reliable scale for usability tests [37] to rate the satisfaction of the ease of completing each task and the amount of time it took to complete each task using the smartphone app. The three statements of the ASQ, which uses a 7-point rating scale, are shown in Figure 4.

Textbox 2. Scenario proposed to participants during lab testing.

You have an appointment with your dietitian tomorrow to assess your diet. The dietitian wants to get the smartphone images of the food and beverages that you have consumed before the appointment for your dietary assessment. Now, you need to accomplish the following three tasks using your smartphone:

- Capture an image of all the food and beverages served for your lunch.
- Review the captured image to make sure the image complies with the predefined instructions.
- Send the reviewed smartphone image of your lunch food and beverages to your dietitian.

Figure 4. After-scenario questionnaire for older adults with diabetes.

Please respond to the following questions.
1. Please mark ✓ after photographing the images.
"I am satisfied with the ease of completing the task of photographing images of food and beverages."
Strongly disagree ○ ○ ○ ○ ○ ○ ○ Strongly agree

"I am satisfied with the amount of time it took to complete the task of photographing images of food and beverages."
Strongly disagree ○ ○ ○ ○ ○ ○ ○ Strongly agree

2. Please mark ✓ after reviewing images.
"I am satisfied with the ease of completing the task of reviewing images of food and beverages."
Strongly disagree ○ ○ ○ ○ ○ ○ ○ Strongly agree

"I am satisfied with the amount of time it took to complete the task of reviewing images of food and beverages."
Strongly disagree ○ ○ ○ ○ ○ ○ ○ Strongly agree

3. Please mark ✓ after sending the images to your dietitian.
"I am satisfied with the ease of completing the task of sending images of food and beverages."
Strongly disagree ○ ○ ○ ○ ○ ○ ○ Strongly agree

"I am satisfied with the amount of time it took to complete the task of sending images of food and beverages."
Strongly disagree ○ ○ ○ ○ ○ ○ ○ Strongly agree

4. Please share any comments, suggestions, or thoughts that you have about the tasks.

After each participant completed the posttask questionnaire, we conducted a posttest semistructured interview with them in order to answer RQ3 through RQ10. The topics of the interview questions addressed the participant's experience when he or she used the app to perform each task (see Textbox 3). The interview questions did not ask about relative preference for mobile app versus 24HR versus written food records, as the study participants did not compare these different tools directly. Each interview lasted 20-30 minutes and was conducted in person. All interviews were audiorecorded and transcribed.

Textbox 3. Sample posttest semistructured interview questions for older adults with diabetes.

- What are your overall impressions of the smartphone app?
- If you had to give the smartphone app a grade, from A to F, where A was exemplary and F was failing, what grade would you give it and why?
- Name three words or characteristics that describe this smartphone app.
- What are the three things you like best about the smartphone app?
- What are the three things you like least about the smartphone app?
- If you could make one significant change to this smartphone app, what change would you make?
- Would you return to this smartphone app on your own in the future? Why/why not?
- What would entice you to return?
- Are there materials you would like to see added to the smartphone app? Which ones?
- Would you recommend this smartphone app to a colleague? To a friend?
- Do you have any other questions or comments about the smartphone app or your experiences with it?

Data Analysis

To analyze the responses from the ASQ, we summarized the numbers and percentages of ratings and responses. Regarding the analysis of qualitative data from the interviews, we used an open coding method guided by grounded theory [38]. As a first step, the lead researcher of this study (HJ) read the transcribed interview text as a whole and highlighted statements that included important information (ie, participants' experiences, preferences, and impressions). After reviewing the highlighted statements repeatedly, the researcher marked each statement with an appropriate label. The labeled statements under the same concept were then grouped into categories based on the common properties, each of which corresponded to a research question we aimed to answer (see Textbox 1). The whole process of open coding was carried out by a single coder.

Results

Study Participants

Participant demographics are illustrated in Table 2. In total, 14 participants (11 female, 3 male) took part in the study. The average age of participants was 73.6 (SD 5.0, range 65-80) years. The education level of the participants varied: bachelor's degree (n=5), master's degree (n=3), high school graduate (n=3), professional degree (n=2), and other (n=1). Participants used mobile devices with various operating systems: Android (n=10), iPhone operating system (n=3), and Amazon Fire (n=1). Of the 14 participants, 8 used smartphones for 2 or more years, while 5 used smartphones for less than 2 years (data was not reported for 1 participant).

Table 2. Participant demographics.

ID	Gender	Age (years)	Race/ethnicity	Education level	Number of years using a smartphone
P1	Female	76	White/Caucasian	Professional degree	2-3
P2	Female	80	White/Caucasian	Master's degree	>3
P3	Male	79	White/Caucasian	Bachelor's degree	<1
P4	Female	72	Asian/Pacific Islander	High school graduate	>3
P5	Female	67	White/Caucasian	Bachelor's degree	Not reported
P6	Female	65	White/Caucasian	High school graduate	>3
P7	Male	74	White/Caucasian	Professional degree	1-2
P8	Female	70	Asian/Pacific Islander	Bachelor's degree	2-3
P9	Female	76	White/Caucasian	Master's degree	>3
P10	Female	67	White/Caucasian	Bachelor's degree	>3
P11	Female	78	White/Caucasian	Bachelor's degree	<1
P12	Female	70	White/Caucasian	Other	>3
P13	Male	79	White/Caucasian	High school graduate	1-2
P14	Female	77	White/Caucasian	Master's degree	1-2

Survey Results

Survey results based on ASQ revealed that participants tended to be satisfied with the ease of completing the tasks of photographing, reviewing, and sending the images of food and beverages. In addition, it seemed that they were satisfied with the amount of time it took to complete the task of photographing, reviewing, and sending the images of food and beverages. The average scores for completing the task of photographing, reviewing, and sending the images of food items were: 6.8 (SD 0.6), 6.9 (SD 0.3), and 6.9 (SD 0.3) out of 7 points, respectively. In particular, 12 out of 14 participants reported 7 points for all of the questions.

Interview Results

Qualitative data were organized into eight categories through qualitative analysis steps guided by grounded theory [38]: (1) usability of FRADA, (2) potential benefits of using FRADA, (3) concerns of older adults, (4) willingness to use FRADA, (5) potential features to be added to FRADA, (6) easy instructions, (7) tablet as an alternative device, and (8) potential target populations.

Usability of FRADA

Participants reported that it was efficient to perform tasks such as capturing, viewing, and transmitting images of food items using FRADA. They also stated that it was easy to interact with the user interfaces of FRADA. P9 stated, "There's only three moves basically, you know. Take a new picture, take the picture, and send the picture. It's very efficient. I can't think of any suggestions to make it better." P4 noted the simplicity of the process of taking and sending a picture of food items: "Well, probably just take a picture and sending it to a dietitian in one step." Furthermore, participants reported that FRADA was simple to use to perform the required tasks. P6 stated, "A+. It's very simple and very easy to use." P14 stated, "So, I think it's very, very useful. I think it's very worthwhile and excellent thing that you've come up with. And, as with all things that are excellent, it's simple." Moreover, P12 addressed the usability of the app by comparing it to other apps he had used: "Oh, yeah, well, like I said, it's so much easier than anything that I've tried.

I'm looking forward to seeing how you develop this app." In particular, P1 and P11 reported that they did not have any difficulty in interacting with the app. P1 stated, "No, I didn't have any difficulty." P11 said, "It's very easy to use. It's very intuitive. I had no problem with it at all."

In addition to the efficiency of using FRADA, participants mentioned that they were satisfied with the app's user interface. For instance, the majority of the participants liked the large font size of the letters on the app. P2 said, "But, I did notice that your app has large letters, so it's easy to read. You don't have that little, teeny letter you have to look at." P10 mentioned that the large print will help potential users of the app: "It was very easy to use. And the large print, I think is very helpful to people who have a hard time seeing. It was, it was easy. I, I—it was easy to do." Similarly, P11 enjoyed using big buttons on the user interface: "The app buttons, the big buttons, they were very large, which for me, another guy can see that for an elderly person because in texting with a phone I don't have small enough fingers or touchy enough fingers to do it well, but these buttons would make the app very easy to use for me."

Potential Benefits of Using FRADA

We discovered that FRADA is perceived as beneficial in multiple ways. For instance, we learned that the images of food items collected by FRADA might bring about improved communications between older adults with diabetes and health care providers. In addition, we found that FRADA may be used to improve participants' personal health and their experiences with keeping track of food items, as well as manipulating a smartphone.

First of all, participants stated that FRADA would likely facilitate improved interactions with health care providers. P11 stated, "Apparently this is going to send data to a dietitian and the dietitian then can give the person using it feedback on what they might do to correct their diet, too, I guess that's what it is...so it's an ongoing relationship between the patient and the dietitian." P10 said that the images from the app might support the practice of dietitians: "...because sometimes we don't tell the dietitian everything, but this way she can see everything we ate... It would be something that would be very helpful to people when, when discussing their, their eating habits with a dietitian." Similarly, P6 mentioned that health providers would benefit from the images collected by the app: "...because it'll help people deal with their dietitian and their doctor at the same time. So that everybody can get together and see what you're doing." P12 mentioned that dietitians will be able to provide service by using the collected images of food items: "...And then it goes to the dietician, and the dietitian's gonna be able to give me information." P1 also mentioned that the app would be beneficial to meeting with a dietitian: "But if I—as I go through the day, if I just clicked a picture each time, I think that would be valuable, so not only meeting with the dietitian, but just for my own."

Further, participants stated that using FRADA would likely help them improve their personal health. P9 anticipated that FRADA would be valuable "in helping somebody to decide how to change their diet for optimal health." Similarly, some participants expected improved health after using the app. P5 stated, "You know, if they asked me to take pictures, if they were asking me to use the app, I think I'd eat even better." P14 said, "But this has a function that's directly related to promoting my health. So, that's a clear, pragmatic use." Two participants mentioned that FRADA would improve their experiences with keeping track of meals and snacks. P9 stated, "This would be faster if I use that. Take a picture of what you normally eat or what you just ate for your lunch and tell me if that's a good example of what you would have... In that case, I could do it and it would be very fast. Much faster than seeing a handwritten or a computer-generated list of what they had." P1 described the process of taking pictures of food items by comparing with her existing practice of keeping a food diary: "Like I said, keeping a food diary is just so boring, but if I could take a picture several days in a row — then I could just write all those things down, in my food diary." In particular, P9 mentioned that the images captured by the app provide information describing the actual project: "Instead of serving size, then you see the product, the actual product."

In addition to the direct benefits of using the app, P14 stated that the action of using FRADA enabled him to learn to take pictures using his smartphone—an indirect benefit: "Well, I like it because it gives me practice taking pictures with my smartphone because I generally use a camera and not a smartphone. But here, I'd be doing it frequently. So, I would have experience doing it. And I like that sort of side effect of the app that it's teaching me."

Concerns of Older Adults

We identified participants' concerns about the use of FRADA. One of the critical concerns that participants expressed was the potential financial costs that might occur when they interact with FRADA for an image-assisted dietary assessment. Other identified issues included (1) whether the collected data would be shared with other people appropriately, (2) whether older adults would be able to use FRADA effectively in real-world scenarios, and (3) whether health care providers would look at the data shared by older adults in detail.

Participants expressed concerns about their potential use of FRADA. Most participants were concerned about the costs they might incur when scheduling a meeting with a dietitian and purchasing FRADA. P11 stated, "I mean that I can see that if that's going to be a continuous thing it would have to be almost, like, a doctor's relationship where depending upon how much time the dietitian spends on your particular diet." P5 mentioned, "My only concern was how much would it cost you to have to have a nutritionist or doctor look at it, see." P1 was aware of how expensive it would be to involve a dietitian, although she uses FRADA: "Well, I just wondered how you would get the dietitian involved. You know dietitians are expensive." Also, P12 was concerned about the cost of the app itself: "That's huge. That's huge. We're seniors. You know, we live on Social Security, so I don't have a lot of money. Any of the apps that I have are free."

In addition, participants mentioned trust issues regarding food images collected by FRADA. For instance, P7 did not believe that all of the images reflect the truth: "You don't know what's in there (cup) ... Vodka." Similarly, P2 said, "You're going to

end up picking your own favorite foods anyway. I mean, just like you have your favorite foods." In addition to the accuracy of the images of food items reported by patients, P7 was uncertain whether the system would affect adherence: "A lot of patients aren't cooperative. Patients do what they want. When I prescribe drugs for a patient, what percentage of them do you think take the drugs like they're supposed to? What percentage of patients follow the instructions, for example with pharmacy, what percentage would you guess?" Furthermore, participants were concerned about other issues, such as privacy, learning how to use FRADA, and dietitians' concerns. Regarding privacy, P2 stated, "Yes. And, truthfully, to me that would be eventually, for some people it's going to work, for me it's invasion of my privacy...it's just personal. That's a personal thing." Although P2 was concerned about privacy, she still wanted to use FRADA if needed: "I would probably share now and then. If I was really having a problem, I probably would be more willing to share." P7 was particularly concerned about whether other older adults could use this app. P1 was worried about dietitians' concerns: "The only thing I might wonder about is if the dietitian would like to be able to see the ingredients on anything instead of just looking at the title, especially if she wasn't familiar with that particular item."

Willingness to Use FRADA

We discovered that the request of health care providers might be essential to motivate older adults with diabetes to use FRADA continuously in the future. Also, we learned that older adults with diabetes might not want to keep using FRADA if they do not have a strong, external motivation to use it.

Participants expressed that they were willing to use FRADA potentially in the future if FRADA was required to manage their health. They said that they would like to use the app if asked by health care providers. P1 said, "If it [FRADA] was available and the dietitian was available, it would be a great learning device and diagnostic device, for what you were eating, to how you could improve your diet habits." P5 expressed interest: "Sure, especially, you know, if I had a nutritionist or doctor who wanted me to send them pictures, I'd be happy to." P4 stated, "I would use the app if dietitian asks me." P3 stated that he would choose to use the app if there were known benefits of using it: "I—well, I would return it, if it was part of a health, ongoing health procedure that I wanted to be involved with to, you know, to see that I was eating the right things, that's all, because I presume when this goes in you get feedback on it, saying this ice cream cone here may not be a good idea. I don't know."

Nevertheless, P2 stated that she would not want to use FRADA in the future, as she was still satisfied with the process of using a food diary: "I think it's easy to use. I personally probably wouldn't use it because I don't mind writing things down." Even though P2 did not want to use the app in the future, she was satisfied with its usability: "It's a very easy. It's a really easy app to use because once you understand it and, as I said, it probably would work for some people. Not necessarily for me, that's all."

Potential Features to be Added to FRADA

We found that participants were interested in a potential feature that would enable them to exchange health information with health care providers. For instance, they wanted to receive feedback on the collected images of food items from dietitians. In addition, they were eager to supplement any missing information from the collected images transmitted to health care providers.

Participants reported that they wanted to have a space to communicate with health care providers, such as receiving information from health care providers and supplying them with additional information. P3 and P12 wanted to view any feedback on the images of food items from health providers. P12 stated, "…having your app that you just have to snap the picture without having to do the labels, just take your picture. And I'm not sure how you would do that with the dietary feedback from the dietitian. I'm not sure how that would work, but it would make it easy." In particular, P3 emphasized the importance of getting feedback from health care providers: "I mean if you don't get any feedback the whole thing is worthless."

While many participants wanted to get feedback from dietitians, P2 wanted to provide dietitians with additional information about the portion sizes of the food items. To supply accurate information of food items, P2 stated, "...I think you've got about the right size of plate, but I would definitely check that out... I don't have that knowledge. I'm sure that being—this is kind of a national brand to it, so they probably have a pretty good idea what's in that, too." Similarly, P10 was eager to supply additional information by leaving comments on the images of food items: "And if there was maybe a place on the app where you could put in a comment—a comment would be nice, I only ate half of this meal."

Easy Instructions

Participants reported that the instructions that were provided on how to take, review, and transmit the images of food items using the app met their needs. The instructions given for taking images of food items were to (1) include all the food items in one single photograph, and (2) hold the smartphone at a 45-degree angle when taking the images of food items. Participants felt that the instructions for taking, reviewing, and transmitting the images of food items using the app were easy to follow. P14 stated, "Probably A [grade] because it's so clear. The instructions are clear. And the instructions on being able to accomplish the task is very clear. I feel like I could accomplish it with one request to do so." P9 mentioned, "Oh, I think it's great. It's very easy to learn and the instructions are good." In brief, study participants felt that the instructions for capturing images of food items using FRADA were simple and easy to follow.

Tablet as an Alternative Device

Participants reported that they were interested in interacting with a tablet as an alternative device for taking, reviewing, and transmitting images of food items.

Although most participants were satisfied with the user interface of their smartphone, three participants expressed interest in

using a tablet for performing the tasks of an image-assisted dietary assessment method. P10 said, "I mean it's bigger, you know, but it's still easy. It's still easy to use. It's as easy to use as my phone is." P2 stated, "But, the tablet's bigger, but it still works. It would probably work the same." P14 expressed her interest in using the app on both her smartphone and her tablet: "Well, the only change that I would like to make is I have both an Android phone and an Android tablet. And my tablet, I would hope that this app can be available on the tablet as well."

Potential Target Populations

Our study revealed multiple groups of potential users who could benefit from using FRADA. In addition to older adults with diabetes, potential target populations include patients with diabetes, newly diagnosed patients with diabetes, and individuals sensitive to food intake. First, participants agreed with the statement that this app would support patients with diabetes. P1 stated, "I would recommend it to people with diabetes. I don't know what other people would use it for, but people with diabetes, pre-diabetes." Also, P2 expressed her recommendation: "I would recommend that diabetes patients use this app." Next, participants mentioned that FRADA could be particularly beneficial to newly diagnosed patients with diabetes. P2 said, "I guess, it's very useful, as I say. I think for a new diabetic, it would be very useful. A person that's been newly diagnosed with diabetes." In addition, participants reported that a potential target user population might be individuals who are sensitive to food intake in addition to patient with diabetes. P2 said, "Especially if they were, again, I'm talking about new diabetics or people who are trying to, or even people who are trying to lose weight and need to work with a dietitian." P10 suggested that FRADA could benefit people after surgery "because they need to manage their diets and they need to talk with their nutritionists."

Discussion

Principal Findings

Through surveys and interviews with older adults with diabetes in a lab-based usability session, this study revealed that participants tended to be satisfied with the usability of the newly developed FRADA and its instructions after performing three tasks (ie, taking, reviewing, and transmitting images of food items) successfully. Even though responses from participants revealed some concerns about interactions with FRADA, they indicated a willingness to use FRADA based on their needs in the future and identified additional target populations who could benefit from the use of FRADA (ie, patients with newly diagnosed diabetes, high blood pressure, or chronic kidney disease). Based on the findings of this study, there are topics that need to be considered, such as the appropriateness of existing or emerging modalities for older adults with diabetes, instructions, device preferences, target users, understanding multiple stakeholders' needs for better tool design, and a cost-sensitive population.

Appropriateness of Existing or Emerging Modalities for Older Adults with Diabetes

While this study focused on recording images of food items as logs, there still exist a variety of modalities, such as wearable cameras, voice recordings, and sensor technologies that might be appropriate for older adults with diabetes to record their meals and snacks. First, wearable cameras may be appropriate for the older adult population. Since images are captured automatically by wearable cameras [22,28], older adults might not have to learn how to manipulate the devices. Similarly, older adults do not have to follow the instructions (ie, including all food items in one photograph, holding the phone at a 45-degree angle, and capturing images before and after eating events) when collecting images of their meals and snacks. Instead, older adults would only need to learn basic functions, such as how to turn the camera on and off and how to charge it. Even though wearable cameras may reduce the burden on older adults, users might still need to screen collected images prior to analyzing the images. In addition, low-income older adults might not want to purchase wearable cameras for the sole purpose of collecting images of food items.

Next, a voice-recording strategy might work well to support the older adult population. Similar to wearable devices, older adults do not have to follow the instructions that are required for collecting images of food items. Instead, they could simply turn on the voice recorder when logging food intakes. Although a voice-recording strategy may help older adults record food items and their portion sizes, there are still challenges that older adults might face when recording their voices. For instance, older adults would still need to turn on their voice recorder before eating events. Also, it might be difficult for older adults to describe every single food item and its portion size accurately. Similarly, sensor technologies (eg, a jaw motion sensor [39]) may be appropriate for older adults. For example, by monitoring chewing, a jaw motion sensor can detect periods of food intake automatically while people consume food [39]. This might be particularly beneficial to older adults because they do not have to perform any tasks to record food items and their portion sizes during eating events. However, it is still questionable whether such sensor technologies monitoring individuals' eating behaviors might be socially acceptable for the older population.

Instructions

Participants were required to follow two instructions when taking pictures of food items. Although the instructions were based on the findings of previous studies, this study showed that the instructions would need further revisions to reflect the needs of health care providers. For example, dietitians might want to view the images taken at multiple angles for better understanding of the food items and their portion sizes.

Device Preferences

This study showed that some participants were interested in using the app on a tablet device, whose screen is larger than the screen of a smartphone. Since this study focused on evaluating the usability of the smartphone app, the findings do not indicate if older adults with diabetes actually prefer a larger screen. Nonetheless, it would be valuable to conduct additional

experiments to determine the acceptability of other types of devices (eg, tablet, laptop, desktop, or smartwatch).

Target Users

We noticed that some participants did not want to use the smartphone app in the future because they were already familiar with how to manage their diabetes without it. Instead, they suggested that this app might benefit newly diagnosed patients with diabetes. This implies that researchers and designers might need to consider the unique needs of patients with other types of chronic diseases, such as high blood pressure and chronic kidney disease, when asking them to use technologies with mobile devices.

Understanding Multiple Stakeholders' Needs for Better Tool Design

This study focused on evaluating the usability of FRADA with a single population of older adults with diabetes. As a result, we were able to identify potential features to be added to this app and the benefits of using FRADA based on the participants' feedback. Future work would need to incorporate the needs of other stakeholders—such as dietitians, family members, friends, and caregivers—when selecting features to be added to this app and could reveal the benefits to these other stakeholders from using the app.

Cost-Sensitive Population

We found that most participants were sensitive to the potential costs involved in using FRADA. This might reflect the characteristics of participants in this study because they were mainly recruited at senior centers and senior apartments. There are more likely to be more low-income older adults in those facilities than in retirement communities with relatively higher living costs.

Limitations

This study has a number of limitations that will need to be addressed in future work. One of the limitations is that there might be potential biases related to having only one coder in the qualitative data analysis. To analyze the qualitative data from the interviews, the lead author applied an open coding method [38] to collect statements from transcripts, identify recurring concepts, and group the statements into categories as a single coder. Thus, it is possible for a single coder to only accept categories from his or her own perspective and omit categories from other perspectives.

In addition, the study sample may not be representative of the larger target population (ie, older adults with diabetes). This is because our study only focused on older adults with diabetes who had prior experience with smartphones; some older adults with diabetes do not have previous experience with smartphones. Further, study participants were recruited only in the Pacific Northwest region of the United States. This sampling may limit how the study findings can be generalized.

Next, even though it was easy and efficient for older adults with diabetes to use FRADA for collecting images of food items, it is still questionable whether design implications from this study could be generalized and used for redesigning FRADA. For example, this study did not report the usability of FRADA with stakeholders other than older adults with diabetes. The findings of this study did not reveal needs and barriers related to other direct and indirect stakeholders (eg, dietitians, family members, friends, and caregivers) in the process of the image-assisted dietary assessment. Further usability testing with a more diverse sample in terms of race, ethnicity, literacy, health literacy, and technology experience would produce more generalizable insights.

Furthermore, special considerations for older adults with diabetes who also have cognitive or physical disabilities (eg, dementia or vision problems) were not addressed when we developed FRADA, although it is known that older adults with diabetes are twice as likely to develop dementia than older adults without diabetes [22]. Similarly, FRADA may not reflect the needs of older adults who have trouble holding a mobile device, as the user interface of FRADA was based on design guidelines [35] that address the needs of a general population of older adults rather than addressing the needs of people who experience specific functional or cognitive limitations (eg, limitations resulting from Parkinson disease).

While this study demonstrates the usability of FRADA for older adults with diabetes in a lab-based setting, there still remain questions about the validity of FRADA in a real-life setting. For instance, the accuracy of portion size estimation using FRADA is still unknown, as FRADA was not validated against an actual dietary assessment method (eg, 24HR interviews) at this time. Further validity testing involving dietitians could confirm whether using FRADA improves the accuracy of a traditional dietary assessment method, in which dietitians conduct 24HR interviews with older adults with diabetes.

Conclusions

The goal of this study was to create a smartphone app that enables older adults with diabetes to collect images of food items and determine its usability. We achieved this goal via the development of FRADA and lab-based usability sessions with older adults with diabetes. Achieving this goal demonstrates three contributions. First, we created FRADA for an image-assisted dietary assessment based on design requirements that reflect the special considerations of older adults, which were not reflected in other apps used in previous studies. Therefore, designers, developers, and researchers could use the findings of this study to create smartphone apps targeting older adults with diabetes. Second, we obtained structured feedback about FRADA from participants through three types of questionnaires: pretest, posttask, and posttest using surveys and interviews. Our findings expand on existing knowledge about how to design smartphone apps for an image-assisted dietary assessment in older adults. Finally, we demonstrated the potential opportunities for evaluating the feasibility and validity of FRADA in a deployment study. While our study focused on evaluating the usability of FRADA by older adults with diabetes, further work remains to evaluate its usability with both direct and indirect stakeholders, such as dietitians, family members, friends, and caregivers to identify potential features to incorporate into FRADA. In addition, we plan to evaluate the feasibility and validity of an image-assisted dietary assessment

using FRADA with older adults with diabetes so that we can determine if the method is clinically meaningful.

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Conflicts of Interest

None declared.

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Abbreviations

24HR: 24-hour dietary recall
ASQ: after-scenario questionnaire
FRADA: food record app for dietary assessments
MNT: medical nutrition therapy

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Original Paper

Usage and Weekly Attrition in a Smartphone-Based Health Behavior Intervention for Adolescents: Pilot Randomized Controlled Trial

Erlendur Egilsson[1*]; Ragnar Bjarnason[2,3*], MD, DrMed; Urdur Njardvik[1*], MA, PhD

[1]Department of Psychology, University of Iceland, Reykjavik, Iceland

[2]Faculty of Medicine, University of Iceland, Reykjavik, Iceland

[3]Children's Hospital, Landspitali University Hospital, Reykjavik, Iceland

[*]all authors contributed equally

Corresponding Author:
Erlendur Egilsson
Department of Psychology
University of Iceland
Sturlugata 1
Reykjavik, 101
Iceland
Phone: 354 6184805
Email: erlendu@hi.is

Abstract

Background: The majority of adolescents own smartphones, although only 8% of them use health apps. Attrition rates from adolescent mobile health (mHealth) interventions for treating mental health problems such as anxiety and depression are an issue with a high degree of variation. Attrition in mHealth interventions targeting adolescent populations is frequently presented in a two-point fashion, from initiation of the intervention to the end of treatment, lacking more time-specific information on usage and times of attrition. Self-efficacy could provide an avenue to lower attrition rates, although a better understanding of the relationship between mental health factors and time-specific attrition rates is needed.

Objective: The aims of this study were to obtain time-specific attrition rates among adolescents in an mHealth intervention, and to describe the intervention's usage and feasibility in relation to adolescent self-efficacy levels, and emotional and physical health.

Methods: A single-center randomized controlled public school pilot trial was undertaken with 41 adolescents. Outcome measures were assessed at baseline and after 6 weeks, while in-app activity and attrition rates were continually assessed throughout the intervention period. The primary outcome was attrition based on time and type of in-app health behavior usage, and feasibility of the mHealth app. Secondary outcome measures were self-efficacy levels, depressive and anxiety symptoms, as well as standardized BMI and sleep. Analyses of group mean variances with adjusted α levels through Bonferroni corrections were used to assess main outcome effects.

Results: The attrition from initiation of the intervention to 6-week follow up was 35%. Attrition started in the third week of the intervention and was related to daily time of app usage (R_t=0.43, P<.001). The number of average weekly in-app health exercises completed decreased significantly from the first week of the intervention (mean 55.25, SD 10.96) to the next week (mean 13.63, SD 2.94). However, usage increased by 22% between week 2 and the last week of the intervention (mean 16.69, SD 8.37). Usability measures revealed satisfactory scores (mean 78.09, SD 9.82) without gender differences (P=.85). Self-reported daily physical activity increased by 19.61% in the intervention group but dropped by 26.21% among controls. Self-efficacy levels increased by 8.23% in the invention arm compared to a 3.03% decrease in the control group.

Conclusions: This pilot study demonstrated the feasibility and usability of an mHealth intervention among adolescent participants. Indications were toward beneficial effects on physical and mental health that warrant further research. Focus on time-specific attrition measures alongside daily times of usage and ways to increase participants' self-efficacy levels appear to be a promising avenue for research on mHealth interventions for adolescent populations with the aim to ultimately lower attrition rates.

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KEYWORDS

mHealth; intervention; adolescent; attrition; self-efficacy; mental health; physical activity; young adult; behavior

Introduction

Recent systematic reviews on the global prevalence of psychiatric disorders in children and adolescents have produced varying results ranging from 6.8% to a notably higher pooled rate of 13.4% [1,2]. Emotional disorders as well as significantly distressing subthreshold emotional problems are among the most common psychiatric problems reported in adolescent populations [1-3]. According to the Centers for Disease Control and Prevention, over 6% of US children between 12 and 17 years old have been diagnosed with depression and over 10% have been diagnosed with anxiety disorders [4]. Globally, it is estimated that 10% to 20% of youth experience mental health problems [5-7].

Smartphone ownership is growing fast worldwide. In the United States, smartphone ownership or access among adolescents was estimated at 95% in 2018, representing an increase from 73% in 2015 [8,9]. Similar development is evident elsewhere, with youth smartphone ownership surpassing the 90th percentile in the majority of developed economies [9]. Not only are smartphones widely distributed but people also tend to carry their phones with them, spending an estimated 170 minutes per day using smartphone apps [10]. Some studies indicate that daily smartphone usage among adolescents is often more than 270 minutes [11]. The number of mobile health (mHealth) interventions available has risen steeply in a steady fashion since first appearing roughly a decade ago, with an estimated 325,000 apps available on the market in 2017 [12]. However, only 8% of adolescents use health apps and relatively few studies have documented how they specifically function in adolescent populations [13]. Although mental health problems disproportionally burden minority and lower socioeconomic status groups in terms of receiving evidence-based interventions, smartphones may be used as a tool to diminish such disparities [14,15]. For example, in the United States, adolescent smartphone ownership is not related to gender, race, parental educational levels, or socioeconomic status [9].

Smartphones offer possibilities of a uniquely personalized platform to tailor the many aspects of treatment to individual patients. Patient treatment through support by smartphones or other mobile devices such as tablets, patient monitoring devices, and personal digital assistants have been collectively labeled “mHealth” [16]. mHealth interventions have shown promising cost-effective outcomes related to lowered anxiety and depression symptoms in youth populations despite recurring issues of high attrition rates [15,17-22]. Attrition is here defined as leaving treatment before obtaining a required level of improvement or completion of intervention goals [23,24]. Treatment attrition is common, costly, and important, although varying definitions of the term have challenged research on the matter [17,24].

Studies on mHealth interventions targeting emotional disorders or subthreshold emotional problems in adolescent populations have frequently lacked time-specific data alongside a lack of accurate definitions and analysis of treatment attrition [15,25]. Usability data in mHealth studies targeting adolescent populations are frequently presented with attrition rates from the initiation of intervention, either at the time of recruitment or launch of the intervention’s first section. For instance, average weighted attrition rates prior to commencing online treatment and after treatment have been reported to be 21%, whereas the rate was 8% from treatment completion to follow up [23].

Attrition in mental health care interventions has been shown to be up to twice as common compared to that in other medical fields [24]. For example, attrition from cognitive behavioral therapy (CBT) was reported to range from 20% to up to nearly 44%, although some indications are toward lower attrition in CBT at the group level [26]. Recent research has found that online CBT programs are effective in treating adolescent mental health problems such as anxiety and depression [5,15,25,27]. However, attrition from these programs remains an issue, with a high degree of variation and attrition rates reaching up to 50% [15,28]. To ultimately lower attrition in adolescent mental mHealth interventions, a better understanding of what factors explain mHealth usage in different adolescent subgroups and time-specific attrition is direly needed.

Adolescents with significant emotional problems (ie, anxiety and depression) were reported to have lower general self-efficacy than their peers and were more likely to either not seek treatment or drop out [3,29,30]. Originating from social cognitive theory, self-efficacy is defined as an individual’s belief that ability is sufficient to succeed or accomplish a task and has been used extensively to guide a theoretical framework for interventions targeting health behaviors [3,29-31]. Individuals with higher levels of self-efficacy are more likely to seek treatment and persist longer in their efforts to change behavior [32]. A partial reason for this appears to be effective use of self-regulatory skills such as planning, problem-solving, and self-incentives [32]. Research has shown a positive relationship between higher levels of self-efficacy and successful health behavior change in terms of weight management and exercise behavior [33]. Studies have also revealed a mediating relationship between higher levels of self-efficacy and treatment adherence in diverse chronic illnesses [34]. Attrition rates in adolescent mHealth interventions could perhaps be better accounted for by an increased understanding of the relationship between self-efficacy levels and detailed descriptions of time- and content-based usage. The purpose of this study was to assess time-specific attrition rates in an adolescent mHealth intervention, as well as to describe usage and the intervention’s feasibility in relation to self-efficacy levels and participants’ emotional and physical health.

Methods

Participants

Participants were 41 individuals, including 17 girls and 24 boys, between 15 and 16 years of age attending a public school in the greater capital area of Iceland. The average age at baseline was

15.6 years (SD 0.26). All children born in 2001 attending a participating public school in Iceland's capital area were eligible participants. All participants were native Icelandic speakers and owned smartphones at baseline; 56% (n=23) of participants had smartphones operating on iOS and 44% (n=18) had those operating on Android devices. Exclusion criteria were obesity rooted in recognizable medical illness; mental retardation; physical, developmental, and mental illness significantly restricting diet or physical exercise; and not having access to an Android or iOS operating device. No participant was excluded from the study based on these criteria. Research specifications and mobile app introduction were sent to parents and legal guardians of all eligible participants through school officials by email, including a confirmative survey link along with parental information about possible exclusion criteria. Participation in the online survey was regarded as consent. The study was approved by the National Bioethics Committee (license number VSNb2015060065/03-01).

Measurements

The primary outcome measure was app acceptability and functionality, assessed with the Systematic Usability Scale (SUS), a widely used and relatively well-studied 10-item questionnaire on app usability where the scores range from 0 to 100, and a total score over 70 indicates satisfactory usability and user acceptance [35,36]. Further primary measures were the amount, frequency, and time of daily physical activity measured through in-app activity; self-reported stress levels; and quality of sleep and energy levels, measured through levels of health app usage and completion of in-app health tasks. Cronbach α for the current sample was .73.

Self-efficacy was assessed with the General Self Efficacy Scale (GSE), a 10-item self-report questionnaire with scores ranging from 10 to 40, with a higher score yielding increases in self-efficacy [37]. GSE has shown acceptable psychometric properties in studies, and was used in global youth populations [38]. Cronbach α for the current sample was .94.

Secondary outcome measures included the standardized BMI (BMI-SDS) based on BMI index reference values for Swedish children adjusted for age and sex. Participants were weighed in kilograms in light clothing without shoes using a digital scale (Marel type C2; Marel, Reykjavik, Iceland). Height was measured in centimeters using a wall-mounted stadiometer (Seca stadiometer; Seca, Hamburg, Germany).

Participants' depressive symptoms were assessed with Children's Depression Inventory (CDI), a self-report assessment tool for children and youth. A T-score over 70 was used as the clinical cut-off point. The CDI's psychometrics have been studied with acceptable findings in both US and Icelandic pediatric populations [39,40]. Cronbach α for the current sample was .82.

The Multidimensional Anxiety Scale (MASC) was used to measure anxiety symptoms. The MASC is a self-report scale with a clinical cut-off T-score over 64 and the following subscales: physical symptoms, harm avoidance, social anxiety, and separation anxiety. Acceptable psychometric properties of the MASC have been documented overall as well as in the Icelandic population [41,42]. Cronbach α for the current sample was .90.

The BEARS sleep screening algorithm was used to assess sleep problems among participants. BEARS is a screening instrument for children from 2 to 18 years old, divided into five sleep domains: bedtime problems, excessive daytime sleepiness, awakenings during the night, regularity and duration of sleep, and snoring [43]. Cronbach α for the current sample was .71.

mHealth App

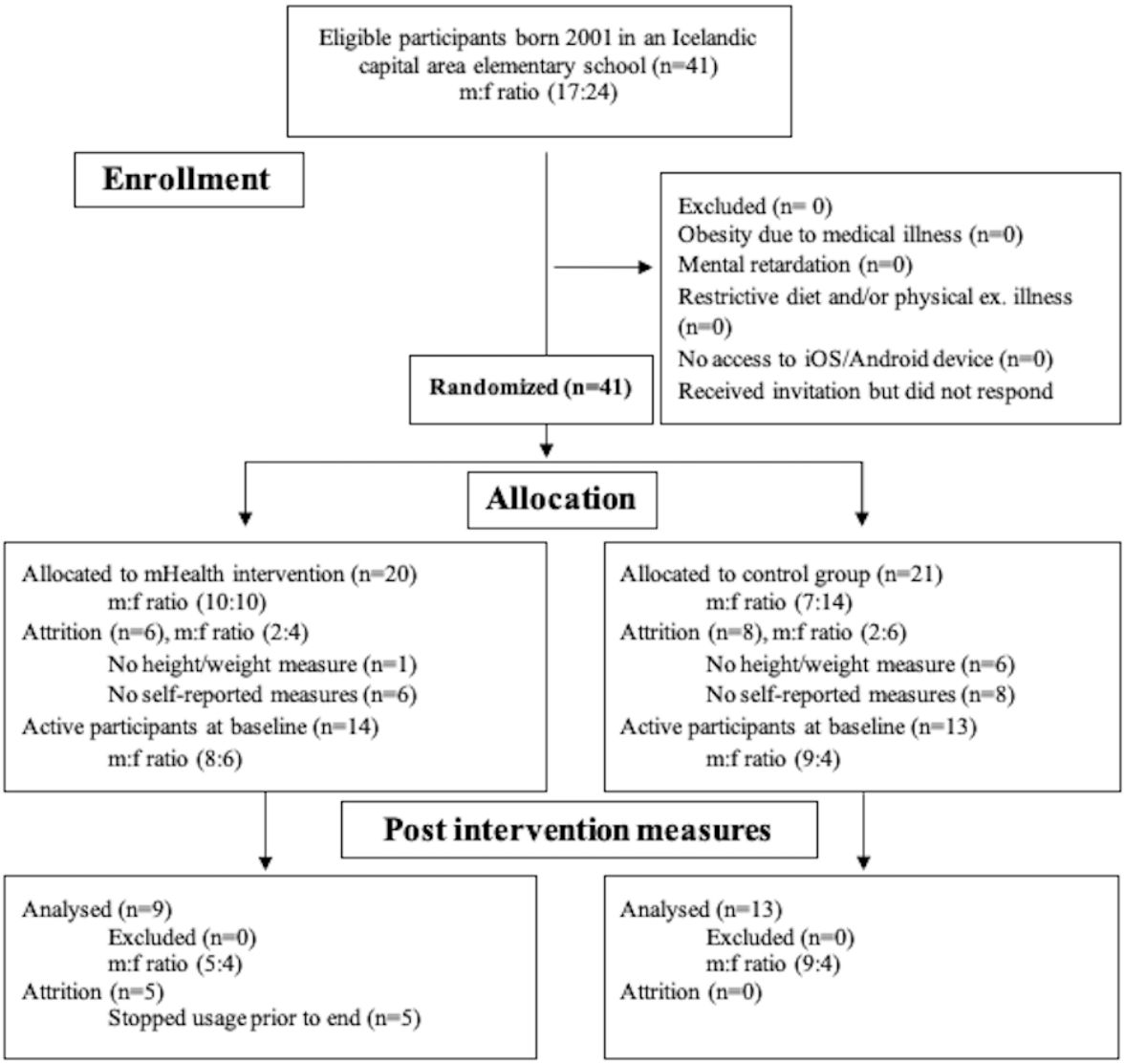
Multiple focus group studies were performed among both Icelandic public school students and adolescents in the obesity clinic at Landspitali University Hospital in Iceland to design and implement the smartphone app named SidekickHealth. Based on results from focus group studies and design advisors, the app took the form of a social health game (see Multimedia Appendix 1). Functionality is centered on helping the user set goals and create health-related missions (gamification of tasks) in three main categories: food and drink (eg, daily fruits, vegetable and water intake), physical activity (eg, body weight exercises, minutes of sports activity, GPS-based biking, walking, or running), and mental health (eg, improving sleep, reducing stress, and exercising gratitude). By completing missions and friendly competitions, the user accumulates badges, moves to higher levels, and aggregates points (called "kicks") providing altruistic rewards (liters of water or polio vaccinations that are sent in their name to children in need through UNICEF). A visual representation of user performance in different categories is provided along with a storyline highlighting progress. Emphasis is on keeping the app fun, entertaining, and easy to use. The smartphone app operates on the Android and iOS platforms. The app's function focuses on education and enablement through essentials of the benefits of physical activity and relaxation exercises, as well as a healthy diet, portion sizes, and appetite awareness training (AAT). AAT is a behavior tool that is used in obesity treatment, which encourages overweight/obese children and teenagers to eat in response to internal appetite cues, and has shown promise for the treatment of overweight and obese children and teenagers [44,45]; thus, AAT was visually developed as an individual mission in the app's nutrition category. Throughout this study, mHealth usage was focused on overall health promotion in groups and individually. In weeks 2 to 4, the in-app focus was on individual mental health promotion, dietary habits, and physical exercise, respectively. Participants were randomly ascribed to health teams consisting of 6 individuals that collectively and individually competed in point collection through completion of in-app health tasks. Winners of competitions, groups and individuals, received confirmation that UNICEF had sent polio vaccinations to children in need. Further, through completion of in-app health exercises, participants collected liters of water that were sent in their name to children in need through UNICEF. The total cost for the altruistic rewards, paid for by the first author, for all in-app rewards throughout the treatment period was roughly US $16 or US $0.40 per participant.

Procedure

The study was a randomized controlled pilot study with blind raters. The waitlist-control method with simple parallel group

randomization was used to distinguish control and intervention groups. Research specifications and mobile app introduction were sent via email to the parents and legal caretakers of all eligible participants through school officials along with a confirmative survey link, which if answered yielded confirmation for participation. Measures were taken at baseline and 6 weeks later at the study end. All participants received an approximately 5-minute-long introduction regarding the study specifications. The control group received no further contact or information until study-end measures. Anthropometric measures were performed by four research assistants, all of whom were senior undergraduate students at the Psychology Department of University of Iceland. The research assistants were blinded to group assignment. The treatment group received a 10-minute introduction about the mobile app and its functions. Participants were randomly assigned with the coin toss method to teams consisting of 6 individuals that collectively and individually competed in point collection through completion of in-app health tasks. Participation in the intervention arm was defined as downloading the SidekickHealth app and completing at least 3 health exercises within the app. Weekly retention was defined as completing health exercises in the app during each week of the intervention period. Attrition rates were therefore assessed on a weekly basis. A flow chart of the study is provided in Figure 1.

Figure 1. Pilot intervention flow chart. mHealth: mobile health; m: male; f: female.



Statistical Analysis

Data are presented as means (SD) and frequency of observed behaviors. Paired-sampled *t* tests and repeated-measures analysis of variance with adjusted α levels through Bonferroni corrections were used for assessing mean treatment effects (ie, app usage, frequency of in-app exercises, and changes in BMI-SDS and health behavior variables) from baseline to post-treatment. Statistical analysis for the pilot study is mainly descriptive. Differences between population groups for categorical variables (gender, research group, mobile operating system), frequency of health behaviors (intake of fruits and vegetables, water consumption, physical activity), daily screen time, hours of sleep, and clinical cut-off rates of psychometric measures (CDI, MASC) at baseline were assessed with χ^2 tests.

Bidirectional correlations were assessed between predictive variables (gender, research groups, weight category); scoring in the clinical range or above the cutoff of concern on the psychological measures (CDI, MASC, BEARS, GSE); and frequency of in-app categorical health exercises and the outcome variables (treatment adherence, in-app exercises, and BMI-SDS change from baseline to post-treatment). Kendall τ was used to assess the relationship between app usage time categories and completion group. The variables of in-app frequency of different health category exercises (nutrition, mental health, and physical activity) were used for predicting the BMI-SDS change from pretreatment to post-treatment along with treatment adherence through standard multiple regression analyses. Data were analyzed using IBM SPSS Statistics, Release Version 26.00 (SPSS, Inc, 2009, Chicago, IL, USA).

Results

Among all invited participants in the intervention group, 70% (male:female ratio 8:6) began the intervention. Participants' descriptive characteristics at baseline are summarized in Table 1. Retention after 6 weeks of the intervention was 65% among those who began the intervention (male:female ratio 5:4). No significant gender difference was evident in retention rates ($\chi^2_{2,14}$=0.83, *P*=.36). The mean total score on the SUS was satisfactory (78.09, SD 9.82). There was no gender difference in total score on the SUS (*P*=.85) or in-app activity (*P*=.72), although female participants showed a higher frequency of usage on average than male participants in all health behavior categories (Table 2).

Table 1. Baseline characteristics of participants.

Characteristic	Control (n=21)	Intervention (n=20)
Age (years), mean (SD)	15.60 (0.26)	15.64 (0.25)
Male:female ratio	14:7	10:10
Height and weight classification		
Height (m), mean (SD)	1.70 (0.74)	1.71 (0.74)
Underweight, n (%)	4 (21)	3 (20)
Normal weight, n (%)	14 (74)	11 (73)
Overweight, n (%)	0 (0)	1 (7)
Obesity, n (%)	1 (5)	0 (0)
BMI, mean (SD)	22.01 (3.27)	21.42 (3.07)
BMI-SDS[a], mean	0.48	0.26
Hours of nightly sleep, mean (SD)	7.70 (1.07)	7.40 (1.71)
≥3 hours daily active screen time, n (%)	13 (92)	11 (85)
Daily consumption of vegetables, n (%)	12 (86)	9 (69)
Daily consumption of fruits or berries, n (%)	5 (36)	3 (23)
≥3 glasses daily water consumption, n (%)	9 (64)	9 (69)
Clinical anxiety symptoms, n (%)	3 (21)	5 (38)
Clinical depression symptoms, n (%)	1 (7)	2 (15)
General self-efficacy, mean (SD)	34 (4.29)	29 (6.90)

[a]BMI-SDS: standardized BMI.

Table 2. Weekly comparison of usage and attrition.

Week	In-app health exercises completed, n (M:F)	Attrition (%)	Active in app (%)	Individual exercises completed, mean (SD)	*P* values
1	859 (337:552)	0	100	55.25 (10.96)	N/A[a]
2	209 (60:149)	0	100	13.63 (2.94)	<.001
3	280 (142:138)	35	65	17.5 (5.33)	<.001
4	272 (193:77)	35	79	17 (6.35)	<.001
5	157 (109:48)	35	73	9.81 (4.07)	<.001
6	267 (143:124)	35	65	16.69 (8.37)	.02

[a]N/A: not applicable; all weeks were compared to week 1.

There was a significant 76% decrease in the total number of in-app health exercises from week 1 to week 2. However, from week 2 to study end, there was a 22% increase in the total number of exercises. The weekly individual mean number of in-app exercises is shown in Figure 2 and the average usage throughout the intervention is summarized in Table 2.

Figure 2. Weekly mean frequency of individual in-app exercises.

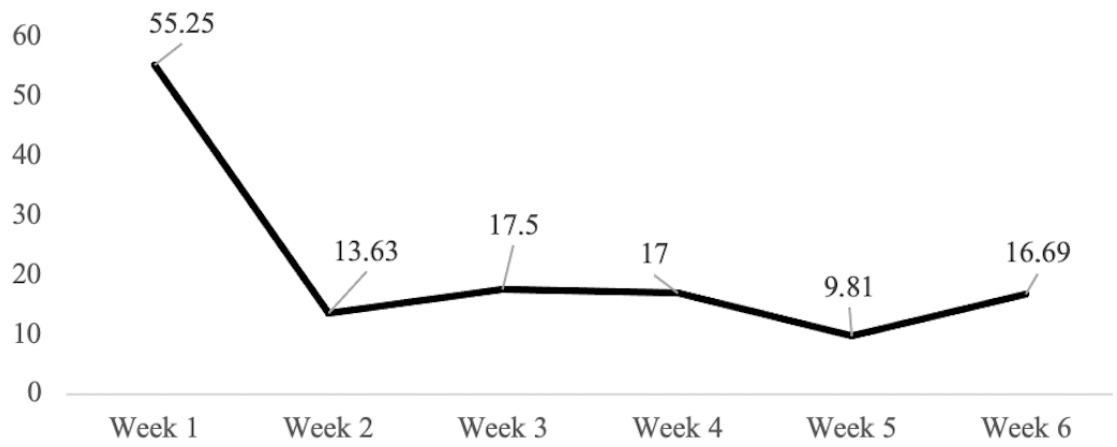


Table 3. Times of day spent on each exercise category.

Time of usage	Food, n (%)	Physical, n (%)	Mental health, n (%)	All categories, n (%)
12 AM to 5:59 AM	42 (5.3)	40 (4.4)	24 (7.8)	106 (5.3)
6 AM to 11:59 AM	149 (18.9)	105 (11.5)	34 (11.1)	288 (14.3)
12 PM to 5:59 PM	303 (38.5)	289 (31.6)	93 (30.3)	685 (34.1)
6 PM to 11:59 PM	294 (37.3)	482 (52.6)	156 (50.8)	932 (46.3)
Total, N	788	916	307	2011

Among the 23 participants who answered the baseline questionnaire, 13 (57%) participants were either interested or very interested in using the app to increase health behavior. Four participants (17%) had never downloaded a health app prior to the intervention. However, 9 participants (39%) had never used health apps, which indicates that 5 (22%) participants had downloaded a health app that they never used. All participants had downloaded and used social media apps. Daily active screen time did not significantly differ between the intervention and control groups or between genders at baseline and at study end ($\chi^2_{1,23}$=3.73, *P*=.16). At baseline, the intervention group had more problems with daytime sleepiness than the control group ($\chi^2_{5,20}$=11.29, *P*=.04) but this difference was no longer detected at study end ($\chi^2_{5,23}$= 2.35, *P*=.80). There were significantly greater problems with disruptive wake-ups during night sleep for participants in the intervention group than for participants in the control arm ($\chi^2_{5,20}$=11.87, *P*=.04) at baseline, although no such difference was evident at study end. Mean hours of sleep did not differ significantly between the intervention group (6.90, SD 1.29) and the control group (7.15, SD 0.69; t_{21}=0.4, *P*=.64) at study end.

Participants who dropped out of the intervention were significantly more likely to use the app between midnight and midday than those who completed the intervention (R_t=0.43, *P*<.001). Details of when the participants used the app and the types of health exercises they completed are shown in Table 3.

There were no significant differences in daily portions of vegetables or fruits and berries between the intervention and control groups. There were also no differences regarding the frequency and amount of sugary or sugar-free soft drinks at pre and post measures, as well as for the consumption of salted chips, French fries, or popcorn and candy or sweets. In addition, there were no differences between the intervention and control groups in terms of the consumption of energy drinks at baseline or at study end. The perceived amount of physical exercise was increased by nearly 20% in the intervention group between baseline and study end but decreased by 26% in the control group. Total anxiety scores did not differ significantly between groups at baseline; however, an 8% decrease was found for the intervention group compared to a 4% increase in the control group (Multimedia Appendix 2). Symptoms of depression were also more evident in the SidekickHealth app intervention group at baseline. However, these differences were not apparent at study end. There was also a significant difference between the intervention group and control group in terms of negative self-esteem at baseline, which was not evident after the intervention (Multimedia Appendix 2). The total score on the GSE scale revealed a roughly 8% increase in self-efficacy scores in the intervention group compared to a 3% decrease in the control group from baseline to study end.

Correlations were found between the count of app exercises during the intervention period and weight difference from baseline to intervention end. However, none of the correlations found was statistically significant due to the small sample size. When underweight participants were excluded from the calculations, the decrease in BMI-SDS from baseline to study end appeared to be significantly more apparent in the intervention group (mean 0.48, SD 0.36) compared to that of the control group (mean 0.08, SD 0.44; t_{17}=–2.14, *P*=.04).

Discussion

There has been a steep and steady increase in mHealth interventions since their appearance roughly a decade ago, with an estimated 325,000 mHealth apps available on the market in 2017 [12]. The purpose of this study was to report attrition rates in a pilot study of an adolescent mHealth intervention and to begin to depict different attrition periods. Time-specific data alongside accurate definitions and analysis of attrition in adolescent mHealth interventions (ie, online CBT programs) targeting emotional disorders or subthreshold emotional problems in adolescent populations are lacking in the literature [15]. Studies on attrition in mHealth interventions targeting adolescent populations frequently present attrition rates in a two-point fashion, from initiation of the intervention to the end of treatment. This study offers some insight into mHealth usage among adolescents in this regard with an observed 35% attrition rate from program initiation to termination, which is similar to reported rates in previous online youth CBT programs [5]. However, as this study focused on usage and attrition rates on a weekly basis throughout the intervention, some interesting findings emerged regarding usage of the app. There was a 22% increase in usage between the second week of the intervention and termination, suggesting a sensitive attrition period shortly after instigation of mHealth interventions treating adolescents that warrants further examination. A better understanding of the timeline from treatment instigation to attrition in adolescent mHealth interventions and how emotional disorders or subthreshold emotional problems are connected to that timeline would be a reasonable next step.

Daily time of usage seemed to play a contributing role to gaining an increased understanding of attrition rates. Participants who dropped out of the intervention were significantly more likely to use the app between midnight and midday than those who completed the intervention. Those who completed the intervention were both more likely to use the app from midday to midnight as well as to complete more in-app exercises on average than those who dropped out. The latter finding may seem somewhat rudimentary but is of importance, since this indicates that participants who dropped out are not less motivated to use the app at initiation of treatment. These findings do perhaps highlight the importance of examining time of usage through survival analysis in subsequent studies assessing the factors contributing to attrition from interventions.

An integral measuring factor in the development and implementation of mHealth interventions for adolescent populations is assessing the intervention's feasibility and usability for the desired research population. Participants reported on the app's adequate usability on the SUS and seemed willing to engage in health exercises, completing over 21 in-app exercises on a weekly basis throughout the intervention. A significant decrease in average exercises performed between the first week of the intervention and subsequent intervention weeks was evident, although average usage leveled off at roughly 15 weekly in-app exercises throughout the intervention period. Interestingly, roughly 39% of the participants had never used an mHealth solution prior to this study, although all participants were accustomed to apps since all had downloaded and used social media apps on their smartphones. These findings reveal higher usage rates among participants as previous studies have shown that merely 8% of adolescents use health apps [13].

This study also highlights noteworthy health behavior changes based on app usage. Indications were toward a positive impact on reported sleep problems, in disruptive night sleep wake-ups, and problematic daytime sleepiness, although these findings need to be studied and documented in a more thorough manner. Reported daily physical exercise was increased by nearly 20% in the intervention group, whereas these numbers dropped by roughly 26% in the control arm. These findings could either point to the fact that in-app usage may heighten perceived levels of physical exercise or simply increase how much the adolescents are physically exercising through the intervention. This could be assessed in a more detailed manner in subsequent studies by comparing the self-reporting and frequency of actual exercise simultaneously. Both factors could aid in increasing health behavior since a perceived increase in behavior can increase self-efficacy levels among adolescents in general mHealth interventions or online CBT interventions targeting emotional problems [30]. These findings are related to the fact that self-efficacy levels increased by 8% among adolescents in the intervention arm while decreasing by 3% among controls.

In conclusion, this pilot study was designed to assess time-specific attrition rates in an adolescent mHealth intervention, as well as the usage and feasibility in relation to self-efficacy levels and participants' emotional and physical health. The study was limited to a single research site and the results are based on a small convenience sample, which limits the ability to generalize the findings and determine the intervention's overall efficacy. However, the results revealed interesting findings regarding sensitive attrition periods that warrant further examination. The obtained attrition rates point to a sensitive period during the first week, and indicate that adolescents who use the app in the afternoons and evenings are less likely to drop out. More research in this area seems called for as this could be studied in relation to app features such as the timing and frequency of notifications and instructions.

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Conflicts of Interest

EE is a minority shareholder and former employee of SidekickHealth AB. The other authors have no conflicts of interest to declare.

Multimedia Appendix 1
App function.
[PNG File , 904 KB - formative_v5i2e21432_app1.png]

Multimedia Appendix 2
Anxiety, depression and self-efficacy measures between research groups.
[PDF File (Adobe PDF File), 77 KB - formative_v5i2e21432_app2.pdf]

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Abbreviations

AAT: appetite awareness training
BMI-SDS: standardized body mass index
CBT: cognitive behavioral therapy
CDI: Children's Depression Inventory
GSE: General Self Efficacy Scale
MASC: Multidimensional Anxiety Scale
mHealth: mobile health
SUS: Systematic Usability Scale

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Original Paper

Improving Efficiency of Clinical Studies Using a Total Digital Approach: Prospective Observational Study

Karin Schenck-Gustafsson[1,2*], MD, Prof Dr; Carina Carnlöf[2*], PhD; Mats Jensen-Urstad[2], MD, Prof Dr; Per Insulander[2*], MD, PhD

[1]Institute of Medicine, Karolinska Institutet, Stockholm, Sweden

[2]Heart and Vascular Theme, Karolinska University Hospital, Karolinska Institutet, Stockholm, Sweden

[*]these authors contributed equally

Corresponding Author:
Karin Schenck-Gustafsson, MD, Prof Dr
Heart and Vascular Theme
Karolinska University Hospital
Karolinska Institutet
Norrbacka S1:02
Stockholm, S 17176
Sweden
Phone: 46 707686487
Email: karin.schenck-gustafsson@ki.se

Abstract

Background: In general, most clinical studies have long recruitment periods. Signing the informed consent is particularly time-consuming when the participant must meet physically with the researchers. Therefore, introducing fully web-based techniques with the use of eAuthentication (BankID) and new digital electrocardiogram (ECG) monitoring could speed up inclusion time, increase adherence, and also reach out to more remote regions.

Objective: The objectives of this study were to explore whether inclusion of a large number of participants could be realized quickly by using a total digital approach both for information and signing of informed consent, along with ECG monitoring and instant feedback on a mobile device. We also explored whether this approach can increase adherence in registration of ECG recordings and answering questionnaires, and if it would result in a more geographically uniform distribution of participants covering a wide age span.

Methods: Women with palpitations were intensively studied over 2 months by means of a handheld ECG monitoring device (Coala Heart Monitor). The device connects to a smartphone or tablet, which allows the participants to obtain the results immediately. Recruitment, study information, and signing the informed consent form with the help of BankID were performed in a completely digital manner.

Results: Between March and May 2018, 2424 women indicated their interest in participating in the study. On June 19, 2018, presumptive participants were invited to log in and register. After 25 days, 1082 women were included in the study; among these, 1020 women fulfilled the inclusion criteria, 913 of whom completed all phases of the study: recording ECG using the handheld device, completion of the prestudy questionnaires, and completion of the poststudy questionnaires 2 months after the ECG recordings. The dropout rate was 9%. In total, 101,804 ECG recordings were made. The mean age was 56 (SD 11) years (range 21-88 years) and 35 participants were 75 years or older. The participants were evenly distributed between living in the countryside and in cities.

Conclusions: Total digital inclusion recruitment of 1082 participants was achieved in only 25 days, and resulted in a good geographical distribution, excellent adherence, and ability to reach a vast age span, including elderly women. Studies using a total digital design would be particularly appealing during a pandemic since physical contact should be avoided as much as possible.

Trial Registration: ISRCTN Registry ISRCTN22495299; http://www.isrctn.com/ISRCTN22495299

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KEYWORDS

ECG recordings; women; palpitations; full digitalization; eAuthentication; BankID; clinical trial; mHealth; electrocardiogram

Introduction

Background

Clinical studies often take longer to finalize than originally planned [1,2] as recruitment requires time-consuming activities such as conducting information meetings and gathering signed informed consent forms. In addition, recruitment often under-represents people living in rural areas because participants are usually recruited from metropolitan areas where research centers tend to be located. To overcome similar difficulties and limitations, some industries have successfully incorporated recent developments in software technology. For example, in Sweden, companies, banks, organizations, and authorities are communicating with and entering into agreements with individuals using BankID software via the internet. Recently, BankID has also been used in psychiatry research to collect signed informed consent [3].

A total digital approach could be used to shorten recruitment time, increase protocol adherence, and ensure representative sampling. That is, this approach could be used to more efficiently recruit participants nationally, provide study information to potential participants, collect signed informed consent forms, deliver interventions, receive and give feedback, and evaluate participants' experiences. Specifically, the aim of this study was to investigate the use of a digital approach in the context of women using a handheld digital electrocardiogram (ECG) device to monitor palpitation symptoms (The Red Heart Study).

Objectives

This study had four objectives: (1) to determine whether rapid inclusion of a large number of participants is possible using only a digital approach (eg, providing study information via the web and collecting signed informed consent using digital signature technology); (2) to determine whether a web-based inclusion approach would result in a geographically uniform distribution of participants; (3) to determine whether a broad age span, including the elderly, could be achieved using only a digital approach; and (4) to determine whether the participants would be more adherent to study protocols using only a digital approach.

Methods

Recruitment and Participants

This was a nonrandomized prospective observational study. Information about the study and a request to participate were advertised on social media platforms such as Facebook and Instagram, and mailed to the female members of the 1.6 Million Club [4], a nongovernmental organization that focuses on women's health. In this communication, the prospective participants were informed that they would be participating in a study that collects ECG recordings using a handheld device (Coala Heart Monitor) for 60 days, and that they would be required to complete four questionnaires before the study and 60 days after the end of the study (ie, after the ECG recordings) [5]. In addition, the prospective participants were informed of the inclusion criteria: aged>18 years, experiencing at least intermittent symptomatic palpitations, ability to read and write Swedish fluently, access to a smartphone or tablet, enrolled in eAuthentication (BankID), and sufficiently fluent in digital technology to complete the questionnaires online. The exclusion criterion was previously known atrial fibrillation or atrial flutter.

Recruitment Period

Between March and May 2018, the study was advertised and prospective participants could register their interest to take part in the study at a dedicated website. On June 19, 2018, the study website was opened for 25 days for participants to register on a first come-first served basis with the expectation that this would be enough time to recruit 1000 women according to the calculated sample size of the Red Heart Study. If this goal was not met, the recruitment period would be extended. During the same visit to the website, the prospective participants signed an informed consent form; provided demographic information; and completed four questionnaires regarding their anxiety, symptoms, depression, and health-related quality of life.

BankID, a Swedish eAuthentication electronic identification document, is comparable to a passport, driver's license, or other physical identification document, and is considered to be secure. BankID enables companies, banks, organizations, and authorities to identify and enter into agreements with private individuals via the internet. The Swedish BankID system consists of a security program downloaded from a bank to a computer, mobile phone, or tablet. BankID is downloaded from a bank's online platform for use with a mobile phone or tablet, or can be mailed to the individual's home in the form of a smart card for use with a computer. At the end of 2018, up to 7.9 of the 9 million possible bank customers in Sweden were using BankID [6].

ECG monitoring with instant feedback on a cell phone or tablet was performed using the Coala Monitor described elsewhere [5]. In this study, Swedish BankID was used to confirm the identity of the participants before they read the study information, signed the informed consent form, and completed the questionnaires [3]. Using the demographic information provided by the participants, we determined the number of participants living in metropolitan areas and the number of participants living in nonmetropolitan areas. In Sweden, the largest metropolitan areas surround the three largest cities: Stockholm, Gothenburg, and Malmö. The results were compared with the actual distribution of the Swedish population (data retrieved from Statistics Sweden) [7].

Statistical Analysis

Only descriptive analyses were used to summarize the sample and study variables, which are presented as mean (SD) or n (%).

Ethics

The investigation conformed to the principles outlined in the 2013 revised Declaration of Helsinki and was approved by the Stockholm Regional Institutional Ethics Committee

(Dnr: 4-84/2018) [8]. The study was performed in accordance with the international conference on Harmonization in Good Clinical Practice guidelines to protect the rights, integrity, confidentiality, and well-being of the trial subjects. All patients signed written consent forms with Swedish BankID. This study is registered as a clinical trial at ISRCTN (ISRCTN22495299).

Results

Participants and Recruitment

Between March and May 2018, 2424 people registered their interest in participating. On June 19, 2018, the website opened for 25 days, and presumptive participants were invited to log in and register. After 25 days (ie, on July 13, 2018), 1082 women were included in the study. After exclusion due to previous use of the ECG recording device, or previously known atrial fibrillation or atrial flutter (Figure 1), 1020 women were included. Of these, 913 completed all phases of the study: recording ECG using the handheld device, completion of the prestudy questionnaires, and completion of the poststudy questionnaires (2 months after the ECG recordings). That is, the dropout rate was 9%. In total, 101,804 ECG recordings were made. The mean age of the women was 56 (SD 11) years (range 21-88 years) and 35 participants were 75 years or older.

The participants were recruited from all over Sweden and 45% lived in metropolitan areas. Currently, 41% of the Swedish population lives in the metropolitan areas of Stockholm, Gothenburg, and Malmö (Table 1).

Figure 1. Flow chart for recruitment of the 2024 presumptive participants. AF: atrial fibrillation; ECG: electrocardiogram.

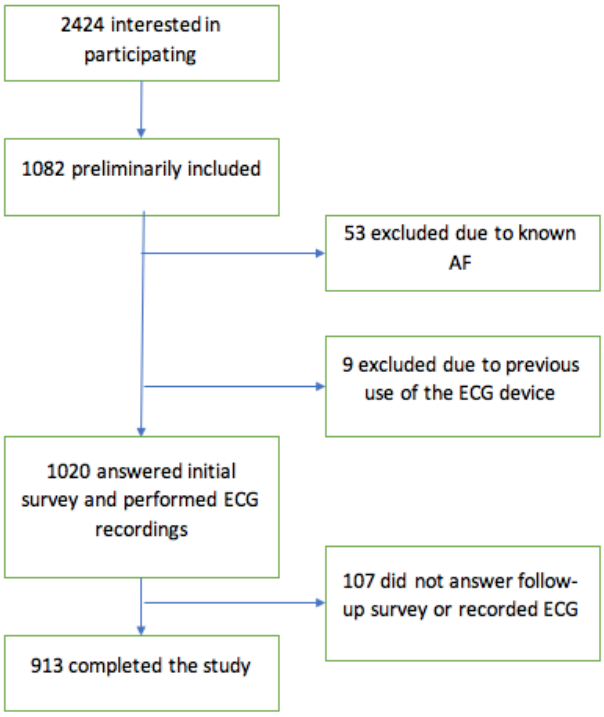

Table 1. Geographical distributions of the Swedish population and study participants.

Area	Population (N=10,230,185), n (%)	Participants (N=1089), n (%)
Stockholm metropolitan	2,371,774 (23.18)	384 (35.26)
Gothenburg metropolitan	1,039,511 (10.16)	66 (6.06)
Malmö metropolitan	739,312 (7.23)	45 (4.13)
Total metropolitan	4,150,597 (40.57)	495 (45.45)
Nonmetropolitan	6,079,588 (59)	594 (54.55)

Discussion

Principal Findings

For the Red Heart Study investigating underlying heart rhythms during palpitations, the use of BankID and other web-based strategies dramatically improved recruitment, information dispersal, adherence, and the collection of informed consent. In total, 1020 women were recruited in 25 days. The actual study, including daily recordings of ECGs with handheld recording devices and the completion of several questionnaires, was performed using only digital technology. Only 107 of the 1020 participants did not complete the study, resulting in a 9%

dropout rate. By comparison, a recent randomized controlled trial of myocardial infarction that offered cognitive behavioral treatment for depression and anxiety had a high dropout rate and low adherence, with 46% of the participants not completing the study, mainly because they were unable or unwilling to use the internet or a mobile phone [9].

In addition, the use of digital recruitment in our study resulted in a uniform geographical distribution of participants with respect to the actual population distribution in Sweden, and an even distribution of the age of participants, who were mainly middle-aged but with a large range spanning from 21 to 88 years. Furthermore, the elderly participants managed well with eAuthentication and the ECG monitoring device connected to a smartphone or tablet.

Previously, eAuthentication using BankID has been used to collect signed informed consent as reported by Nilsson et al [3]. Very recently, BankID has been used to access eHealth platforms, mostly in psychiatric studies, as well as in lifestyle change programs for patients with diabetes and other diseases [10-12]. However, this study used eAuthentication in the context of a total digital protocol to improve adherence, representative distribution of participants, and speed of the recruitment process.

Web-based study information and informed consent may have an advantage compared to standard person-to-person meetings, as it offers the presumptive participant more time to digest, reflect, and fully understand both the study interventions and the informed consent. For example, a recent study found that patients often misunderstand the meaning of informed consent as it pertains to person-to-person appointments [13]. However, we did not compare comprehension between reading information and informed consent online and at a person-to-person meeting.

Swedish bank data reveal that 90% of BankID users are between 21 and 60 years old [6]. This percentage is likely to increase in the near future, making it possible to run fully digitalized studies, including eAuthentication, that include the elderly. In Sweden, the same proportion of women as men use Bank ID.

To date, the recruitment of study participants has been restricted to subjects living close to a research center, as the dispersal of information and informed consent often require a person-to-person interaction. As most research centers are located in metropolitan areas, subjects living in rural areas are often under-represented in trials. Using a web-based recruitment method, which included collecting signed informed consent, we were able to recruit and include subjects from all of Sweden, including less densely populated areas in the most northern parts of the country. This fully digital method also likely resulted in a more unbiased selection of subjects regarding socioeconomic status. Moreover, these digital protocols have the potential to improve stratification regarding age, sex, income, education, concomitant diseases, and drug therapies. That is, a suitable questionnaire can easily be included in a web-based model to help stratify participants. Furthermore, this digital approach to studies has the potential to save a substantial amount of money as it minimizes travel expenses, staff salary, room facilities, and compensation to participants for their time.

Some studies have found success in using digital technology to recruit participants and collect data. For example, in 2003, an internet clinical trial of 205 osteoarthritis patients randomized to either glucosamine or placebo (1200 patients applied online to take part in the study) concluded that their approach saved money, but the study was delayed because the patients needed to sign a physical written consent form and deliver their medical records to the study coordinator [14].

Strengths and Limitations

It is reasonable to assume that the speed of recruitment in this study would not have been possible using traditional person-to-person meetings to disperse information and collect signed informed consent. Moreover, participants, including the elderly, had no problems with the digital approach. They were able to receive information, understand the study, and provide signed informed consent using BankID in this fully web-based study.

Only women with a smartphone, tablet, or computer and BankID were eligible for inclusion. Consequently, selection bias may be present as individuals uncomfortable using these digital technologies may have self-selected out. Moreover, a previous study showed that people who agree to participate in digital studies, compared to those who do not, are younger; mostly male; and have better health, quality of life, socioeconomic status, and digital skills [15]. Therefore, our study included women of all ages. Studies using a total digital design would be particularly appealing during a pandemic, as physical contact should be avoided as much as possible. Finally, the digital study design saves money both for participants and study investigators.

Conclusion

By using online information and eAuthentication for signing informed consent, recruitment of 1020 participants was achieved in only 25 days, which is a relatively short period. Furthermore, this digital design resulted in a geographically uniform distribution of participants compared with the actual national population distribution, and therefore our study had a more unbiased selection of subjects regarding socioeconomic status. Finally, high adherence regarding questionnaires and ECG recordings was achieved using this fully digital design.

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Authors' Contributions

KG, PI, and CC designed the study. KG, PI, and CC supervised the production process, analyzed the data, and wrote the manuscript. MU advised during the process and reviewed the manuscript. All authors read and approved the final paper.

Conflicts of Interest

None declared.

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Abbreviations

ECG: electrocardiogram

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Original Paper

Evaluating Closures of Fresh Fruit and Vegetable Vendors During the COVID-19 Pandemic: Methodology and Preliminary Results Using Omnidirectional Street View Imagery

Shahmir H Ali[1], BA; Valerie M Imbruce[2], PhD; Rienna G Russo[3], MHS; Samuel Kaplan[4]; Kaye Stevenson[4]; Tamar Adjoian Mezzacca, MPH; Victoria Foster[3], MPH; Ashley Radee[3], BA; Stella Chong[3], BA; Felice Tsui[5], BA; Julie Kranick[3], MA; Stella S Yi[3], PhD

[1]Department of Social and Behavioral Sciences, School of Global Public Health, New York University, New York, NY, United States

[2]Environmental Studies Program, Binghamton University, State University of New York, New York, NY, United States

[3]Department of Population Health, NYU Grossman School of Medicine, New York, NY, United States

[4]Chatham High School, Chatham, NJ, United States

[5]Mailman School of Public Health, Columbia University, New York, NY, United States

Corresponding Author:
Stella S Yi, PhD
Department of Population Health
NYU Grossman School of Medicine
8th Floor, Room 8-13
180 Madison Avenue
New York, NY
United States
Phone: 1 646 501 3477
Email: Stella.Yi@nyulangone.org

Abstract

Background: The COVID-19 pandemic has significantly disrupted the food retail environment. However, its impact on fresh fruit and vegetable vendors remains unclear; these are often smaller, more community centered, and may lack the financial infrastructure to withstand supply and demand changes induced by such crises.

Objective: This study documents the methodology used to assess fresh fruit and vegetable vendor closures in New York City (NYC) following the start of the COVID-19 pandemic by using Google Street View, the new Apple Look Around database, and in-person checks.

Methods: In total, 6 NYC neighborhoods (in Manhattan and Brooklyn) were selected for analysis; these included two socioeconomically advantaged neighborhoods (Upper East Side, Park Slope), two socioeconomically disadvantaged neighborhoods (East Harlem, Brownsville), and two Chinese ethnic neighborhoods (Chinatown, Sunset Park). For each neighborhood, Google Street View was used to virtually walk down each street and identify vendors (stores, storefronts, street vendors, or wholesalers) that were open and active in 2019 (ie, both produce and vendor personnel were present at a location). Past vendor surveillance (when available) was used to guide these virtual walks. Each identified vendor was geotagged as a Google Maps pinpoint that research assistants then physically visited. Using the “notes” feature of Google Maps as a data collection tool, notes were made on which of three categories best described each vendor: (1) open, (2) open with a more limited setup (eg, certain sections of the vendor unit that were open and active in 2019 were missing or closed during in-person checks), or (3) closed/absent.

Results: Of the 135 open vendors identified in 2019 imagery data, 35% (n=47) were absent/closed and 10% (n=13) were open with more limited setups following the beginning of the COVID-19 pandemic. When comparing boroughs, 35% (28/80) of vendors in Manhattan were absent/closed, as were 35% (19/55) of vendors in Brooklyn. Although Google Street View was able to provide 2019 street view imagery data for most neighborhoods, Apple Look Around was required for 2019 imagery data for some areas of Park Slope. Past surveillance data helped to identify 3 additional established vendors in Chinatown that had been missed in street view imagery. The Google Maps “notes” feature was used by multiple research assistants simultaneously to rapidly collect observational data on mobile devices.

Conclusions: The methodology employed enabled the identification of closures in the fresh fruit and vegetable retail environment and can be used to assess closures in other contexts. The use of past baseline surveillance data to aid vendor identification was valuable for identifying vendors that may have been absent or visually obstructed in the street view imagery data. Data collection using Google Maps likewise has the potential to enhance the efficiency of fieldwork in future studies.

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KEYWORDS

built environment; Google Street View; food retail environment; COVID-19; geographic surveillance; food; longitudinal; supply chain; economy; demand; service; vendor; surveillance

Introduction

The COVID-19 pandemic has evolved into one of the most significant and socially disruptive health crises in recent history, with growing concern for how food systems at both the global and local levels are being affected by the dramatic economic and social impacts of the pandemic [1]. Given the significance of the retail food environment in fostering and maintaining healthy diets [2], disruptions to certain components of this environment, such as access to fresh fruits and vegetables, have the potential to detrimentally impact population health, which has already been identified as an area of concern [3]. However, early observational evidence from Google Search frequency data suggests greater search-based interest in fresh foods during the COVID-19 pandemic [4], which supports shopping behavior data showing a significant increase in fresh fruit and vegetable sales during the early months of the pandemic (although demand is stabilizing) [5]. Moreover, social distancing measures are significantly impacting direct sources of fresh produce, such as farmers' markets [3].

Although national and international supermarket chains, warehouse clubs, and supercenters dominate grocery retail [6], fruits and vegetables are sold in a variety of other food retail environments as well. Fresh fruit and vegetable vendors are often smaller and more community-oriented than other restaurant or retail food outlets, and can include chain or independent grocery stores, greengrocers, storefront stands (or simply "storefronts," which are areas in front of stores used to sell fresh fruits and vegetables), street carts, and even makeshift platforms focused on the sale of fresh fruits and vegetables [7]. Although fresh produce—as opposed to processed produce (ie, canned, dried, or frozen produce that can often be found in other larger food retailers)—may not have a substantially higher nutritional value [8] (and fresh produce may also be purchased at these larger food retailers [9]), smaller community fresh fruit and vegetable vendors who may conduct business on the sides of major streets or on storefronts have played an integral role in the food environment in large urban centers such as New York City (NYC) [10], particularly in ethnic enclaves where they represent a significant source of fruits and vegetables [7].

Many fresh fruit and vegetable vendors (particularly street carts selling fresh fruits and vegetables) in cities across the United States, including NYC, have been forced to close since the COVID-19 pandemic began due to the dual concerns of plummeting demand and fear of contracting COVID-19 [11,12]. Within cities, the importance and presence of fresh fruit and vegetable vendors varies by neighborhood. In Manhattan's Chinatown, fresh fruit and vegetable vendors are known for their low prices and play a significant role in the food retail environment as a critical food source for socially and economically vulnerable populations (eg, the elderly [13]), which have been a growing proportion of Manhattan's Chinatown demographic makeup. Furthermore, these fresh fruit and vegetable vendors are magnets for tourists and interborough shoppers from diverse cultural backgrounds—not only Asian backgrounds—who are looking for items that cannot be found elsewhere in the city, or for the same low costs [7].

Unlike larger, well-established grocery store vendors, these fresh fruit and vegetable vendors (which are relatively smaller and more community-centered) may not have the financial infrastructure to withstand the changes in supply and demand induced by the COVID-19 pandemic [14]; thus, the risk of closure or changes in services may be more significant for these vendors. Likewise, many fresh fruit and vegetable vendors in NYC are immigrants [7,15], often with low English proficiency [7], and thus may not have the same social and economic capital or legal protections that enable the retail resiliency of other vendors. Therefore, understanding how the pandemic has impacted fresh fruit and vegetable vendors can provide vital insights into changes in fresh fruit and vegetable food environments in large urban centers, such as NYC, where these community-based vendors are a significant part of the fresh produce environment.

Evaluating the impact of the COVID-19 pandemic on services provided by fresh fruit and vegetable vendors fundamentally requires surveillance data both before and after the onset of the pandemic. Given that updated surveillance data of the diverse types of community fresh fruit and vegetable vendors may not be available (particularly for the more informal, street-based vendors), Google Street View is a promising platform for data collection in this context. Google Street View has been employed in a variety of health research contexts [16], including assessing local food environments [17,18], and is a less resource-intensive, easily accessible source of visual data in comparison to other forms of visual data collection, such as those relying upon in-person fieldwork [16]. Google Street View data is usually collected from cars sent out by Google, which are equipped with cameras with the ability to capture 360-degree views in a particular location. Image data is then geotagged and uploaded on Google platforms (such as Google Maps) accessible for public use [19]. Importantly, these Google Street View images are routinely updated. Large urban centers in high-income countries (eg, NYC) often have more recent Google Street View imagery data in comparison to other locations [16],

which is likely because a location's population density contributes to the frequency of street view imagery updates conducted by Google [19]. For example, in June 2020, NYC Google Street View imagery data from June and October 2019 could be accessed.

In the past, Google Street View has been used for cross-sectional or validation-based study designs, and thus the use of the platform for longitudinal health research in neighborhood settings is an area in need of more exploration [16]. Likewise, while longitudinal analysis of Google Street View data has been effective in retrospectively analyzing changes in food retail environments, the use of the platform to analyze more recent changes by triangulating information from the platform with other means of surveillance remains underexplored [20].

Therefore, the aim of this study is to document the methodology developed to assess changes in the food retail environment (notably, closures of fresh fruit and vegetable vendors) before and during the COVID-19 pandemic in NYC using triangulated data from Google Street View, past surveillance (when available), and Google Maps–based, socially distanced in-person assessments. Specifically, we document the following: (1) the specific procedures used to conduct fresh fruit and vegetable surveillance both before and during the pandemic such that they may be replicated by others in other locations, and (2) the strengths and limitations of this methodology, as well as the challenges faced. Importantly, as opposed to analyzing general net changes in the fresh fruit and vegetable food retail environment (which has been explored for other food retail environments using street view data [20]), a specific focus of this methodology was to analyze closures and other visually observable service impacts on pre-existing vendors directly prior to and during disruptive crises such as the COVID-19 pandemic.

Methods

Baseline Fresh Fruit and Vegetable Vendor Assessment: Past Surveillance Data

NYC is divided into five boroughs, which each contain many neighborhoods. The boroughs of Manhattan and Brooklyn were analyzed in this study. Neighborhoods were defined using NYC Neighborhood Tabulation Areas, and further details on their identification have been described elsewhere (RG Russo et al, unpublished data, July 2020; SS Yi et al, unpublished data, July 2020); in short, data on the socioeconomic and health disparities of Manhattan and Brooklyn neighborhoods were used to select one socioeconomically advantaged neighborhood (Upper East Side, Park Slope), one socioeconomically disadvantaged neighborhood (East Harlem, Brownsville), and one Chinese ethnic neighborhood (Chinatown, Sunset Park) in each borough. An ethnic Chinese neighborhood was selected for analysis in each borough given observational evidence identifying the strong role fresh fruit and vegetable vendors play in the fruit and vegetable retail environments within Chinese ethnic neighborhoods in NYC [7]. Past surveillance data on the locations and types of fresh fruit and vegetable vendors in the select 3 neighborhoods in Manhattan (Chinatown, Upper East Side, and East Harlem) and 3 neighborhoods in Brooklyn (Sunset Park, Park Slope, and Brownsville) were first identified to establish the baseline fresh fruit and vegetable vendor landscape from which prepandemic and pandemic assessments were to be conducted.

Identifying past surveillance data to guide the prepandemic fresh fruit and vegetable vendor identification was important for two reasons. First, one of the key limitations of Google Street View data extraction is that visual obstructions in the Google Street View image may conceal fresh fruit and vegetable vendors (eg, in the NYC Chinatown extraction, trucks parked in the street could make sidewalks and some smaller vendors, such as makeshift platforms, difficult to view or notice). Therefore, the non–Google Street View surveillance data allows one to account for these visually obstructed and inconspicuous vendors. Second, some fresh fruit and vegetable vendors in cities such as NYC operate in a temporary capacity, with some operating in makeshift physical locations in areas such as parking lots. Therefore, integrating past cross-sectional non–Google Street View surveillance data with visual data from Google Street View aids in identifying long-term vendors and allows for a more comprehensive, precise evaluation of how the COVID-19 pandemic has impacted established fresh fruit and vegetable vendors that operate in a more sustained capacity within the community.

Imbruce [7] collected in-depth fresh fruit and vegetable surveillance data in Chinatown, which was used as the baseline fresh fruit and vegetable vendor assessment data for this neighborhood, given the diversity of fresh fruit and vegetable vendors and specificity of geographic information included in the data set. Equivalent information was not available for the other five neighborhoods. However, Fuchs et al [15] did collect geographic data on a small percentage of Green Carts (mobile street vendors specially permitted to sell exclusively fresh fruits and vegetables) in East Harlem and Brooklyn. Therefore, this information was used as a guide to identify the potential locations of fresh fruit and vegetable vendors in the prepandemic assessment of these neighborhoods, using Google Street View to concretely identify fresh fruit and vegetable vendor locations. Importantly, given this past surveillance data was quite dated (ranging from 2003 to 2013) and that fresh fruit and vegetable vendors are likely to have changed between then and 2019, this supplementary surveillance data was largely used to identify any additional potential vendors or locations of past clusters of vendors during in-person checks; additional vendors identified during in-person checks may have been missing or visually obstructed in the 2019 street view imagery data. For the Upper East Side, Park Slope, and Sunset Park, for which there were no comprehensive or reliable baseline fresh fruit and vegetable vendor assessment data sources, Google Street View was solely relied upon to identify prepandemic vendors (Table 1).

Table 1. Data sources used to assess COVID closures of fresh fruit and vegetable vendors.

Neighborhood	Baseline data	Prepandemic data	Data during the pandemic
Chinatown	2003-2005 (Imbruce, 2015 [7])	June-October 2019 (Google Street View)	June-July 2020 (in-person)
Upper East Side	None	June-October 2019 (Google Street View)	June-July 2020 (in-person)
East Harlem	2013 (Fuchs et al, 2014 [15])[a]	June-October 2019 (Google Street View)	June-July 2020 (in-person)
Sunset Park	None	June-October 2019 (Google Street View)	June-July 2020 (in-person)
Park Slope	None	June-October 2019 (Google Street View)[b]	June-July 2020 (in-person)
Brownsville	2013 (Fuchs et al, 2014 [15])[a]	June-October 2019 (Google Street View)	June-July 2020 (in-person)

[a]Since geographic surveillance data only captured 45/121 of the Green Carts given permits in Manhattan and 19/132 of those in Brooklyn, and specific location data was not available, this data source was only used to provide a general understanding of potential prior locations.

[b]Some streets did not have Google Street View data from 2019, and these areas were supplemented with street-view surveillance from Apple Look Around.

To allow for disaggregated analyses, fresh fruit and vegetable vendors identified in either the baseline or prepandemic assessments were categorized into four types (store/supermarket, storefront, street vendor/other, and wholesale) based on criteria identified by Imbruce [7] (Table 2). Although some of the terminology for these categorizations has been employed in different ways in past research [21], for the purposes of this study, the definitions provided by Imbruce, which were based on in-depth fieldwork in NYC's Chinatown, were used to define different fresh fruit and vegetable vendors.

Table 2. Types of fresh fruit and vegetable vendors analyzed, adapted from a study by Imbruce [7].

Type	Description
Store/supermarket	Both the sidewalk in front of the store and the inside of the store are used primarily for selling produce (operated by same owner).
Storefront	Only the sidewalk in front of a store is used to sell produce.
Street vendor/other	Produce sold in areas of high foot traffic in spaces near streets, sometimes by itinerant vendors. Other types of fresh fruit and vegetable vendors (eg, outdoor markets, makeshift stores) were also included.
Wholesale	Produce is bought from farms or other produce brokers in high volumes and is sold to retail vendors, restaurants, or individuals by the box.

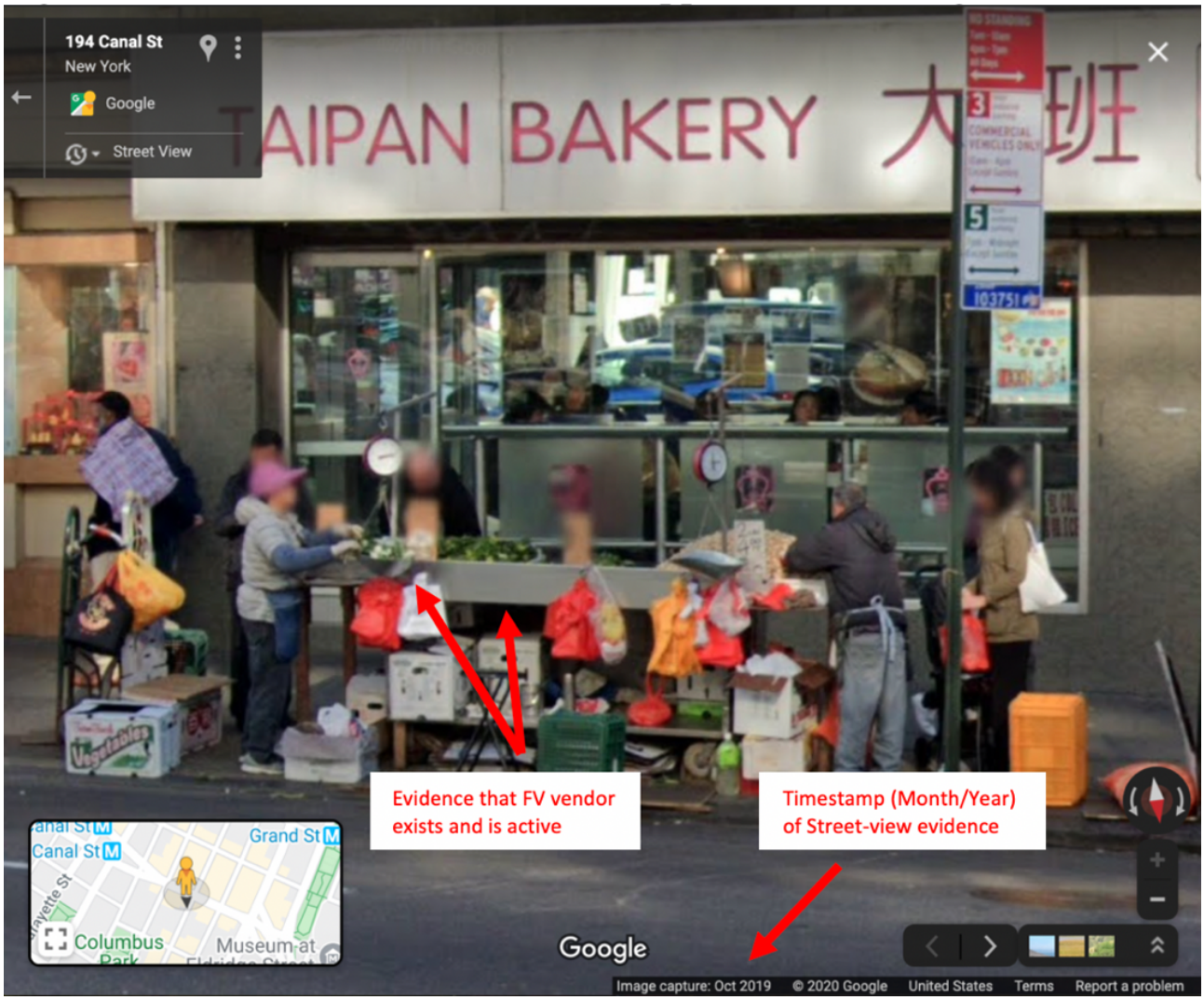
Prepandemic Fresh Fruit and Vegetable Vendor Assessment: Google Street View Extraction

A spreadsheet was created using the data points identified from the baseline fresh fruit and vegetable assessment. For Chinatown, each baseline data point was given a unique ID number from this prior surveillance data [7], and any other information provided by the survey (eg, street location, category of fresh fruit and vegetable vendor) was included. Given that many fresh fruit and vegetable vendors (notably street carts) may not have visibly identifying features, the identification of these unique fresh fruit and vegetable data points was informed by (1) the specific street address where a particular vendor was located, (2) the type of vendor (eg, if a street cart fresh fruit and vegetable vendor was stationed in front of a store/storefront fresh fruit and vegetable vendor at the same street address, these would each get unique ID numbers). Google Street View was then employed to ascertain whether the fresh fruit and vegetable vendor corresponding with each unique ID was visible (labeled as "found") from a 2019 Google Street View image at the approximate location identified from the prior surveillance data [7]. For all other neighborhoods, since reliable past surveillance data was not available to guide the Google Street View assessment, research assistants virtually walked down each street of the neighborhoods using Google Street View and catalogued all fresh fruit and vegetable vendors they identified in a spreadsheet along with the approximate street location, date of Google Street View image, and any notes relevant to the vendor's services or its location.

From the street view image at the location of the baseline site, a fresh fruit and vegetable vendor data point was labeled as "found" if the following was true: (1) the physical location of a fresh fruit and vegetable vendor was able to be clearly identified, based on the description or category of the vendor provided by the prior survey (eg, cart, storefront, wholesaler), and (2) there was visual evidence to support the vendor being active, such as the presence of fruits and vegetables and/or individuals actively engaging in consumer activity (eg, exchanging cash or multiple people holding grocery bags in the vicinity of the location). Fresh fruit and vegetable vendors that did not qualify as being "active" included those with signage indicating ongoing construction or renovation, or an indication that the vendor had not yet formally opened for business (ie, "opening soon"). Vendors with signage that indicated changed services (eg, delivery or takeout only) were classified as "active." Vendors exclusively selling items other than fruit and vegetables (eg, clothes or toys) were not included. Any fresh fruit and vegetable vendor data point that did not satisfy these conditions was labeled as "not-found"; furthermore, if there was visual evidence to suggest that there was a temporarily or permanently closed fresh fruit and vegetable vendor matching

the description from the prior survey at the location of the data point, then these observations were noted in a separate "notes" column in the extraction data sheet. Likewise, any other anomalies regarding the visual Google Street View evidence from the "found" or "not found" fresh fruit and vegetable vendors were noted in this "notes" column. The time stamp of the Google Street View image (month and year) was also catalogued. A visual depiction of the information gleaned from the Google Street View scan is displayed in Figure 1.

Figure 1. Data extracted from Google Street View to support fruit and vegetable vendor presence. FV: fruit and vegetable.



Although Google Street View image data across all neighborhoods were largely time-stamped with a 2019 date, some streets in Park Slope were observed to only have Google Street View imagery data from dates prior to 2019. To address this, research assistants collected street imagery data from Apple Look Around, a new geographic imagery system implemented by Apple Inc in 2019-2020, which is analogous to Google Street View [22]. Similar to Google Street View, Apple Look Around relies upon ground surveys conducted by commissioned vehicles to collect geographic imagery data [23]. Select areas of Park Slope without 2019 time-stamped Google Street View data were supplemented with 2019 time-stamped Apple Look Around imagery to complete the data collection for this neighborhood.

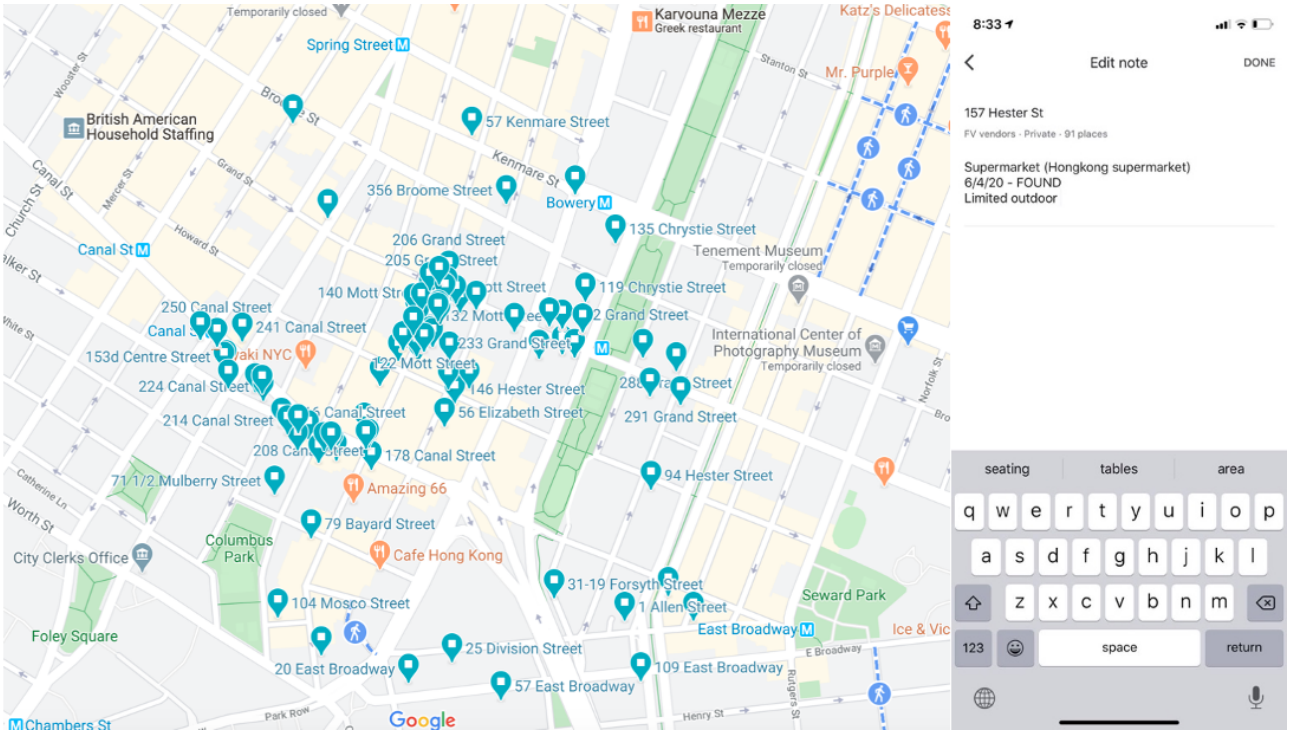
Fresh Fruit and Vegetable Vendor Assessment After the Start of the COVID-19 Pandemic: Google Maps–Based In-Person Checks

Following the 2019 Google Street View data extraction, an in-person check was conducted for each fresh fruit and vegetable vendor between June and July of 2020. All fresh fruit and vegetable vendors, including those that were either "found" or "not found," received in-person checks to ensure vendors that may not have been found due to the aforementioned limitations of Google Street View imagery were not excluded. A protocol for rapid in-person assessments was designed to specifically incorporate principles of social distancing and minimize outside exposure for research staff. These principles were achieved through two key components of the protocol. First, to minimize the time needed to find the locations of each fresh fruit and vegetable vendor and enhance the speed of data collection, several functions in Google Maps were used. Specifically, the "Your Places" feature was used to create lists containing the

pinpoint locations of each fresh fruit and vegetable vendor in a shared Google Maps account. The "notes" feature of each pinpoint was then used to record the unique vendor ID, and other information from the prepandemic assessment stage relevant to the in-person checks (such as the name and category of vendor, as identified from Google Street View or baseline surveillance). From the spatial data of the fresh fruit and vegetable vendor pinpoints, an in-person check route was designed to minimize the amount of walking or driving required. During the in-person checks, research staff accessed Google Maps on their mobile phones using the shared account with the fresh fruit and vegetable vendor lists and pinpoints. Second, measures were taken to also enhance social distancing for research stuff, which (along with the standard government-mandated use of face masks at the time of the visit) included conducting in-person checks by car when possible (largely to identify street cart or storefront vendors that could be identified from a car). Finally, data collection was conducted largely during the afternoon, on different days of the week, and not during periods of inclement weather to minimize the potential of conducting data collection during routine or temporary fresh fruit and vegetable vendor closures.

When a pinpoint was reached, research staff used the "notes" feature, which contained the prepandemic information, to catalog the pandemic assessment data, including the following: (1) whether the vendor was found and, if so, whether the vendor was observed to be open, open with a more limited setup, or closed, (2) the date the in-person check was conducted, and (3) any notes about the vendor or its services. Given that the physical location of vendors may have slightly changed (notably street cart vendors), to help in the identification of a particular vendor, research assistants examined all street addresses in close proximity to the noted location (eg, examining a few street numbers to the left and right of the location), as well as information from the prepandemic street view imagery indicating the types of produce being sold at the location. "Open with more limited setups" was noted when vendors appeared to have slightly changed or offered fewer services than what was observed during the Google Street View prepandemic extraction (eg, fresh fruit and vegetable stores closing the outdoor portions of their services, or certain sections of street carts closed or selling fewer quantities or varieties of produce). Examples of notes made during in-person assessments included if a vendor was likely replaced by a new store, or if the vendor was sharing services or affiliating with another vendor. Figure 2 displays an example of the Google Map pinpoints and "notes" feature interface used for the in-person data collection.

Figure 2. Example of Google Maps pins and the "notes" feature used for in-person checks (Chinatown).



Importantly, during data collection, research assistants may have also encountered fresh fruit and vegetable vendors that did not have Google Maps pinpoints based on the baseline and street view imagery data. Given the focus of this methodology was to evaluate closures and other visually observable service impacts on fresh fruit and vegetable vendors, such vendors lacked the prepandemic 2019 street view or baseline surveillance data to be eligible to be included in the longitudinal assessment of fresh fruit and vegetable vendor closures; therefore, systematic data collection was not conducted for these vendors. Nevertheless, throughout data collection, research assistants reported these additional vendors to the study team.

Results

The initial Google Street View extraction (partially informed by baseline data in the case of Chinatown) identified 80 vendors in the three Manhattan neighborhoods: 56 in Chinatown, 12 on the Upper East Side, and 12 in East Harlem. A total of 55

vendors were also identified in the three Brooklyn neighborhoods: 48 in Sunset Park, 4 in Park Slope, and 3 in Brownsville. Although only 53 vendors were identified using Google Street View in Chinatown, during in-person checks, 3 additional vendors were identified that had been noted in the baseline surveillance data but were not found using Google Street View, increasing the total vendor sample of Chinatown to 56. A summary of the preliminary extraction data and COVID-19 pandemic closure data is presented in Table 3. An example of the data visualization methods used to highlight pandemic-related closures is displayed in Figure 3. Overall, 60 of the 135 vendors (44%) identified in all 6 neighborhoods were either absent/closed or had more limited setups following the beginning of the COVID-19 pandemic.

Figure 3. Example of consolidated visual output using data collected from prepandemic and pandemic assessments (Chinatown).

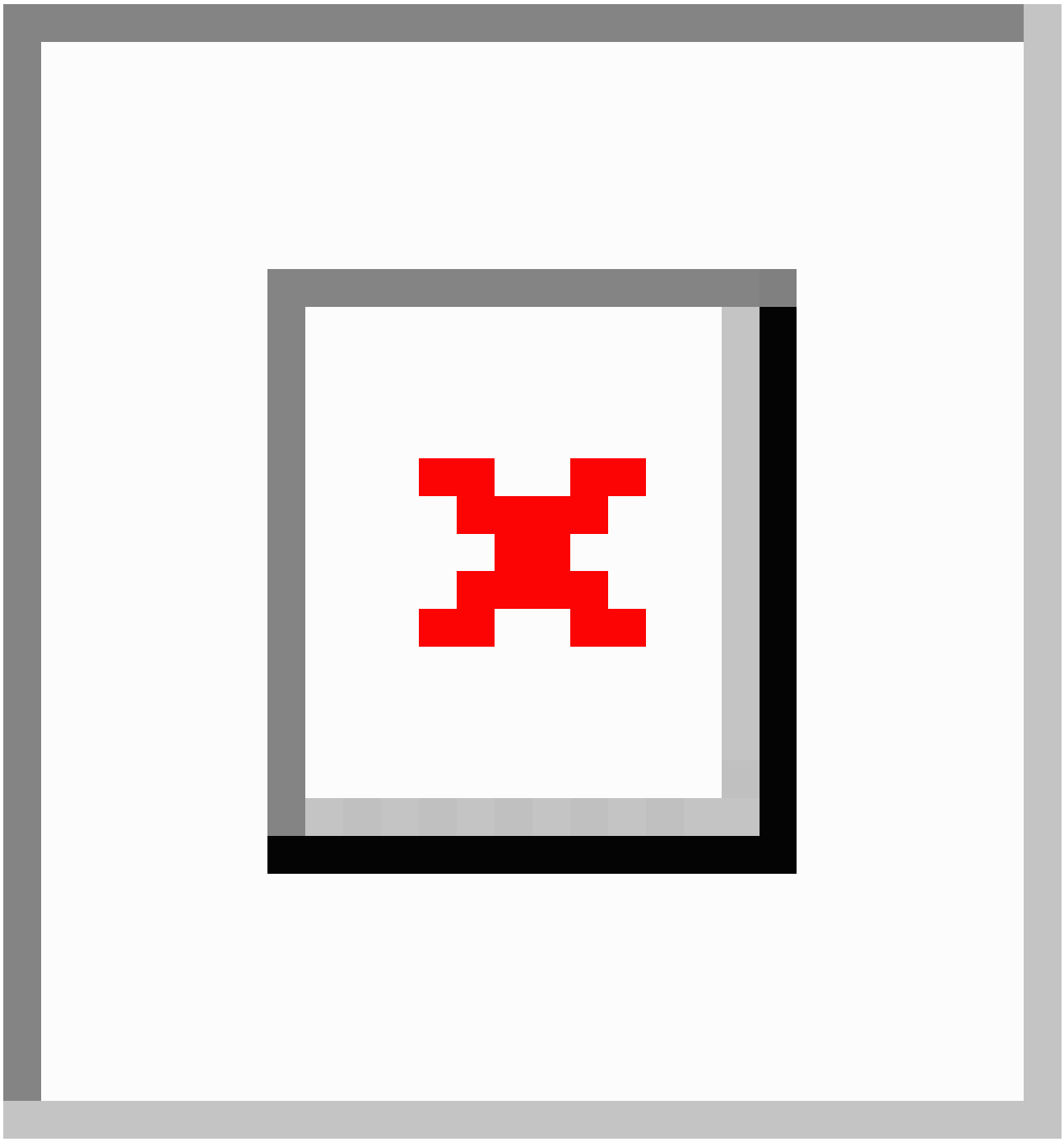


Table 3. Preliminary findings on closures of fresh fruit and vegetable vendors in select New York City neighborhoods during the COVID-19 pandemic using Google Street View analysis.

Neighborhood	No change, n (%)	Closure during the pandemic, n (%)	More limited setups during the pandemic, n (%)
Manhattan			
Chinatown (n=56)[a]	27 (48.2)	24 (42.9)	5 (8.9)
Upper East Side (n=12)	5 (41.7)	0 (0.0)	7 (58.3)
East Harlem (n=12)	7 (58.3)	4 (33.3)	1 (8.3)
Brooklyn			
Sunset Park (n=48)	30 (62.5)	18 (37.5)	0 (0.0)
Park Slope (n=4)	3 (75.0)	1 (33.3)	0 (0.0)
Brownsville (n=3)	3 (100.0)	0 (0.0)	0 (0.0)

[a]Includes vendors found in the 2019 Google Street View check (n=53) and additional vendors found during in-person checks (n=3), which were also identified in other baseline surveillance.

Discussion

The integrated Google Street View–centered longitudinal assessment of fresh fruit and vegetable vendors was able to identify significant closures among these vendors during the COVID-19 pandemic by comparing evidence from shortly before the pandemic in 2019 and during the pandemic. Although the identified closures cannot all be directly attributed to the COVID-19 pandemic itself using this preliminary surveillance evidence, this approach helped to highlight the extent of pandemic-related closures within a facet of the food retail environment with limited formal, consistent surveillance, which nonetheless plays an integral role in underserved ethnic minority communities, such as those in Manhattan's Chinatown [7]. Likewise, Google Street View data could be transferred efficiently into Google Maps as pinpoints to facilitate time-efficient and resource-efficient in-person checks. To the best of our knowledge, the use of the "notes" feature of Google Maps has not been explicitly employed as a data collection tool in past health research. Google Maps was able to provide real-time information to multiple members of the study team on which sites had been catalogued; this is evidence that the platform can significantly enhance the efficiency of fieldwork for future studies, particularly in resource- and time-scarce contexts such as the COVID-19 pandemic.

Importantly, use of past baseline surveillance data (when available) to assist in fresh fruit and vegetable vendor identification during the prepandemic assessment was found to be valuable; the identification of 3 vendors in Chinatown that were not found using Google Street View but were found in both the baseline assessment and in-person visits supports preliminary concerns that visually obstructed vendors may be missed in Google Street View imagery. Further use of Google Street View should also consider supplementing assessments with other data sources, particularly when assessing objects that may be susceptible to being missed or obscured in Google Street View imagery [16]. These findings directly support evidence from prior Google Street View research, which similarly identified image quality and visual obstructions as areas of concern [16]. However, unlike many past studies, the date of capture for the analyzed Google Street View imagery was consistently recent (almost always sometime in 2019) [16]; this was likely due to NYC—a large, populated area likely to be frequented by Google-commissioned cars for Google Street View surveillance—being the study setting of this project. Given that large, urban environments have been particularly affected by the COVID-19 pandemic [24], Google Street View may be particularly useful for conducting prepandemic versus pandemic (or postpandemic) assessments in these environments.

Likewise, given the significant disparities in food purchasing behavior—including the quantity and quality of food as well as purchasing frequency and sources of food access—across various minority populations in the United States, the importance of this methodology also lies in its ability to survey aspects of the food retail environment that may be critical for underserved minorities, such as Asian Americans [7]. Although conducting prepandemic/pandemic closure assessments for storefront food vendors (eg, restaurants or grocery stores) can be done through the use of a variety of sources of information, such as the internet (eg, Yelp, Google, social media) or publicly available phone numbers (RG Russo et al, unpublished data, July 2020), fresh fruit and vegetable vendors are relatively disconnected from public information databases as they cater to localized populations and may operate less formally than other food retail outlets. Given these fresh fruit and vegetable vendors both serve and are often managed by vulnerable minority populations [7,15], understanding the significance of this methodology with respect to health equity concerns in food retail environment surveillance is paramount.

Nonetheless, there were a number of limitations faced throughout the study. First, it is important to acknowledge that some vendors may have been closed for the day at the time of Google Street View image capture or in-person checks, which may have led to an overestimation of pandemic-related closures. These potential routine or temporary closures have particularly impacted the assessment of street vendors (as opposed to stores or storefronts, which may have more established operating hours or more staff to assist in maintaining consistent operations). These concerns were mitigated in two ways: (1) baseline data helped to corroborate any vendors that might have been missed in Google Street View extraction, and (2) in-person checks were conducted at times of the day when most food retail vendors

(including fresh fruit and vegetable vendors) are open (ie, afternoon, early afternoon).

Moreover, while steps were taken to assist in-person checks of fresh fruit and vegetable vendors that may have a slightly changed geographic location, some vendors may have moved to an entirely different street or completely changed their services between 2019 and 2020. Likewise, while the sample of vendors included in the prepandemic assessment was maximized by using recent (largely June and October 2019) imagery data along with supplemental past surveillance data to identify established fresh fruit and vegetable vendors that may have been obstructed or missed in street view imagery but were present in in-person checks, some vendors that been missed by these data sources or that had opened later in 2019 but still prior to the impact of the COVID-19 pandemic in the United States were unable to be examined. However, while systematic data collection of additional vendors identified during in-person checks was not conducted, research assistants did not report more than a few additional fresh fruit and vegetable vendors in each neighborhood outside of the prepandemic sample, in part due to the aforementioned efforts as well as the short time frame between the prepandemic data assessments and those obtained during the pandemic. Nonetheless, while examining net changes in the food retail environment was not a focus of this particular methodology, the incorporation of systematic analysis of new vendor openings after disruptive crises such as the COVID-19 pandemic is another area worthy of exploration (including across different types of food retail outlets).

Finally, it is likely that some fresh fruit and vegetable vendors may have closed for some time early on in the pandemic but may have recently reopened. Alternatively, vendors may have opened shortly after the particular day in-person checks were conducted, but still within the June-July 2020 endpoint time frame. This is a limitation of the approach; to provide the most accurate, cross-sectional COVID-19 pandemic surveillance data, data collection must occur within a short period of time. In this case, due to the novelty of the methodology, many of its components were being developed and tested by the study authors throughout each stage, thus limiting the speed of the in-person checks. Likewise, due to the COVID-19 pandemic, caution also had to be taken in the timing of the in-person checks to minimize outdoor exposure for research staff. However, we intend on doing targeted follow-up assessments in subsequent months.

Indeed, the methodology described in this study has significant implications for research aimed at longitudinally assessing recent closures in the food retail environment (particularly among fresh fruit and vegetable vendors or other retailers with limited public surveillance data) during time- or resource-sensitive time frames, including disruptive health crises such as the COVID-19 pandemic. For example, the impact of the COVID-19 pandemic on the fresh fruit and vegetable retail environment has been felt by other communities across the United States; fresh fruit and vegetable vendors in Los Angeles have witnessed a dramatic drop in sales [25], which may be catalyzing vendor closures. Moreover, to address the sales and logistical disruptions faced by many fresh fruit and vegetable vendors, new online-based delivery services for these vendors have been explored in limited settings [26]; future research may involve surveillance of different strategies being explored by fresh fruit and vegetable vendors to adapt services and prevent closures. Likewise, it is important to contextualize the potential economic or food access impacts related to fresh fruit and vegetable vendor closures identified in this methodology with the broader health or social impacts of the COVID-19 pandemic; complementing this methodology with other mixed methods approaches to assess the economic, health, and social impacts of the COVID-19 pandemic is warranted. Finally, to the best of our knowledge, this study was the first to use the new Apple Look Around geographic data system for health research. The platform was observed to be efficient and user-friendly in identifying fresh fruit and vegetable vendors in Park Slope in a manner similar to the use of Google Street View; however, since the platform was not used in the other examined neighborhoods, further research is needed to assess its effectiveness for health research both in NYC and in other settings. With these preliminary insights from Park Slope, future in-depth analysis comparing the utility of Apple Look Around with Google Street View and other means of geographic surveillance is warranted, particularly with respect to parameters such as image quality, geographic scope of the data, timeliness of surveillance updates, and other features of the platform that can assist in health research.

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Conflicts of Interest

None declared.

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Abbreviations

NYC: New York City

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Review

Characteristics and Outcomes of Physician-to-Physician Telephone Consultation Programs: Environmental Scan

Peter George Jaminal Tian[1], MSc, MD; Jeffrey Richard Harris[2], MHA, MD; Hadi Seikaly[2], MA, MD; Thane Chambers[3], MLIS; Sara Alvarado[1], MPH; Dean Eurich[4], MSc, PhD

[1]Department of Family Medicine, University of Alberta, Edmonton, AB, Canada

[2]Division of Otolaryngology, Department of Surgery, University of Alberta, Edmonton, AB, Canada

[3]University of Alberta Libraries, University of Alberta, Edmonton, AB, Canada

[4]School of Public Health, University of Alberta, Edmonton, AB, Canada

Corresponding Author:
Peter George Jaminal Tian, MSc, MD
Department of Family Medicine
University of Alberta
6-40 University Terrace
8303 112 St NW
Edmonton, AB, T6G 2T4
Canada
Phone: 1 780 492 6306
Email: petergeo@ualberta.ca

Abstract

Background: Telephone consultations between physicians provide quick access to medical advice, allowing patients to be cared for by calling physicians in their local settings.

Objective: As part of a quality assurance study of a physician-to-physician consultation program in Alberta, Canada, this environmental scan aims to identify the characteristics and outcomes of physician-to-physician telephone consultation programs across several countries.

Methods: We searched 7 databases to identify English publications in 2007-2017 describing physician-to-physician consultations using telephones as the main technology. To identify Canadian programs, the literature search was supplemented with an additional internet search.

Results: The literature search yielded 2336 citations, of which 17 publications were included. Across 7 countries, 14 telephone consultation programs provided primary care providers with access to various specialists through hotlines, paging systems, or call centers. The programs reported on the avoidance of hospitalizations, emergency department visits and specialty visits, caller satisfaction with the telephone consultation, and cost avoidance.

Conclusions: Telephone consultation programs between health care providers have facilitated access to specialist care and prevented acute care use.

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KEYWORDS

telephone consultations; teleconsultations; remote consultations; telemedicine; eHealth; environmental scan

Introduction

Health care systems continuously evolve. At this point, a health care system's efficiency is a measure of its ability to rapidly collect, store, and analyze information and make it accessible in real time to a wide range of health care providers to optimize patient care. A key component of these systems is the use of technology to allow health care providers to easily consult and securely share patient information with other providers. The World Health Organization (WHO) promotes this use of information communication technology (called eHealth) in support of health care services and training. In a 2016 survey, the WHO reported that 58% of responding member states had eHealth strategies, and 62% of member states had a consultation service using mobile information communication technology

between health care practitioners or between health care practitioners and patients [1].

This ubiquitous use of technology in health care is reflected in published literature, and the benefits of these systems to care processes have been well documented. A systematic review by Deldar et al [2] found 174 publications examining the role of teleconsultations. Another systematic review by Saliba et al [3] identified 94 studies evaluating the facilitators and barriers of various telemedicine services. The delivery of such eHealth solutions is substantial. Teleconsultations in dermatology [4] and psychiatry [5], for example, may come in different modalities and be provided using videoconferencing and store-and-forward systems (ie, sending images and text information). Teleradiology, which has been around for decades, allows for the transmission, storage, and retrieval of images between radiologists and other professionals [6]. Many other technologies may be used to serve as a means of accessible electronic medical records, mobile telephone symptom recordings, and dedicated support lines, as used, for example, in palliative care [7].

In Alberta, Canada, physicians have access to telephone consultations with specialists through a 24/7 call center called RAAPID (Referral, Access, Advice, Placement, Information, and Destination). RAAPID ensures that physicians have quick access to other physicians (often specialists) for advice, allowing patients to be cared for by the calling physician in their local setting. However, if patients require transfer to other institutions for care, RAAPID also facilitates these transfers [8]. One component of the RAAPID system that has been increasingly utilized is telephone consultation with Otolaryngology–Head and Neck Surgery (OHNS). As part of a quality assurance study to evaluate RAAPID's telephone consults with OHNS, we conducted an environmental scan of similar programs in other parts of the world, searching for program characteristics and outcomes associated with similar physician-to-physician telephone consultation programs.

Methods

We used a combination of formal literature searches and internet searches based on methods adapted for the conduct of an environmental scan [9]. Other published environmental scans have also used internet searches for gathering data [10,11]. Since the RAAPID program provides consultation using only phones between physicians, we limited our search to programs that included physician-to-physician consultation with telephone as the main technology.

An information technologist (author TC) performed the literature search. The search was done on the following databases: Ovid MEDLINE(R), Embase, Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials, NHS Economic Evaluation Database, CINAHL, and Web of Science Core Collection. The search was limited to English publications in the 10-year range of 2007-2017 to ensure that identified articles reflected more contemporary practice in the field. To identify Canadian programs, the literature search was supplemented with an additional internet search (by author PT) using the following search terms in Google: (Physician or Doctor) AND (Telephone Consultation or Phone Consultation). Then we reviewed potentially relevant search results and websites. The internet search results were limited to the first 10 search result pages (~100 results).

Three authors (PT, TC, SA) screened the search results for programs providing access to specialists through telephone consultations. For the results from the literature search, a 2-step screening was performed: title-abstract screening and full-text review to identify relevant studies. The title-abstract screening was performed independently by 2 authors (PT and TC; PT and SA). Then, full-text screening was independently reviewed by 2 authors (PT and SA). Disagreements in the screening decisions were resolved by discussion. Only consultation programs that used the telephone as the main technology were included, as well as studies that used telephones for initial consultations before using other technologies at a later time. However, consultation programs that used the telephone in combination with other technologies (such as fax, video platform, electronic communication, mobile messaging, and web-based platforms) were excluded.

One author (PT) extracted the data, and the data were verified by a second author (SA). The following data were extracted from the publications and the internet search results: the name of the program, the country within which the program operates, a description of the program, who the program is available to, the scheduled times and specialty areas in which the service is available, reported measures (ie, the volume of calls, response times), disposition after consultation (ie, sent home, sent to the emergency department or hospital, elective consultation in a specialty clinic), satisfaction with the calls, and potential costs or cost avoidance. For the supplemental internet search, one author (PT) reviewed the search results and extracted the data.

Results

Literature and Internet Search

The literature search yielded 2336 citations, of which 17 publications were identified and included (Figure 1). These 17 publications described 14 telephone consultation programs: 4 programs in the United States, 3 programs each in Canada and France, and 1 program each in Australia, the Netherlands, the United Kingdom, and Italy (Table 1). The sample sizes of the included consultation programs ranged from 19 to 4436. In addition to these publications, the internet search yielded 17 webpages linked to 13 Canadian telephone consultation programs (Table 2).

Figure 1. Flow chart of the literature review process.

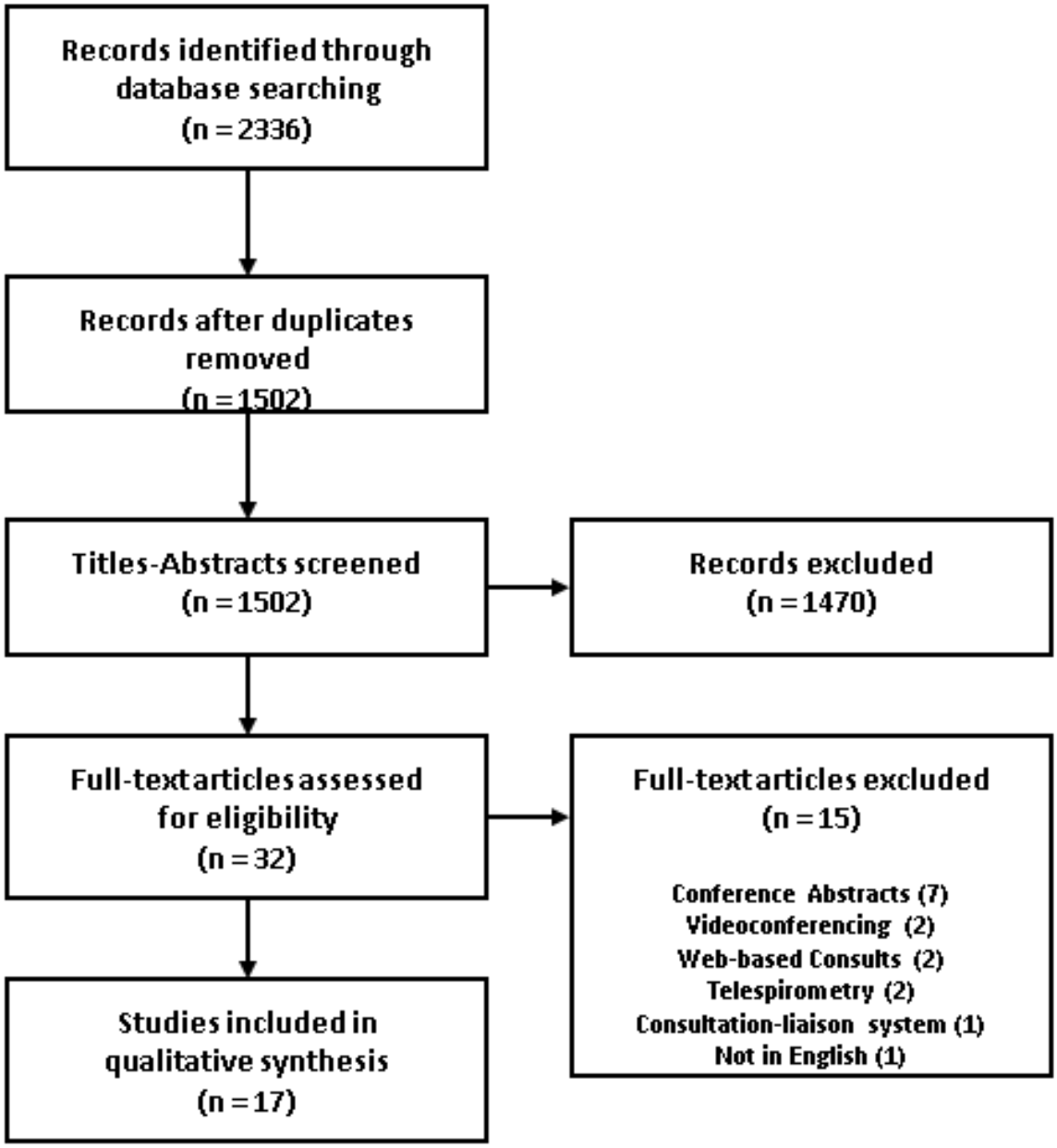


Table 1. Characteristics of telephone consultation programs (n=14).

Publication (first author, publication year, country)	Program name or description	Access schedule	Physician seeking consultation	Physician providing consultation (number of calls and duration)	Post-call patient disposition
Bal, 2011, France.	Hotline on a dedicated cellular telephone	24 hours per day, 7 days per week	General practitioner	Infectious disease resident and specialist (284 calls in 6 months)	__[a]
Clark, 2015, Canada.	Randomized trial comparing usual care with telephone consult	—	Primary care physician	Pain specialist at 0 months, 3 months, and 6 months (n= 41)	—
Hilt, 2013, US.	The Partnership Access Line (toll-free number)	8 AM-5 PM, Monday-Friday	Primary care provider	Child and adolescent psychiatrist (2285 calls in 37 months)	—
Hobbs, 2014, US; Sarvet, 2011, US; Sarvet, 2010, US; Straus, 2014, US.	Massachusetts Child Psychiatry Access Hotline (answered by the care coordinator and routed to an appropriate team member)	Business hours, Monday-Friday	Pediatric primary care clinician (eg, pediatrician, family practice physician, nurse practitioner)	Child psychiatrist, family psychotherapist, care coordinator (4436 calls in 1 year)	24% (1974/8223) of consults resulted in the primary care clinician maintaining primary clinical responsibility
Lear, 2010, Canada.	Rapid Access to Cardiology Expertise (pilot project for Wilson, 2016, Canada, listed below; paging system which initiates a call)	Business day	Family physician	Cardiologist (118 calls in 7 month); the cardiologist calls the paging family physician	17.8% of consults resulted in further consultation with the cardiologist
Linklater, 2009, UK.	Telephone advice line	24 hours per day, 7 days per week	Primary care clinician (eg, general practitioner, hospital doctor, hospital/community nurse, patient or carer)	Consultant or specialist registrar in palliative medicine (1146 calls in 6 years and 1 month)	—
Marquet, 2013, France.	National network of infectious disease experts	—	Community and health care professional	Infectious disease specialist (323 calls in 5 days)	6% of consults led to infectious disease consultation; 5.5% led to hospitalization
Salles, 2014, France.	Hotline	9 AM-7 PM, Monday-Friday	General practitioner	Geriatrician (714 calls in 16 months)	38.3% of consults resulted in advice; 5.3% resulted in geriatric consultation; 9.2% resulted in a hospital day visit; 42.9% resulted in hospitalization in the geriatrics ward; 4.3% resulted in direct admission to the emergency department
Sankaranarayanan, 2010, Australia.	Telephone line	12 PM-1 PM, Monday-Friday	General practitioner	Psychiatrist (19 discussions in 3 months)	—
van Heest, 2008, Netherlands.	Telephone line	24 hours per day, 7 days per week	Health care provider (eg, general practitioner, nurse, pharmacist, other health care provider)	General practitioner adviser in palliative care on treating nausea and vomiting (572 consultations in 1 year)	—
Waldura, 2013, US.	HIV Warmline	9 AM-8 PM	Primary care clinician (eg, physician, other health care provider)	HIV specialist (eg, physician, pharmacist)	—

Publication (first author, publication year, country)	Program name or description	Access schedule	Physician seeking consultation	Physician providing consultation (number of calls and duration)	Post-call patient disposition
Wegner, 2008, US.	Telephone line	—[a]	Primary care physician	Pediatric subspecialist (306 consults in 8 months)	32% of consults avoided a PS[b] visit; 11% avoided a hospital transfer; 5% avoided a hospital admission; 5% avoided an emergency department visit
Wilson, 2016, Canada.	Rapid Access to Consultative Expertise (hotline that automatically routes to a specialist's pager/mobile phone)	8 AM - 5 PM, Monday-Friday	Family physician or nurse practitioner	Various specialists (a subset of 2000 calls in 2 years)	60% of consults prevented a face-to-face consultation; 32% prevented an emergency department visit
Zanaboni, 2009, Italy.	Telephone calls routed through a service center; for specific consultations, callers were invited to use biomedical devices for specific consultations	—	General practitioner	Cardiologist, dermatologist, or diabetologist (927 cardiology calls in 25 months)	8% of consults resulted in an emergency department visit or hospitalization; 1% resulted in an in-clinic visit; 77% avoided an emergency department visit, hospitalization, or an in-clinic consult

[a]—: not available.

[b]PS: pediatric subspecialist.

Table 2. Characteristics of Canadian physician-to-physician telephone consultation programs yielded from an internet search (n=13).

Program Name	Province	Program description	Physician seeking consultation	Physician providing consultation
Cancer Line	Alberta	Assists with cancer-related questions	Physician or other health care provider	Medical or radiation oncologist, or expert oncology nurse
Orthopedic Consult Line	Alberta (Edmonton)	—[a]	—	—
PaedLink Telephone Consultation Service[b]	Alberta (Calgary)	Single access number; accessible from 8 AM-8 PM, Monday-Sunday	—	—
Referral, Access, Advice, Placement, Information, and Destination (RAAPID)	Alberta	Hotline accessible 24 hours per day, 7 days per week	Physician	Multiple specialists
Specialist LINK[b]	Alberta (Calgary)	Telephone advice for nonurgent cases; accessible from 8 AM-5 PM, Monday-Friday, except on statutory holidays	Physician, nurse practitioner, midwife, pediatrician	Multiple specialists
Rapid Access to Consultative Expertise	British Columbia, Yukon	Accessible from 8 AM-5 PM, Monday-Friday	Physician, nurse practitioner	Multiple specialists
Rapid Access to Consultative Expertise	Manitoba	—	—	—
Med-Response	North West Territories	—	—	—
CritiCall-Ontario	Ontario	—	—	—
Ontario Shores	Ontario	Telephone advice; online booking	Family physician, nurse practitioner	Psychiatrist
Leveraging Immediate Non-urgent Knowledge (LINK)	Saskatchewan	Physician-to-physician telephone consultation service for nonurgent conditions; accessible from 8 AM-5 PM, Monday-Friday	—	Multiple specialists
Acute Care Access Line (ACAL)	Saskatchewan	Urgent calls; complementary to LINK service	—	—
Bedline	Saskatchewan	—	—	—

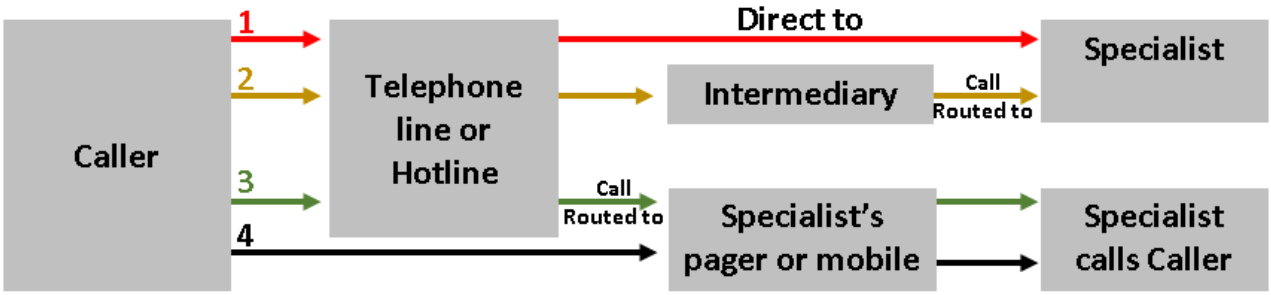
[a]—: not available.

[b]Eligible for continuing medical education (CME) credits.

Telephone Consultation Process

The process starts with the provision of a telephone line. Some publications used the term *hotline*; however, since no reported definitions of a hotline differentiate it from a regular telephone line, we extracted the terms as published. Of the 17 included studies, 10 reported a program in which the call connects and is answered directly by the specialist [12-21], 4 indicated programs in which the call is answered by an intermediary who then routes the call to the specialist [22-25], and 2 indicated that the call is routed to a specialist's pager or mobile messaging service, requiring the specialist to respond with a call to the physician (Figure 2) [26,27].

Figure 2. Various telephone consultation processes.



Accessibility

The accessibility of telephone consultations varied. Some were available 24 hours a day, 7 days a week [12,15]. Others were only available during business hours or extended business hours, Mondays to Fridays [13,16,22,26,27]. One program was limited to 1 hour a day, 5 days a week [14].

Response time between the programs also varied. Wilson [27] reported that 78% of calls were responded to within 10 minutes. Lear [26] reported that 81.4% of calls were returned within 1 hour or less. These 2 studies used a system where providers paged specialists who called them back. Marquet [28] reported that 19.8% of calls were answered immediately.

Callers

Most of the programs were geared toward family physicians, general practitioners, or primary care providers [12-15,19,24,26,27]. In addition to physician callers, some programs also had nonphysician callers: nurse practitioners, pharmacists, and other professionals [15,16,27,28]. Other programs were highly restricted, such as the Massachusetts Child Psychiatry Access, which was limited to pediatric primary care clinicians like pediatricians, nurse practitioners, and family physicians [21-23].

Consulted Specialists

The different programs offered consults with different specialties. The Rapid Access to Consultative Expertise (RACE) in British Columbia offered access to a wide number of specialists [27]. However, the majority of the studies reported consults with only certain physician specialists, namely, psychiatrists [14,22], infectious disease specialists [12,28], geriatricians [13], pediatricians [17,22], and cardiologists [24,26]. One reported access to general practitioners who served as advisers [15]. Others provided access to nonphysician members of the team, such as pharmacists, psychotherapists, or care coordinators [16,22].

Patient Disposition

Only 6 (35%) of the 17 publications assessed any type of disposition within the program. With respect to patient and medical advice, only 1 publication explicitly noted this feature. Salles [13] reported that 38.3% resulted in advice. Although Hobbs [22] did not report this, another publication reported that in the Massachusetts Child Psychiatry Access program, 24% of consults resulted in the primary care clinician maintaining primary care responsibility [21]. Several publications noted that additional consultation occurred as a result of the call. Lear [26] reported that 17.8% resulted in further consultation with the cardiologist. Marquet [28] reported that 6% led to infectious disease consultation. Salles [13] reported that 5.3% resulted in geriatric consultation. Wegner [17] reported that 32% avoided pediatric subspecialists' visits. Wilson [27] reported that 60% prevented a face-to-face consultation. Several publications (5/17, 29%) assessed emergency department visits or hospitalization as an outcome of the program [13,17,24,27,28]. However, the studies differed in how the patient dispositions were reported. Zanaboni [24] reported that 8% resulted in emergency department visits or hospitalization. Marquet [28] reported that 5.5% led to hospitalization. Salles [13] reported that 9.2% resulted in a hospital day visit, 42.9% resulted in hospitalization or a visit to a geriatrics ward, and 4.3% in a direct emergency department admission [13]. Conversely, several publications noted large effects with respect to avoidance of emergency department visits or hospitalizations. Indeed, Zanaboni [24] reported that 77% of calls avoided emergency department visits or hospitalizations. Wilson [27] reported that 32% avoided emergency department visits, while Wegner [17] reported that 5% avoided emergency department visits and 5% avoided hospital admissions.

Cost Avoidance

Cost avoidance from the telephone consultations was reported in 3 of 17 publications (18%) and varied depending on how the studies determined cost avoidance. Wegner [17] reported cost savings of $477,274 for 306 consults over 8 months. These cost savings included subspecialist visit and telephone consultation costs, as well as potential costs from avoided hospitalizations. Wilson [27] reported cost savings of $9005 for 148 calls. Zanaboni [24] reported €20,472 of direct savings for in-clinic visits for 927 calls [24].

Satisfaction With Calls

Of the 17 publications, 9 (53%) determined satisfaction levels after the telephone consultations. Physicians rated the telephone consultations positively, ranging from 80%-100% [12,24,26]. The ratings comprised satisfaction with the specialist's recommendations, whether issues were addressed adequately, and improved confidence in managing patients. Also, compliance to recommendations were rated high, ranging from 90%-93% [12,15,24].

Discussion

Our environmental scan identified 17 studies on telephone consultation programs between health care practitioners, and 13 programs across Canada. Programs were widely dispersed across a wide range of specialties and disease states. Overall, the most common model for accessing care was having the physician connect directly with the specialist or consultant rather than using a routing system or call-back procedure. The majority of programs were for physicians; however, many were supportive of calls from other members of the care team.

Interestingly, less than half of the publications evaluated outcomes related to patients' dispositions or costs. In the few studies that evaluated health care utilization, all reported an avoidance in either emergency department visits or hospitalizations. As expected, this translated into major cost savings for the programs. However, it is relatively unclear what the overall net savings and costs of these programs were, as few (if any) analyses accounted for the input costs of operating and maintaining these programs. Indeed, British Columbia's RACE program [27] has a low operating cost. It provides a hotline system that directly pages a specialist who, in turn, calls the referring physician. RACE reports a cost of only $120/month for the telephone system support and an administrative support cost for 1 day per month. Costs savings and some costs occurrence to the system would be expected; however, the benefits to patients in terms of timely medical advice and indirect cost savings (eg, travel to the emergency department, time away from work) would likely offset any cost occurrences. Coupled with reduced pressure on the emergency department and hospital system reported by the programs, the benefits are likely substantial.

RAAPID's 24/7 call center shares some similarities to other telephone programs, but also notable differences. Unlike most programs that involve direct calling to specialists, physicians call a hotline and the call center connects them to specialists, if needed. The call center provides extensive support. At the consultation level, the call center triages the call to specialists, ascertains that the consultation occurred, and provides logistical support during and after the consultation. At a system level, the call center, when required, coordinates the transfer of patients to appropriate centers, with due consideration to bed management. However, this labor-intensive process impacts the operating cost (ie, the cost from 24/7 staffing).

Although more expensive to implement, the RAAPID program has previously reported that from November 2014 to October 2015, of 51,171 telephone consultations, 36% were not referred to the emergency department (29.1% resulted in the provision of advice and 6.9% were referred to a specialist clinic) [29]. This coincides with the figures observed in other programs reported in this paper. British Columbia's RACE reported a 32% prevention rate in emergency department visits [27]. Wegner's study [17] on pediatric subspecialist consultations reported that 52% avoided emergency department visits, specialty visits, and hospital transfers and admissions. Zanaboni's study [24] on consultation calls to cardiology, dermatology, and diabetology reported that 77% avoided emergency department visits, hospitalizations, or in-clinic consults.

This environmental scan is the first narrative review of telephone consultation programs. We have reviewed the published literature and performed a supplemental internet search. However, the heterogeneity of programs and outcome measures limited comparison across programs. Moreover, limitations in resources have precluded a systematic review and a more extensive review of internet searches. The pervasive use of technology in health care consultations was evident in the literature search and internet search. The use of phones for consultations was minor compared to the use of more recent technologies like videoconferencing, mobile messaging, and other electronic and web-based platforms.

Conclusion

Telephone consultation programs between health care providers have facilitated access to specialists. The programs have allowed primary care providers to retain the care for their patients while avoiding patient use of acute care resources. These telephone consultation programs, along with newer technologies, have increased the efficiency of health care.

Conflicts of Interest

This study received funding from the Alberta Head and Neck Centre for Oncology and Reconstruction (AHNCOR) Foundation.

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Abbreviations

OHNS: Otolaryngology–Head and Neck Surgery
RAAPID: Referral, Access, Advice, Placement, Information, and Destination
RACE: Rapid Access to Consultative Expertise
WHO: World Health Organization

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Original Paper

A Mobile Health App to Support Patients Receiving Medication-Assisted Treatment for Opioid Use Disorder: Development and Feasibility Study

Marika Elise Waselewski[1], MPH; Tabor Elisabeth Flickinger[2], MPH, MD; Chelsea Canan[2], PhD; William Harrington[2], MPH; Taylor Franklin[3], BS; Kori Nicole Otero[2], MPH; Jacqueline Huynh[2], BA; Ava Lena Davila Waldman[2], MHS, CHES, CCRP; Michelle Hilgart[4], MEd, PhD; Karen Ingersoll[5], PhD; Nassima Ait-Daoud Tiouririne[5], MD; Rebecca Anne Dillingham[2], MPH, MD

[1]Department of Family Medicine, University of Michigan Medical School, Ann Arbor, MI, United States

[2]Department of Medicine, University of Virginia School of Medicine, Charlottesville, VA, United States

[3]University of Virginia School of Medicine, Charlottesville, VA, United States

[4]Department of Psychiatry and Neurobehavioral Sciences, Center for Behavioral Health and Technology, University of Virginia School of Medicine, Charlottesville, VA, United States

[5]Department Psychiatry and Neurobehavioral Sciences, University of Virginia School of Medicine, Charlottesville, VA, United States

Corresponding Author:
Marika Elise Waselewski, MPH
Department of Family Medicine
University of Michigan Medical School
1018 Fuller St
Ann Arbor, MI, 48104
United States
Phone: 1 734 647 3305
Email: marikag@med.umich.edu

Abstract

Background: Opioid use disorder (OUD) is a public health crisis with more than 2 million people living with OUD in the United States. Medication-assisted treatment (MAT) is an evidence-based approach for the treatment of OUD that relies on a combination of behavioral therapy and medication. Less than half of those living with OUD are accessing this treatment. Mobile technology can enhance the treatment of chronic diseases in readily accessible and cost-effective ways through self-monitoring and support.

Objective: The aim of this study is to describe the adaptation of a mobile platform for patients undergoing treatment for OUD and preliminary pilot testing results.

Methods: Our study was conducted with patient and provider participants at the University of Virginia MAT clinic and was approved by the institutional review board. The formative phase included semistructured interviews to understand the needs of patients with OUD, providers' perspectives, and opportunities for MAT support via a mobile app. A second round of formative interviews used mock-ups of app features to collect feedback on feature function and desirability. Formative participants' input from 16 interviews then informed the development of a functional smartphone app. Patient participants (n=25) and provider participants (n=3) were enrolled in a 6-month pilot study of the completed platform. Patient app use and usability interviews, including a system usability score and open-ended questions, were completed 1 month into the pilot study. Open-ended responses were analyzed for prevalent themes.

Results: Formative interviews resulted in the development of a mobile app, named HOPE, which includes both evidence-based and participant-suggested features. The features included daily prompts for monitoring mood, stress, treatment adherence, and substance use; patient tracking of goals, reminders, and triggering or encouraging experiences; informational resources; an anonymous community board to share support with other patients; and secure messaging for communication between patients and providers. All patient participants engaged with at least one app feature during their first month of pilot study participation, and the daily self-monitoring prompts were the most used. Patients and providers reported high levels of system usability (mean 86.9, SD 10.2 and mean 83.3, SD 12.8, respectively). Qualitative analysis of open-ended usability questions highlighted the value

of self-monitoring, access to support through the app, and perceived improvement in connection to care and communication for both patient and provider participants.

Conclusions: The use of the HOPE program by pilot participants, high usability scoring, and positive perceptions from 1-month interviews indicate successful program development. By engaging with end users and eliciting feedback throughout the development process, we were able to create an app and a web portal that was highly usable and acceptable to study participants. Further work is needed to understand the program's effect on clinical outcomes, patient linkage, and engagement in care.

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KEYWORDS

opioid use disorder; mHealth; retention in care; self-management; opioids; public health; mobile phone

Introduction

Opioid use disorder (OUD) has become a serious chronic health concern and public health crisis in the United States, with more than 2 million people living with OUD [1,2]. Across the country, 68% of drug overdose deaths involve an opioid, and approximately 130 people die from opioid overdose every day [3]. Nonfatal health consequences include increased rates of hepatitis C, HIV, and co-occurring mental health disorders, leading to a significant chronic disease burden [4]. Estimates for the financial impact of the opioid epidemic exceed US $500 billion in the United States [5,6].

Despite the importance of OUD treatment in reducing the burden of the opioid epidemic, less than half of the individuals living with OUD receive medication-assisted treatment (MAT), the most effective type of treatment [7]. MAT is an evidence-based approach to treating OUD that relies on a combination of behavioral therapy and medications, such as suboxone (buprenorphine and naloxone) [8]. Compared with residential abstinence-based programs, MAT is more effective in increasing retention in treatment while reducing illicit opioid use, cravings, and withdrawal symptoms [9]. Interventions that help ensure the success of MAT programs can lead to better treatment outcomes and reduce the effect of OUD on both individuals and society.

One method to bolster the effect of MAT modalities is to improve patients' engagement in care by promoting self-monitoring through interventions such as mobile technology [10]. Evidence also suggests benefit from web-based social interactions in supporting individuals with other mental health disorders that commonly co-occur with OUD [11-14]. An evaluation of web-based discussion among users of suboxone noted that they were more trusting toward each other than health care providers, further highlighting the potential benefits of web-based communities [15]. When used appropriately, mobile technology can enhance the treatment of chronic diseases by providing patients the ability to monitor their condition and receive interactive or automated feedback in ways that are readily accessible and cost effective [16].

PositiveLinks (PL) is a secure self-monitoring and engagement in care mobile platform developed by health care providers at the University of Virginia for people living with HIV [17]. PL includes features such as daily medication reminders, check-ins regarding mood and stress, an anonymous community board to communicate with peers, appointment reminders, messaging with providers, weekly quizzes, and informational resources. Users of the PL platform have shown improvement in retention in care and clinical markers, including HIV viral suppression and increases in CD4 count [18]. The success of PL for people living with HIV suggests that similar benefits may result from mobile interventions for other chronic conditions. However, there is currently limited use of mobile technology related to OUD, particularly from the patient perspective [19]. The work described in this paper highlights the process of adapting PL to meet the needs of patients receiving treatment for OUD. It further describes preliminary results from the first month of a pilot study to evaluate the app's usability and effect on the recovery process for patients receiving treatment for OUD.

Methods

Overview

This study had a formative phase to develop an app prototype, followed by a pilot phase to evaluate app usability. Both phases were conducted at the University of Virginia MAT clinic and approved by the institutional review board, and all participants provided informed consent before participation.

Formative Phase

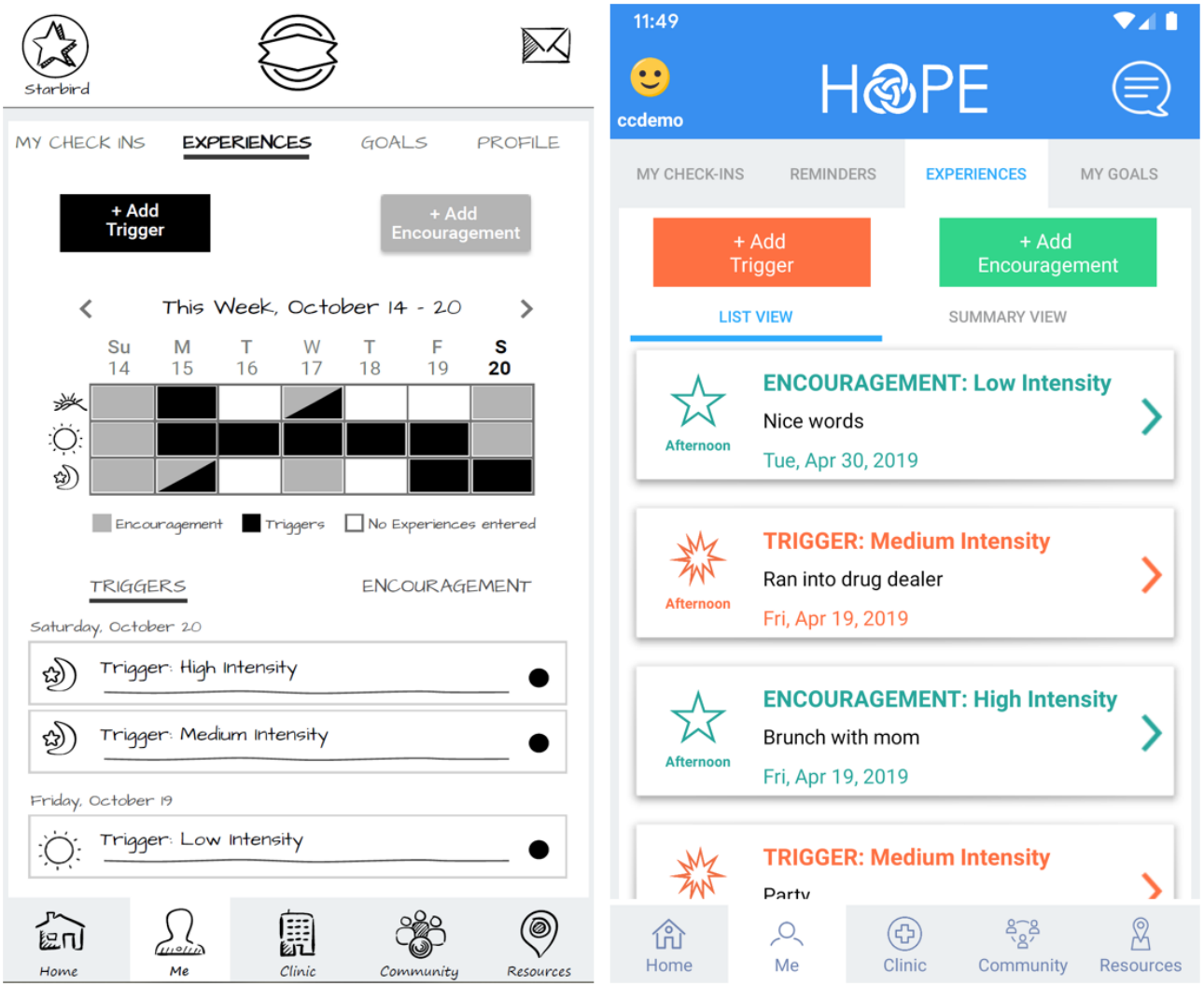
For the formative phase, patients in treatment and providers at the University of Virginia MAT clinic were recruited for in-person open-ended interviews on barriers to care and opportunities for a mobile app to support their needs. Semistructured interviews were initially developed based on our team's previous formative work in developing PL [17], and the content was updated iteratively based on previous interviews and changes to the app design. Participants completed up to 2 interviews during the formative phase.

In the first step of the formative phase, we conducted a needs assessment during which the patient participants were asked about their demographic information, experience with MAT, barriers to engaging with their treatment, and current self-monitoring practices. They were then asked about their experience with a smartphone and preferences or ideas for mobile app features that they would be interested in using (Multimedia Appendix 1). Provider participants were asked similar questions that focused on the challenges they experienced in providing care to patients receiving treatment for OUD and ideas on app features that they, or their patients, might find useful. The interviews were audiorecorded and transcribed. The transcripts were reviewed using inductive

methodology to explore emerging themes. In particular, participants' perspectives on care experiences or preferences related to anticipated app features were elicited. A consolidated summary of barriers, challenges, and needs identified during the interviews led to a list of potential app features for the OUD app. The features included both evidence-based features adapted from PL as well as new features unique to the treatment of OUD.

In the second step of the formative phase, patient participants were asked to comment on the iteratively updated mock-ups of the app features. Initially, wireframe mock-ups of selected features (left side of Figure 1) were designed as minimalistic representations of key app features to allow the interview participants to provide feedback focused on the overall feature rather than coloring or flare. Patients were recruited for interviews and asked open-ended questions about how they believed that the features might function or what they expect to happen when they click on different icons. No demographic data were collected during these functionality-based interviews. The interviewers noted the areas of the app design or layout that seemed confusing and needed further refinement. High-fidelity mock-ups of the app features (right side of Figure 1) were iteratively developed based on participant feedback. Adobe XD was used to create high-fidelity functional mock-ups of the app to allow participants to review the app in more detail [20]. Participants in this step were interviewed using the Think-Aloud Protocol, a widely used qualitative methodology employed in human and user-centered design, to provide insight on the experience of end users [21-23]. The researchers observed and listened to the users during task-based sessions to learn how users think about their experience while using the prototype and to see how they behave while performing the task. The resulting final mock-up incorporated the user perspective and provided functionality that required minimal effort to use and understand.

Figure 1. Screenshots demonstrating HOPE development process with examples of wireframe and high-fidelity mock-ups.



Interviews in both formative steps were conducted until saturation was reached, and no new information was gleaned from additional interviews. During the formative steps of app development, 16 interviews were conducted: 7 patients and 3 providers completed the needs assessment interview, and 6 patients completed the Think-Aloud Protocol interviews. Participants who completed the first round of formative interviews (needs assessment) were on average aged 40 (SD 8) years, 57% (4/7) male, and 100% (7/7) White, and 86% (6/7) were uninsured and qualified for financial assistance to pay for their care. All user-informed details of app design and function were incorporated into a final app prototype and specifications,

which then guided the development of a functional smartphone app that was used in the pilot study.

Pilot Phase

Enrollment for the pilot phase of app development began in October 2019 and ended in December 2019. The aim of the pilot study was to test the usability and functionality of the mobile technology developed in the formative phase.

Both patients and providers were enrolled in the pilot study. The patient participants were referred to the study team by clinic providers at the University of Virginia MAT clinic. All providers at the clinic were eligible to participate and were informed of the study through conversations with the clinic staff. The study team members met with potential participants to explain the study procedures, answer questions, and consent individuals interested in joining. At enrollment, patient participants completed baseline surveys including information on demographic characteristics (age, sex, and race and ethnicity) and their history of substance use and treatment. The provider participants were only asked to share their role in the clinic (physician, social worker, nurse, etc).

Patient participants who did not own a smartphone at enrollment were provided with a smartphone, case, and screen protector. They also received a prepaid account with a service provider (Boost Mobile, StraightTalk, etc). Patients were enrolled for a total of 6 months and were free to use the mobile app as much or as little as they liked, and accounts were deactivated at the end of the study. Patient participants accessed the HOPE program through a mobile app, whereas provider participants used a web-based portal to interface with patients through system features. Data presented in this manuscript are limited to the first month of participation in the pilot study.

The pilot study enrolled 25 patient participants between October 21, 2019, and December 20, 2019. A total of 2 patient participants left the MAT clinic during the study and were considered lost to follow-up. The participants had a mean age of 34 (SD 8) years, 52% (13/25) were male, and 84% (21/25) were non-Hispanic White. Most respondents (17/25, 68%) had a high school education or less and many were unemployed (11/25, 44%). Less than half (9/25, 36%) of the participants previously owned a smartphone, and the mean time in care was 106.8 days (SD 142.7 days; range 1 day to 2 years). The demographic characteristics of the patient participants are summarized in Table 1. In total, 3 provider participants enrolled during this time: 1 physician, 1 nurse, and 1 social worker.

Table 1. Demographic characteristics for patient participants (N=25).

Demographic characteristic	Value
Age (years), mean (SD)	33.7 (8.1)
Gender (male), n (%)	13 (52)
Race and ethnicity, n (%)	
White, non-Hispanic	21 (84)
Black, non-Hispanic	2 (8)
Other race	2 (8)
Education, n (%)	
Less than high school	5 (20)
High school or GED[a]	12 (48)
Some college	7 (28)
College graduate	1 (4)
Employment, n (%)	
Employed full time	3 (12)
Employed part time	7 (28)
Disabled	4 (16)
Unemployed	11 (44)
Owned a smartphone, n (%)	8 (32)
Time in medication-assisted treatment clinic (days), mean (SD)	106.8 (142.7)

[a]GED: General Educational Development high school equivalency diploma.

Data Collection: Participant App Use

App use data were evaluated after the participants had used the app for 1 month, to determine the features that the patients used and the frequency of their use. App data were saved to a central server for all study participants, with participant-level tracking of their activity within the app system. To analyze, the stored data were downloaded from the central server at the participant level and were summarized using absolute frequencies as well as calculated response rates for daily use features. Response rate data were assessed for each participant (total prompts completed compared with total prompts sent) and averaged

across all study participants. All other app use data were summed for each participant (ie, total messages sent per participant) and then averaged across all study participants.

Data Collection: System Usability

Interviews evaluating usability (Multimedia Appendix 2) were completed at 1 month by both patient and provider participants. The interviews were completed over the phone or in-person and were audiorecorded and transcribed. During these interviews, the patient and provider participants completed a scored usability assessment using the System Usability Scale (SUS), which has been validated and shown to be highly reliable even in small sample sizes [24-27]. The SUS scoring total ranges from 0 to 100 and assesses the overall perceived usability, or ease of use, of a wide variety of products and services.

Several open-ended questions were also included in the 1-month interviews. These questions asked the patients about their experiences with the app, how it affected their care, and how the app could be more helpful to them. Provider participants were also asked open-ended questions on the program usability, integration into the clinic, effect on workflow, and their overall satisfaction with the program. The participant responses were categorized by a primary coder (MW, TF, or KO) and checked for accuracy by a secondary coder (MW, TF, or KO), with any discrepancies resolved by consensus. Responses were analyzed for prevalent themes and app feature preferences using Dedoose version 8.0.35 [28]. Once all interviews were coded, the frequencies of response types were assessed.

Results

Formative Phase

Themes emerging from the formative interviews included the importance of self-monitoring, social support, access to information, connection to care, and challenges to recovery. Each of these themes was expressed by both patients and providers, who felt that the app could be useful in addressing them. The frequency of themes differed between patients and providers. The most common theme for patients was social support (mentioned in 11/13, 85% of patient interviews), whereas the most common themes for providers were connection to care (3/3, 100% of provider interviews) and challenges to recovery (3/3, 100% of provider interviews).

With regard to social support, one patient participant stated:

> *There's some people who might be lonely and need to reach out or talk to somebody or relate or even have questions that could be answered.* [Male, aged 41 years]

A provider observed:

> *Peer support is a big feature of a lot of recovery programs. It might be nice for people to be able to reach out to peers.*

Patients expressed difficulty with care continuity and developing trust in providers during their recovery and felt that:

> *If there was one doctor that you had a relationship with, the app might help.* [Female, aged 49 years]

Providers also felt that the app could improve connection to care:

> *Having the ability to communicate through the app might be empowering to some patients. It might enhance the caregiver-patient relationship and help patients have a better chance.*

Participant needs assessments identified a desire for several features used in the PL app as well as new features suggested by the participants. Features from the PL system included daily check-ins, a community board, provider messaging, and resources. New features suggested by participants included a place to track their health and personal goals, tracking of triggering experiences (including date, time of day, and resolution strategy), and an emergency support system. During the interviews, the study team also elicited feedback on names for the mobile app, and participants indicated a preference for positive, simple, and discrete names. Participants were overwhelmingly drawn to the word *hope* because, as one patient explained:

> *That's what everybody needs is hope. You don't have to specify what it's for. Everybody needs a little hope.*

As a result, the app was named *HOPE: Heal. Overcome. Persist. Endure.*

Interviews using wireframe and high-fidelity mock-ups allowed for participant feedback and iteration during the design process. For example, participant feedback relative to the emergency support system led to a name change from *Pick-me-up* to *Get Hope. Get Help.* because a participant noted that "for us to say I need a pick-me-up that means drug."

The daily check-in for substance use reporting, designed to track participant opioid-free days based on self-report, also evolved based on feedback from participants. During the interviews, participants noted that although they were interested in an ongoing count of their opioid-free days, they did not want to lose record of their past successes if they slipped up. As a result, the team created a current opioid-free day count as well as a *max streak* that showed their longest period of opioid-free days. In addition, the language used in the substance use check-in was modified from "Have you used today?" to "Did you take any illicit or nonprescribed substances?" because of participant confusion on the original wording, "I was thinking it was asking if I had used the app. I didn't know if it meant that I had used any substance."

The final list of features selected is shown in Textbox 1. Provider participants enrolled in HOPE were able to view participant medication, mood, and stress check-in responses and use secure messaging to communicate with patients. However, providers were restricted from viewing responses to substance use check-ins, experiences, goals, or the patient community board. These features are only accessible by patient participants and study coordinators to protect patient privacy and promote self-monitoring by patients.

Textbox 1. List of HOPE features and functions.

Check-ins

Daily queries asking patient participants about their mood, stress, suboxone adherence, and nonprescribed substance use

Get Hope. Get Help.

Emergency support system with access to uplifting quotes, request for support from the community, clinic contact number, crisis hotline, and 911 emergency number

My Check-Ins

Self-monitoring tool with query responses displayed over time

My Experiences

Allows patient participants to enter triggering and encouraging experiences

My Reminders

Sends a reminder notification for entered reminders or appointments

My Goals

Allows patient participants to enter and track progress toward recovery goals

Messages

Private, secure messaging between patients and providers or study team members

Documents

Allows patient participants to securely upload documents to share information with clinic providers

Contacts

Names and phone numbers of clinic staff or user-entered contacts

Community

Anonymous community board where patient participants can communicate with each other on topics of their choice

Resources

Frequently asked questions, links to recovery-related information, and scheduling and location information for recovery group meetings

Pilot Phase

Participant App Use

All 25 study participants responded to at least one check-in on the HOPE app over the course of the 1-month study period. On average, participants responded to 86.13% (2584 completed/3000 prompts) of all daily check-ins. In response to medication queries, participants reported taking their suboxone as prescribed in 87.5% (553 instances of suboxone as prescribed/632 medication queries) of the responses, with the remaining indicating either taking more (15/632, 2.4% of responses), less (27/632, 4.3% of responses), or none (37/632, 5.9% of responses). Nonsuboxone drug use was reported in 16.7% (106 instances of nonsuboxone use/632 substance use queries) of responses to the substance use queries, by 11 different participants (11/25, 44% of cohort), which included 20 instances of opioid use.

The HOPE community board was used by 9 different participants (9/25, 36% of the cohort), with an overall average for the full cohort of 0.9 posts per participant during their first month of app use. All enrolled participants received at least one message from a provider or program administrator during their first month of use, and 22 of them (22/25, 88% of the cohort) also sent at least one message. On average, participants sent 7.5 messages and received 8.9 messages during their first month of participation, with all messages sent by the providers being marked as read by the participant.

Almost one-third of the study participants (n=8) used the goals and experiences features of the HOPE app. Participants created an average of 0.5 (SD 0.8) goals and 1.4 (SD 2.6) experiences during their first month.. Use of the experiences feature was approximately equally distributed with patients entering 12 triggering and 15 encouraging experiences. Table 2 shows summary information on participant response rates, community board posts, provider messaging, goals, and experience tracking.

Table 2. Patient participant app use during the first month of enrollment (N=25).

App feature	Use level, mean (SD)	Patients who used the features, n (%)
Overall check-in percent response rate	86.1 (21.6)	25 (100)
Medication response rate	84.3 (22.4)	25 (100)
Substance use response rate	84.3 (22.4)	25 (100)
Mood response rate	88.1 (21.3)	25 (100)
Stress response rate	87.9 (21.5)	25 (100)
Community board posts per participant	0.9 (1.7)	9 (36)
Messages sent per participant	7.5 (7.1)	22 (88)
Messages received per participant	8.9 (7.1)	25 (100)
Goals entered per participant	0.5 (0.8)	8 (32)
Experiences entered per participant	1.4 (2.6)	8 (32)
Triggers entered per participant	0.6 (1.2)	7 (28)
Encouragements entered per participant	0.7 (1.6)	6 (24)

System Usability

Data from 24 patients' SUS were used to calculate the overall perceived usability score for the app. One participant did not complete their 1-month interview and was therefore not included. The patient usability score was 86.9 (SD 10.2), with a range of 70 to 100. Similarly, SUS scores from the 3 enrolled providers averaged 83.3 (SD 12.8), with a range of 72.5 to 97.5. These SUS scores indicate high perceived usability of HOPE by pilot participants [25].

Patient responses to open-ended usability questions were largely positive. In response to their most used app features, participants predominately referenced the daily check-ins (Table 3). Most participants were unable to provide suggestions for what would make them want to use the app more (17/24, 71%), what they disliked about the app (13/24, 54%), and in what ways the app could be more helpful to them (15/24, 63%). Those who provided suggestions focused on a desire to see more community engagement and postings on the board as well as concerns about technical issues or *bugs* that they experienced. When prompted about the effect of the app on their connection to the clinic and provider communication, most participants (18/24 75%) noted a positive change resulting from HOPE use. These changes included easier communication, more direct communication, more access to providers, and quicker communication processes.

Provider participants similarly reported positive experiences regarding the use of HOPE in their clinics. All 3 providers referenced the message component as their most commonly used feature within HOPE and indicated that they were *very satisfied* with their integration into clinical care. Providers also noted a positive effect on patient connection and communication as a result of the program. In particular, providers noted that the use of the app increased access for their patients:

> *I think it makes me a lot more accessible. I think that patients are more likely to message me than they would be to necessarily call and check in. I think that's an added support that they didn't have prior to the app.*

Some providers additionally noted:

> *It definitely has impacted adherence. I think people come if they're connected to the app.*
>
> *It's been less cumbersome, at least for me, to check and get messages.*

Table 3. Patients' perspectives from 1-month usability interviews, frequencies, and example quotes (N=24)

Theme	Participants, n (%)	Example participant quotes
What features of the app do you use the most? Why?		
Check-ins and how am I?	20 (83)	• "Probably just the check-ins like the news press and the daily check-ins. And why is because it is easy to use." (Female, aged 46 years) • "That it keeps track of how many days I've been opioid-free. It's like a reminder." (Male, aged 36 years)
Community board	5 (21)	• "The community board is awesome" (Female, aged 32 years) • "...the community board. It's not just reading the same questions every day." (Male, aged 29 years)
Messages and contacts	5 (21)	• "I like the fact that I can also, you know, contact doctors on and you know, all the staff here you know. That's pretty cool." (Male, aged 29 years) • "The thing I use the most probably is the contacts and talking to like [name] daily." (Female, aged 32 years)
Is there anything that would make you want to use it more? What?		
More community activity	3 (13)	"More people participating in the community section would make me wanna use it more because there would be more people to interact with." (Male, aged 36 years)
Technical improvements	2 (8)	"The only thing that would make me want to use it more is if when I do the check-in, I could do mood, stress, and medication usage. If I could do everything all at one time as opposed to having to do mood and stress for one day and then having to do medication usage—and, the last question..." (Female, aged 46 years)
Nothing	17 (71)	"I don't think so. It was pretty set up pretty good." (Female, aged 31 years)
How has the app changed your connection to your clinic, if at all? How has your use of the app affected how you and your provider communicate?		
Easier communication	12 (50)	• "I'm able to get in touch with the clinical team a lot easier and ask questions any time of day or night" (Male, aged 32 years) • "Instead of looking for a phone number, I can just email him right then and there. I don't have to Google, you know, just to try and find the office and then you just, you know, the physician whatever, so it's just a lot easier to get in touch with each doctor." (Male, aged 29 years)
More direct communication	10 (42)	• "It's straight to the provider instead of having going to talk to other people first." (Female, aged 31 years) • "Instead of having to go the whole hospital there, I can just directly ask." (Female, aged 31 years)
More access to providers	9 (38)	• "It helps the providers here know what's going on with you, and if there's something really bothering you or you—it's an emergency you need to reach out to someone, they're right there on the phone." (Male, aged 38 years) • "Me and [name] keep in touch, and just if I really need anybody to talk to, I can always just reach out to her easily." (Female, aged 32 years)
Quicker communication	8 (33)	"It makes me know that if need help, that I can get in contact and a little bit quicker." (Female, aged 31 years)
What do you dislike about the app?		
Technical issues	4 (17)	"I don't dislike it, but the only thing it does seem like request that there is a message and there is nothing there" (Female, aged 31 years)
Repetitive	4 (17)	• "the repetitiveness of the comments when you're inputting your information." (Female, aged 33 years) • "It's the same 3 questions, and most of the time my answers never change for the most part. There are always almost always the same unless something spectacular happens with my day, but other than that, it's just the same questions, same answers." (Male, aged 29 years)
Nothing	13 (54)	"I don't think there's anything I dislike." (Male, aged 60 years)

Theme	Participants, n (%)	Example participant quotes
What are some ways that the app could be more helpful to you?		
More community activity	4 (17)	• "Just other than more people should interact on the community section. Maybe you can do categories on the community section." (Male, aged 36 years) • "It's nice when like people under the comment section do positive, kind of positive encouragement. Maybe there's a way to, I don't know how to encourage people to maybe daily or once weekly try to post a positive thing." (Female, aged 33 years)
Nothing	15 (63)	• "Right now, it's doing great for me." (Female, aged 33 years) • "I think it's pretty good the way it is, the way I use it." (Female, aged 31 years)

Discussion

Principal Findings

By conducting a rigorous, two-step formative research process, including needs assessment and rapid prototyping, we modified an existing theory-based mobile platform first developed to support people living with HIV for another chronic condition, OUD. This modification included changes to naming and language as well as the design of new features to address the needs specific to OUD care, such as monitoring of triggers. Building on a previously developed platform increased the efficiency of our process, as some time-consuming and expensive steps of initial software development could be reduced [29]. Through the iterative app design and Think-Aloud Protocol usability interviews, we elicited information directly from patients with OUD and their MAT care providers, enabling us to tailor app features to the unique needs and perspectives of the clinic population. Our iterative user-centered methods allowed us to develop a mobile health (mHealth) app to support individuals receiving MAT for OUD and to demonstrate that it was acceptable and highly usable for both patients and providers. Strategies to develop mHealth interventions to support people with OUD efficiently, such as those described in our study, are even more urgently needed in current times, when the COVID-19 pandemic has been exacerbating negative consequences of OUD, disrupting usual clinical care, and creating opportunities for innovative use of technology to enhance care [30].

In pilot testing, the study participants used all interactive features of the mobile app. Daily check-ins and provider messaging features were used most frequently and by most participants. Check-ins were designed to facilitate self-monitoring, which is a particularly important aspect of chronic disease management, including OUD. Social support and care engagement tools were included in response to formative participant input and differed from previously developed mobile technologies for OUD, which primarily focused on the management of medications, cravings, and triggers [31,32]. These features may allow for additional support to those in OUD recovery, both in connecting with peers and with care providers. Building trust may be especially needed in stigmatized conditions such as OUD, and secure web-based messaging between patients and providers has previously been associated with improved communication and trust in providers in other chronic conditions [33]. The community board was not used as often as demonstrated in previous work, despite participant interest in the feature. The staggered enrollment across 2 months may have influenced these rates [17,18]. A larger cohort of participants may be necessary to begin and maintain an active community board. Anonymous web-based discussion boards allow people with OUD to share experiences and find support, but they also carry a risk of misinformation if not moderated by a clinically trained professional [15]. The ideal number of participants and characteristics of web-based communities for promoting chronic care management are yet to be determined.

Participants' willingness to report nonstandard medication use and illicit drug use within the app system suggests participant acceptability and trust of the program. Previous research has noted that patient concern about the consequences of disclosing substance use as well as confidentiality issues have been barriers to completion of substance use screenings [34]. Our results demonstrate the utility of allowing patients to document their use confidentially, as it encourages honest self-reporting of behaviors and may enable participants to monitor their personal recovery process more effectively [35].

In addition to app use demonstrating acceptability of the mobile app and web platform, the SUS scores indicate high perceived usability of HOPE by pilot participants. Notably, our minimum score was 70 out of 100, and previous work suggests that scores above 70 are commonly considered acceptable [25]. These scores are also in the top quartile of SUS scoring and correlate to excellent ratings on an adjective rating scale [25]. Overall, participant interviews highlighted high usability, with most suggestions for improvement focused on minor technical issues and lack of participant engagement with the community board. Both provider and patient participants also reported strong positive perceptions of the program, with a notable perceived positive effect on patient access and connection to the clinic and its providers. Improved care connection may meet an important need in promoting persistence in MAT, which has high rates of discontinuation and negative consequences of treatment interruption, including the risk of relapse and overdose [36].

Limitations

There are several limitations to this study. Participant data are only summarized from the first month of enrollment, and engagement may change over time, particularly for features such as the community board where some threshold of enrollment may be necessary to encourage participants to post. In addition, we are unable to assess whether participants were reading from the message board but not posting on it or scrolling through other app features such as resources, looking at recovery group meeting locations, or viewing their check-in history. Future work should look to evaluate active and passive user behaviors on various app features and track participants over a longer period. Finally, although the SUS scoring is highly reliable and valid, it can only be used to interpret the perceived usability and is not an absolute measure of usability.

Conclusions

Ultimately, the use of the HOPE program by pilot participants, high system usability scoring, and positive perceptions from 1-month interviews indicate successful development of the program. By building on a previously developed evidence-based platform, engaging with end users, and eliciting feedback throughout the development process, we were able to efficiently create an app and a web portal that was highly usable and acceptable to study participants. Use data and interviews from HOPE participants emphasized the importance of self-monitoring, social support, and communication. Additional follow-up is needed to assess whether engagement in care can be improved in association with the use of the app. Mixed methods study could additionally help identify what participants perceive as the most beneficial to their recovery process over a longer period. This information paired with the observed use patterns and assessment of patient-oriented outcome measures will further delineate key mHealth features that contribute to harm reduction and long-term support of OUD recovery.

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Conflicts of Interest

RAD, KI, MH, ALDW, and MEW have consulting agreements with Warm Health Technology, Inc.

Multimedia Appendix 1
Patient and provider formative needs assessments.
[DOCX File , 19 KB - formative_v5i2e24561_app1.docx]

Multimedia Appendix 2
Patient and provider usability survey assessments.
[DOCX File , 18 KB - formative_v5i2e24561_app2.docx]

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Abbreviations

MAT: medication-assisted treatment
mHealth: mobile health
OUD: opioid use disorder
PL: PositiveLinks
SUS: System Usability Scale

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Original Paper

Ecological Momentary Assessment Using Smartphones in Patients With Depression: Feasibility Study

Redwan Maatoug[1*], Dr med, MSc; Nathan Peiffer-Smadja[2,3*], MD, MSc; Guillaume Delval[1], Dr med; Térence Brochu[1], MSc; Benjamin Pitrat[1], Dr med; Bruno Millet[1], Prof Dr

[1]Sorbonne Université, AP-HP, Service de psychiatrie adulte de la Pitié-Salpêtrière, Institut du Cerveau, ICM, F-75013, Paris, France

[2]National Institute for Health Research Health Protection Research Unit in Healthcare Associated Infections and Antimicrobial Resistance, Imperial College London, London, United Kingdom

[3]French Institute for Medical Research (Inserm), Infection Antimicrobials Modelling Evolution, UMR 1137, University Paris Diderot, Paris, France

[*]these authors contributed equally

Corresponding Author:
Redwan Maatoug, Dr med, MSc
Sorbonne Université, AP-HP
Service de psychiatrie adulte de la Pitié-Salpêtrière
Institut du Cerveau, ICM, F-75013
47-83 Boulevard de l'hôpital
Paris, 75013
France
Phone: 33 682476484
Email: redwanmaatoug@gmail.com

Abstract

Background: Ecological momentary assessment (EMA) is a promising tool in the management of psychiatric disorders and particularly depression. It allows for a real-time evaluation of symptoms and an earlier detection of relapse or treatment efficacy. The generalization of the smartphone in the modern world offers a new, large-scale support for EMA.

Objective: The main objective of this study was twofold: (1) to assess patients' compliance with an EMA smartphone app defined by the number of EMAs completed, and (2) to estimate the external validity of the EMA using a correlation between self-esteem/guilt/mood variables and Hamilton Depression Rating Scale (HDRS) score.

Methods: Eleven patients at the Pitié-Salpêtrière Hospital, Paris, France, were monitored for 28 days by means of a smartphone app. Every patient enrolled in the study had two types of assessment: (1) three outpatient consultations with a psychiatrist at three different time points (days 1, 15, and 28), and (2) real-time data collection using an EMA smartphone app with a single, fixed notification per day at 3 pm for 28 days. The results of the real-time data collected were reviewed during the three outpatient consultations by a psychiatrist using a dashboard that aggregated all of the patients' data into a user-friendly format.

Results: Of the 11 patients in the study, 6 patients attended the 3 outpatient consultations with the psychiatrist and completed the HDRS at each consultation. We found a positive correlation between the HDRS score and the variables of self-esteem, guilt, and mood (Spearman correlation coefficient 0.57). Seven patients completed the daily EMAs for 28 days or longer, with an average response rate to the EMAs of 62.5% (175/280). Furthermore, we observed a positive correlation between the number of responses to EMAs and the duration of follow-up (Spearman correlation coefficient 0.63).

Conclusions: This preliminary study with a prolonged follow-up demonstrates significant patient compliance with the smartphone app. In addition, the self-assessments performed by patients seemed faithful to the standardized measurements performed by the psychiatrist. The results also suggest that for some patients it is more convenient to use the smartphone app than to attend outpatient consultations.

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KEYWORDS

ecological momentary assessment; depression; smartphone; feasibility study; user experience

Introduction

A promising development in the treatment of unipolar depression consists of improving the monitoring of depressive symptoms at home. Indeed, a personalized follow-up and continuous assessment of the symptomatology and its contextual influences are paramount to the management of depression.

Ecological momentary assessment (EMA) is a method used in psychiatric research that collects real-time data on symptoms, microenvironmental fluctuations, and medication intake in the everyday environment of patients.

Several reviews have confirmed an interest in EMA in various psychiatric disorders [1-3], particularly mood disorders [4-6] such as depression [7,8]. In the context of mood disorders, symptoms are subjective and usually fluctuate from day to day. Consequently, the evaluation by a clinician at each consultation is necessary but is less precise than a continuous self-assessment. Furthermore, studies such as the one by Ben-Zeev et al [9] highlighted that during consultation patients tended to talk only about the negative aspects of their recent history and forgot about the positive ones. EMA helps reduce this bias and improves our understanding of mood fluctuations, including their links with the environment and medication adherence [10,11].

The first EMA studies were published in the 1980s by Csikszentmihalyi and LeFevre [12]. The authors were interested in knowing whether the quality of human experience was more influenced by whether a person was at work or at leisure or by whether a person was in "flow" (ie, a condition of optimal experience created when one's environment presents high challenges that are met by one's skills). The first EMA studies in depression, conducted using paper-and-pencil daily diaries, were published in the 1990s [13].

In previous EMA studies, data were mostly collected using a notebook that the patient had to complete. To avoid missing data, patients were reminded by a signal to write in the notebook. This method suffered from the risk of recall bias, as it was never certain when the patient filled in the questionnaire. In that regard, Stone et al [14] showed that "although patients reported high compliance, actual compliance was low." Using the patient's smartphone makes it possible to record the time of data collection. Over the last 10 years, smartphone use has become widespread in the population. While the penetration rate of smartphones was 29% in the French population in 2012, it exceeded 65% in 2018, offering an interesting tool for real-time monitoring of symptoms [15,16]. However, EMA studies using a smartphone app associated with an online platform are still scarce [17,18], although a few studies have used EMA apps on the smartphones of participants with depressive symptoms and/or bipolar disorder [19].

Recent EMA studies that included data restitution to patients have demonstrated that patients' knowledge of their mood fluctuations and their context can assist them in understanding and managing their pathologies and, consequently, allow them to switch from passive consumers into active participants in their own care [20]. This innovative use of EMA may have the potential to improve prediction of relapse and remission [21,22].

Finally, a few studies have been published exploring the benefits of using a dashboard to provide data restitution and feedback from the clinician to the patient using the EMA data collected. Simons et al [20,23] demonstrated the therapeutic interest in restoring patient results from the EMA in a randomized trial involving approximately 102 patients with depression. They explored not only the collection of clinical information and their predictive values in terms of prognostic evaluations but also the return of this information to patients living with depression and the economic consequences of such a method.

Thus, coupling EMA with the patient's smartphone has three main goals: (1) the possibility of real-time and continuous evaluation of symptoms [24], (2) early detection of relapse and treatment efficiency [25], and (3) generalization of the tool on a large scale [26,27].

The aim of our work was to highlight the relevance of using EMA with smartphones to track patients with depression. The main objective of this study was twofold: (1) to assess patients' compliance with an EMA smartphone app defined by the number of EMAs completed, and (2) to estimate the external validity of the EMA using a correlation between self-esteem/guilt/mood variables and Hamilton Depression Rating Scale (HDRS) score.

Methods

This 28-day, single-center prospective study took place between August and October 2019. During the study, patients had continuous full access to the EMA app on their smartphone.

Population

All patients included in the study were experiencing a major depressive episode according to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition criteria, with a recent introduction (less than one month) or modification of an antidepressant. Additional inclusion criteria were ownership of a smartphone and age over 18 years. Patients were included over a 2-week period.

The study took place at the psychiatry department of the Pitié-Salpêtrière Hospital (Paris, France). With the help of the psychiatrist, the patients downloaded the EMA app onto their personal smartphone. Additionally, they were informed that the clinical data were processed in real time and reviewed during the outpatient consultations with the psychiatrist.

Assessments

Every patient enrolled in the study was expected to have two forms of assessment: (1) three outpatient consultations with a psychiatrist at three different time points (days 1, 15, and 28), and (2) real-time data collection using the EMA smartphone app, with a single, fixed notification daily at 3 pm.

Outpatient Consultations

During the three outpatient consultations, the psychiatrist assessed anxiety and depressive symptoms using the HDRS. The HDRS is a 17-item questionnaire designed for adults and

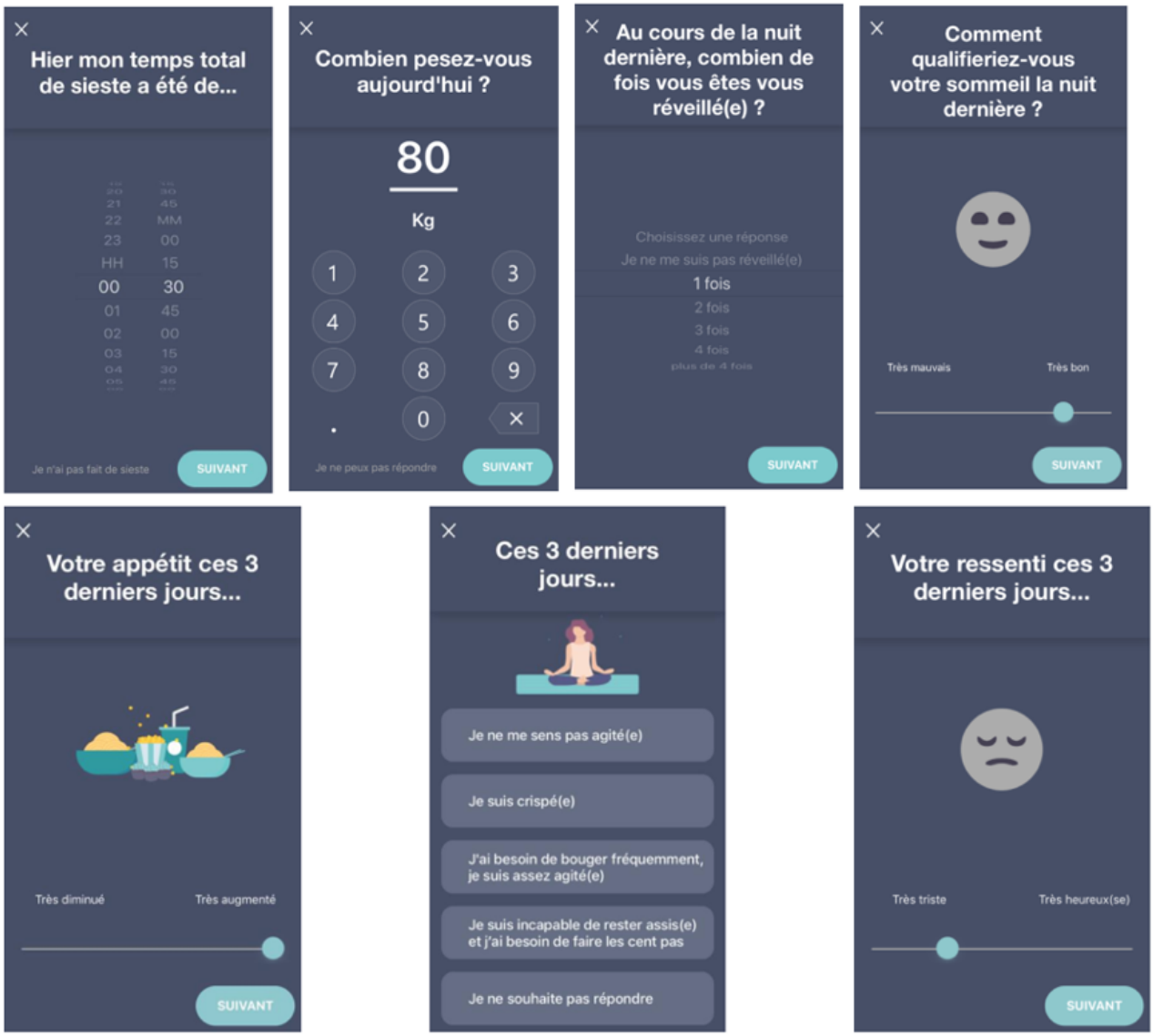
used to rate the severity of their depression from 0 (no symptoms of depression) to 52 (severe depression) by probing mood, feelings of guilt, suicide ideation, insomnia, agitation or retardation, anxiety, weight loss, and somatic symptoms [28].

Smartphone App

The EMA smartphone app is available in both iPhone (iOS) and Android operating systems (Figure 1).

Every day at 3 pm, each patient received a notification on their smartphone to remind them to respond to the EMA questions. However, patients could choose which questions they wished to answer. Indeed, a drop-down menu is present on the app and allows the patient to choose between different questions. This tool was developed to allow the patient to answer any particular question according to their mood or preference. Therefore, patients were not obliged to answer all of the questions and could stop at any time.

Figure 1. Illustration of the ecological momentary assessment smartphone app.



Each patient was asked to answer 10 questions per day for a period of 28 days, for a total of 280 EMAs to be completed over the course of the study. In order to assess the compliance of patients to the smartphone app in their home environment, no external reminders were sent to the patients.

The data collected with the smartphone app were as follows: antidepressant compliance (binary answer); potential side effects of the antidepressant (binary answer); mood evaluation ("Could you please rate your mood over the last 3 days?"); self-esteem ("How self-confident have you been during the last 3 days?"); guilt ("How guilty did you feel during the last 3 days?"); sleep parameters (bedtime and time to fall asleep, sleep quality); appetite (binary answer and weight changes); and general interest.

Each visual analog scale used semantic differentials as anchor points for the patient, which were converted to 0 to 100 for the clinician.

Study Design

The study was developed in collaboration with Ad Scientiam, a French start-up specialized in real-life data, an initiative of

the Brain and Spine Institute at the Pitié Salpêtrière Hospital in Paris, France.

No direct nominative data were collected in this study. All participants were identified by an identification code in the app. The study was approved by the local ethics committee for the protection of persons at Sorbonne University and by the Chair of the data protection commission (Commission nationale de l'informatique et des libertés). Written informed consent was obtained from all participants in the study.

Results

General Description

Eleven patients experiencing a major depressive episode were included in this feasibility study. All patients downloaded the EMA app onto their personal smartphone (Table 1).

Table 1. Summary of compliance with the smartphone app and outpatient consultations for each patient.

Patient	Gender	Age (years)	Days of follow-up[a]	Number of EMAs[b] completed[c]	Number of outpatient consultations attended[d]
1	Female	45	35	300	2
2	Male	52	35	252	3
3	Male	51	35	106	3
4	Female	41	33	280	3
5	Female	37	30	297	2
6	Male	45	29	210	3
7	Male	56	28	56	3
8	Female	57	17	92	3
9	Male	70	11	53	1
10	Male	67	8	78	1
11	Male	69	5	32	1

[a]The duration of follow-up was 28 days. Some patients exceeded 28 days because they continued to use the app after the end of the study.

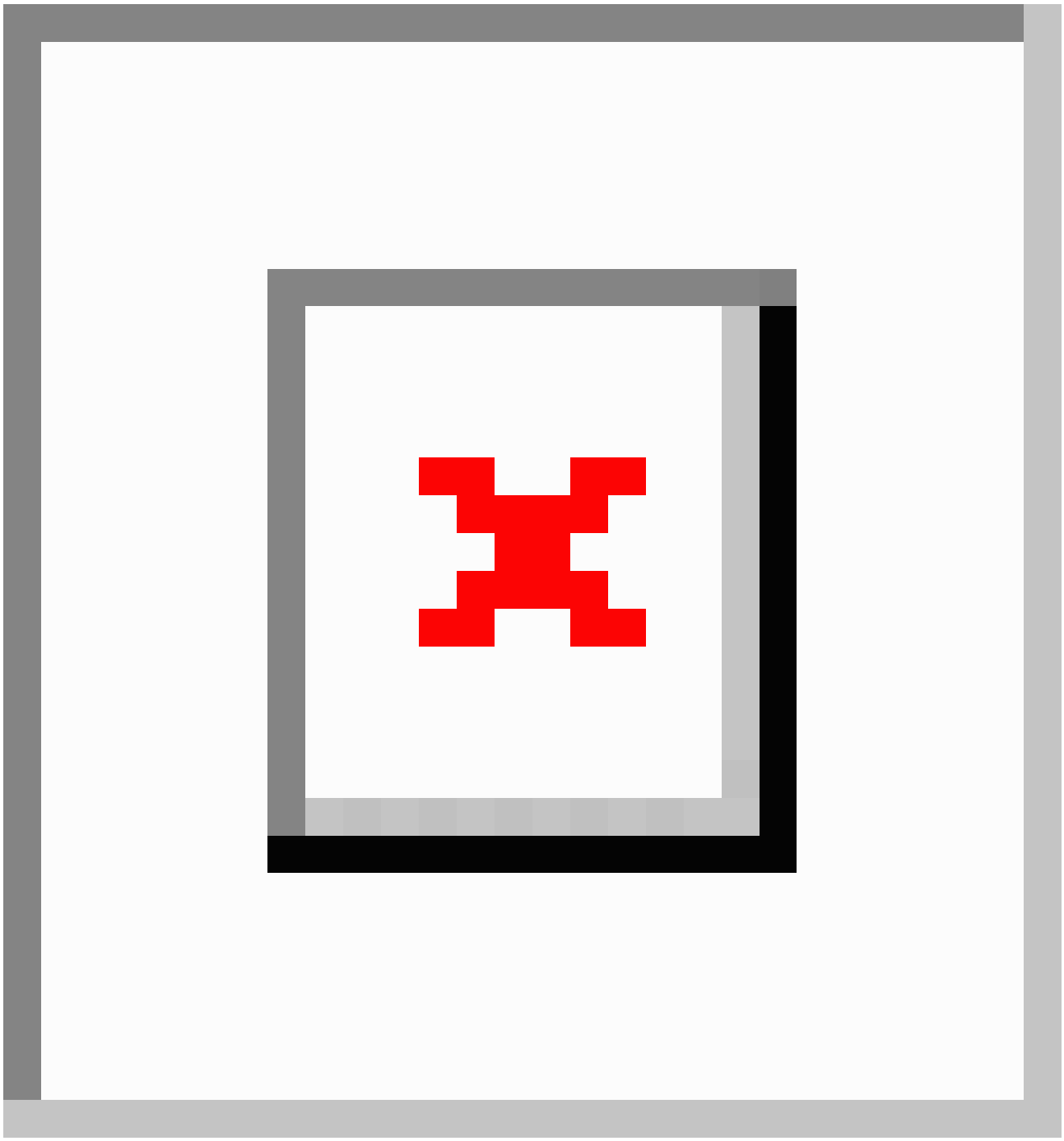
[b]EMAs: ecological momentary assessments.

[c]The number of EMAs completed during the total follow-up period; data collected after the 28th day were included in the total number, as the objective was to measure patient compliance with the smartphone app.

[d]Three outpatient consultations were scheduled (on days 1, 15, and 28).

Of the 11 participants, 6 patients attended the three outpatient consultations with the psychiatrist and completed the HDRS at each consultation. Seven of the 11 patients responded to the EMAs for a duration of 28 days or longer; the mean duration of follow-up was 24 days. It should be noted that of the 7 patients who completed the EMAs for a minimum of 28 days, 6 patients continued to complete them after the end of the study; patients 1 and 5 continued to complete EMAs without attending outpatient consultations with the psychiatrist (Figure 2).

Figure 2. Monitoring of each patient for the 28 days of the study. The first value for each patient corresponds to the Hamilton Depression Rating Scale (HDRS) score at the first outpatient consultation (day 1); the second and third values correspond to the HDRS scores at the second (day 15) and third (day 28) outpatient consultations, respectively. The absence of a value indicates that the patient missed the consultation. The intensity of the green bar correlates with the number of questions out of a total of 10 that were answered in a given day.



EMAs and HDRS Score Correlation

On average, 175 (175/280, 62.5%) EMAs were completed by each patient. The least compliant patient in the smartphone app responded to 53 EMAs and the most compliant patient responded to 278 EMAs.

When we focused on the six patients who completed the HDRS three times, we found a positive correlation between the average HDRS score and the average score for the variables of self-esteem, guilt, and mood (Spearman correlation coefficient 0.57).

Furthermore, there was a correlation between the number of responses to EMAs and the duration of follow-up. In fact, the higher the response rate to EMAs, the longer the follow-up (Spearman correlation coefficient 0.63).

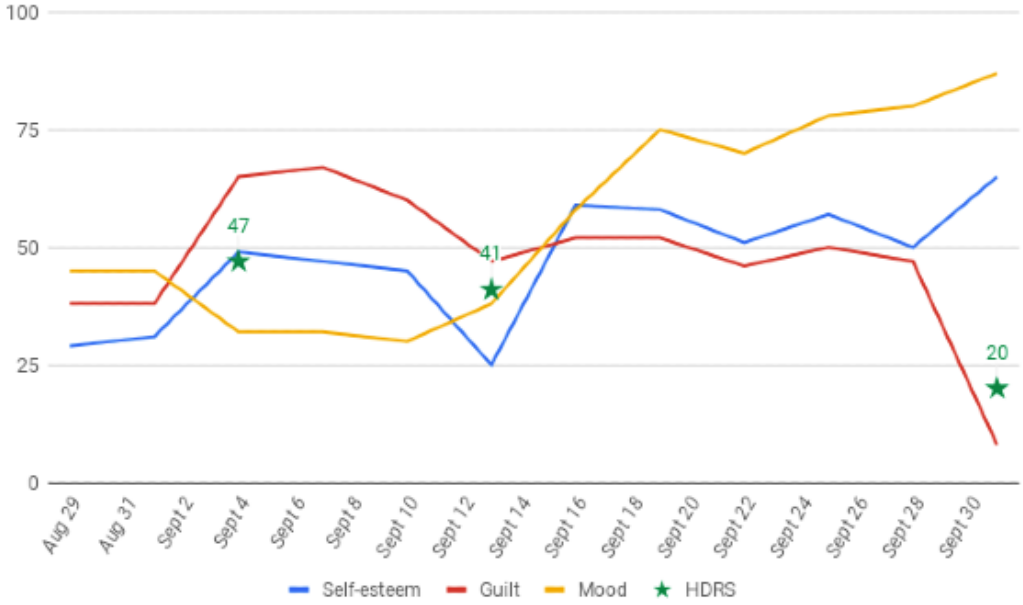
Discussion

This is the first feasibility study of an EMA tool with daily notifications for 28 days in patients experiencing a major depressive episode.

Our first objective was to assess the compliance to the smartphone app using the number of EMAs answered. Of the 11 patients, 7 patients responded to the EMAs for a duration of 28 days or longer; the mean duration of follow-up was 24 days. Moreover, on average, 175 responses (out of 280 possible responses; 62.5%) to EMAs were given. Surprisingly, we observed that two patients preferred answering the EMAs rather than attending the outpatient consultations with the psychiatrist.

The second objective was to estimate the external validity of the EMA using a correlation between self-esteem/guilt/mood variables and HDRS score (Figure 3). Interestingly, patients seemed to assess their self-esteem, guilt, and mood as accurately as a psychiatrist using the standardized HDRS (Spearman correlation coefficient 0.57); these results are consistent with the literature, particularly the papers by Faurholt-Jepsen et al [29,30] and Dogan et al [4]. According to Cuijpers et al [31], self-report measures and clinical assessment are not equivalent but may provide complementary information.

Figure 3. Dashboard used by the psychiatrist to visualize the patient's data during the outpatient consultation. The psychiatrist chose which variable to display (eg, antidepressant compliance, mood evaluation), on which statistical graph (eg, pie chart, histogram, box plot), and over which period of time (eg, daily, weekly, monthly). Aug: August; HDRS: Hamilton Depression Rating Scale; Sept: September.



By comparison, a feasibility study by Husky et al [32], which was conducted over 3 consecutive days with a preprogrammed personal digital assistant, showed an average compliance of 82% in the group of patients with major depression and 86.7% in the group of patients with any mood disorder. Johnson et al [33] found a 78% compliance rate after 1 week of follow-up in patients with severe psychiatric disorders.

Although a few studies, such as one by Vachon et al [34], have reported a high completion rate in patients with depression after 5 months of follow-up, the lower completion rate in our study may have been a result of the long duration of follow-up. In fact, in our study, patients had to complete the EMAs for 28 days, while in the studies by Husky et al [32] and Johnson et al [33], the follow-up periods were 3 days and 1 week, respectively. In addition, fixed notifications at precise times may be less disruptive than random notifications if they appear at a convenient time to the respondent.

Our results are encouraging, as they tend to confirm our initial hypothesis that data collected by patients using their own smartphone are more reliable than data obtained by a clinician during standard medical follow-up. Additionally, real-time data collection highlights the variability in the symptomatology of depression during the introduction or modification of an antidepressant. The analysis of patterns of emotional variability might lead practitioners to improve their understanding of mood disorders and might help us to identify risk factors for depression relapse.

At the patient level, the results obtained for the various self-assessment criteria—in this case mood, self-esteem, guilt, and sadness—allowed us to obtain, thanks to the large volume of data collected, a reliable representation of the symptoms expressed by the patient during the entire study. The availability of such a user-friendly tool could actually lead to a greater investment by the patient in his/her own care.

Our study also points out the difficulties for some patients in using smartphones. In our data, we observed many inconsistent results, especially for older patients, suggesting that they could not master the slide function on their device. In the future, more emphasis should be placed on assisting patients in the use of smartphones.

Acknowledgments

The authors would like to thank Fondation Pierre Deniker and the start-up Ad Scientiam for their contribution to this study.

Conflicts of Interest

Author TB owns stocks of Adscientiam. The other authors declare no conflicts of interest.

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Abbreviations

EMA: ecological momentary assessment
HDRS: Hamilton Depression Rating Scale

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Original Paper

Comparison of Facebook, Google Ads, and Reddit for the Recruitment of People Who Considered but Did Not Obtain Abortion Care in the United States: Cross-sectional Survey

Heidi Moseson[1], MPH, PhD; Alexandra Wollum[1], MPH; Jane W Seymour[2], MPH; Carmela Zuniga[2], MA; Terri-Ann Thompson[2], PhD; Caitlin Gerdts[1], MPH, PhD

[1]Ibis Reproductive Health, Oakland, CA, United States

[2]Ibis Reproductive Health, Cambridge, MA, United States

Corresponding Author:
Heidi Moseson, MPH, PhD
Ibis Reproductive Health
1736 Franklin Street
Suite 600
Oakland, CA, 94612
United States
Phone: 1 5108222696
Email: hmoseson@gmail.com

Abstract

Background: In the United States, abortion access is restricted by numerous logistical, financial, social, and policy barriers. Most studies on abortion-seeking experiences in the United States have recruited participants from abortion clinics. However, clinic-based recruitment strategies fail to capture the experiences of people who consider an abortion but do not make it to an abortion clinic. Research indicates that many people search for abortion information on the web; however, web-based recruitment remains underutilized in abortion research.

Objective: This study aims to establish the feasibility of using Facebook, Google Ads, and Reddit as recruitment platforms for a study on abortion-seeking experiences in the United States.

Methods: From August to September 2018, we posted recruitment advertisements for a survey about abortion-seeking experiences through Facebook, Google Ads, and Reddit. Eligible participants were US residents aged 15-49 years who had been pregnant in the past 5 years and had considered abortion for a pregnancy in this period but did not abort. For each platform, we recorded staff time to develop advertisements and manage recruitment, as well as costs related to advertisement buys and social marketing firm support. We summarized the number of views and clicks for each advertisement where possible, and we calculated metrics related to cost per recruited participant and recruitment rate by week for each platform. We assessed differences across platforms using the chi-square and Kruskal-Wallis tests.

Results: Overall, study advertisements received 77,464 views in the 1-month period (from Facebook and Google; information not available for Reddit) and 2808 study page views. After clicking on the advertisements, there were 1254 initiations of the eligibility screening survey, which resulted in 98 eligible survey participants (75 recruited from Facebook, 14 from Google Ads, and 9 from Reddit). The cost for each eligible participant in each platform was US $49.48 for Facebook, US $265.93 for Google Ads, and US $182.78 for Reddit. A total of 84% (66/79) of those who screened eligible from Facebook completed the short survey compared with 73% (8/11) of those who screened eligible from Reddit and 13% (7/53) of those who screened eligible from Google Ads.

Conclusions: These results suggest that Facebook advertisements may be the most time- and cost-effective strategy to recruit people who considered but did not obtain an abortion in the United States. Adapting and implementing Facebook-based recruitment strategies for research on abortion access could facilitate a more complete understanding of the barriers to abortion care in the United States.

(JMIR Form Res 2021;5(2):e22854) doi:10.2196/22854

KEYWORDS

abortion, induced; abortion seekers; abortion surveys; bias, selection; pregnancy, unplanned; research subject recruitment; reproductive health; social media; social stigma

Introduction

Background

Abortion is a safe and effective essential reproductive health service with social, economic, and physical benefits for those who wish to access care and are able to do so [1-7]. An estimated 862,320 abortions were provided in clinical settings in the United States in 2017, a decline of 7% since 2014 [8]. Due to well-established legal, financial, logistical, social, and other barriers [9-11], many people in the United States are not able to access abortion care [12]. The studies that have identified these barriers to abortion services have recruited participants almost exclusively from abortion clinics. However, this clinic-based sampling mechanism fails to account for pregnant people who want an abortion but are unable to make it to an abortion clinic [13] and may consequently underestimate the barriers and burdens that people face in obtaining abortion care.

As a strategy to address this recruitment gap, we reviewed the published literature on recruitment methods for difficult-to-target populations and evaluated their potential adaptability to the abortion research context. On the basis of this review, we hypothesized that web-based recruitment methods might enable us to reach people who have not traditionally been included in studies of abortion access. The geographic reach of the internet and social media, their ability to target specific population groups, and the privacy conferred by web-based data collection make these methods compelling options for abortion research in the United States. In January 2018, the Pew Research Center found that 88% of all women aged between 18 and 29 years and 78% of women aged between 30 and 49 years used at least one type of social media [14], and sociological research has found high social media engagement among transgender and nonbinary people assigned female at birth [15,16]. Given the widespread use of social media among these groups, these platforms may provide a reasonably complete sampling frame for the population of interest—pregnant people who considered but did not obtain an abortion.

Objectives

Prior studies have successfully recruited people of reproductive age using web-based methods [17-19], including 1 study that recruited 1235 people in 1 month using a Google Ads campaign related to self-managed abortion [20] and another study that similarly used Google Ads to recruit 1706 pregnant people searching for information on abortion over 9 months [21]. In this study, we aim to test the feasibility of recruiting participants through 3 different web platforms and to compare each platform's performance in recruiting a sample of people in the United States who considered but did not obtain an abortion. We sought to answer the following research question: Are Facebook, Google Ads, and Reddit able to recruit people who considered but did not obtain an abortion? Specifically, for each platform, we wanted to measure the cost of recruiting eligible research participants and how many eligible recruits could be enrolled per week, and to compare these values across the three platforms. On the basis of the limited research available at the time of the study design, we hypothesized that Google Ads would be the most successful [20]. Beyond comparison across the individual platforms, we also wanted to explore (1) how advertisement image characteristics related to viewer engagement with the study and (2) social network questions to gauge the feasibility of a future respondent-driven sampling study among this target population.

Methods

Recruitment

This study was approved by the Allendale Investigational Review Board in the United States. After conducting a systematic review of the peer-reviewed literature on nontraditional recruitment methods (results forthcoming), we selected 3 methods with the potential to recruit the target population: Facebook (including Instagram), Google Ads, and Reddit (one thread on birth control and another on menstruation). Over a 1-month period, between August 15, 2018, and September 15, 2018, we posted advertisements in English and Spanish on these platforms for a survey of experiences with unplanned pregnancy. All advertisements mentioned that participants would be entered into a raffle for the chance of winning a US $50 gift card. Modeling a recent study on self-managed abortion [22], we chose a 1-month pilot period recruitment window, which, though brief, would allow the detection of some variation in recruitment by week. A recruitment firm, BUMP Digital Marketing [23], managed the posting and purchasing of advertisements through Facebook and Google Ads, and study authors managed the Reddit campaigns. A background Facebook algorithm determined which advertisements were displayed on Facebook and Instagram based on user engagement with the early displays of each advertisement. For the remainder of this paper, we report both Facebook and Instagram results as *Facebook*.

Recruitment proceeded across all 3 platforms in the following steps: individuals who clicked on a study advertisement were directed to a study-specific web page with additional information about the study and a link to the eligibility screening questionnaire and informed consent materials. The screening questionnaire identified eligible participants: those aged 15-49 years, English- or Spanish-speaking residents of the United States, and those who had been pregnant in the past 5 years but had not visited an abortion clinic or obtained a wanted abortion in that period. In addition, eligible participants were those who responded *yes* to both of the following questions: "Did you consider abortion for any of these pregnancies, even for just one second?" and "If it had been available to you, could abortion have potentially been the best option for any of these pregnancies?" Those who consented were directed to a short web survey that collected data on pregnancy and abortion-seeking experience.

Data Collection

We tracked staff time and overall costs, recruitment strategy performance metrics, and the number of eligible recruits by platform. To estimate the total costs for each recruitment approach, the study team recorded the amount of staff time spent designing the advertisements for the launch of the study, the cost of the advertisements themselves, and the cost of the marketing firm's services. To measure recruitment strategy performance, the study team collected data on (1) impressions, defined as the number of times an advertisement was displayed on the platform; (2) reach, defined as the number of unique users to whom advertisements were displayed on each platform (when available); (3) the number of people who viewed the study website (website view *conversions*); (4) the number of people who began and completed the screening questions; (5) the number of people who were eligible; (6) the number of people who consented to participate; and (7) the number of people who began and completed the survey, overall and by platform. In addition, the study team tracked the specific advertisements that brought people to the study page, the language in which participants viewed the study material, and each participant's internet protocol (IP) address (for identification of potential duplicate entries).

The survey was programmed and fielded in Qualtrics and included open- and closed-ended questions. Survey questions assessed experiences with unwanted pregnancy; interest in abortion; barriers to abortion care; knowledge of others who had not obtained wanted abortion care; and sociodemographic characteristics, including state of residence, number of children, annual household income, work status, gender, education, race and ethnicity, and health insurance coverage. Participants who completed the survey were entered into a raffle for a US $50 gift card.

Statistical Analysis

The total staff time spent on advertisement development was multiplied by an hourly wage of US $30 per hour to estimate costs per platform. To estimate the total cost per platform, we summed all the costs. For some of the tasks (eg, advertisement text development, advertisement text translation, and landing page development), the hours worked or dollars charged were counted for each of the platforms individually, as the task would have been necessary for each platform had we piloted only 1 method, although the amount was only spent once. For other tasks (eg, translation of keywords and image finding), staff time, marketing expenses, and advertisement buys were attributed only to the relevant platform. Marketing firm fees included study website development in 2 languages, building an advertising campaign, and advertising campaign maintenance costs. To estimate the cost per eligible survey, we divided the total cost by platform by the number of eligible surveys completed from that platform.

To assess the performance of each of the 3 recruitment platforms, descriptive analyses of the number of views and clicks for each advertisement and the number of screeners and survey initiations and completions were calculated automatically by analytics on each platform (Facebook and Google) or manually via submissions in Qualtrics (Reddit). The research team manually identified and removed multiple survey submissions from the same IP address but could not do so for clicks or website views. The first survey submission by a unique IP address was chosen by default as the submission to include in the analysis, unless the repeat submission was clearly made only to correct an error in response to the screener questions (eg, entering age *9* in the first submission and *19* in the second submission). To assess the recruitment rate, we calculated the total number of eligible participants recruited by week and the mean and SD of recruits per week from each platform.

To understand whether the *tone* of the image used in an advertisement was associated with engagement, we compared engagement statistics (impression, reach, study website views, and conversions) between 2 advertisements with the same text but different images—one presenting a person looking directly at the camera with confidence and the other showing the profile of someone looking downward out of a window with a more somber expression. We present comparisons of the performance of these 2 advertisements by the language of the advertisement (English and Spanish) among low-income Facebook users; we targeted advertisements toward low-income Facebook users as they might be most likely to face barriers to abortion care.

Additional analyses assessed the distribution of participants' sociodemographic characteristics (age and language) overall and by study recruitment platform, as well as concordance between participant self-report of the web-based platform that led them to the study web page and electronic data on the recruitment platform actually used, with chi-square and Kruskal-Wallis tests for categorical and continuous variables, respectively. The mean number of people known by each respondent who failed to obtain a desired abortion for a previous pregnancy and the mean number to whom the respondent would feel comfortable giving information about the study were calculated to explore the feasibility of using web-based methods to recruit participants for future research using a social network-based approach. Standard deviations (SDs) and ranges were also calculated for both these estimates. All analyses were conducted using Stata version 15.

Results

Advertisement Views and Engagement

During the 1-month period, study advertisements received 77,464 known views, and the study website (or *landing page*; Figure 1) received 2808 views. Advertisement and study website views by platform are displayed in Figures 2-4. Google Ads had the highest conversion of advertisement views to study website views (1187/22,648, 5.24% overall), followed by Facebook (1412/54,816, 2.58% overall). These data were not available for Reddit.

Figure 1. Study website (landing page) displaying study information and offering links to click-through to the survey.

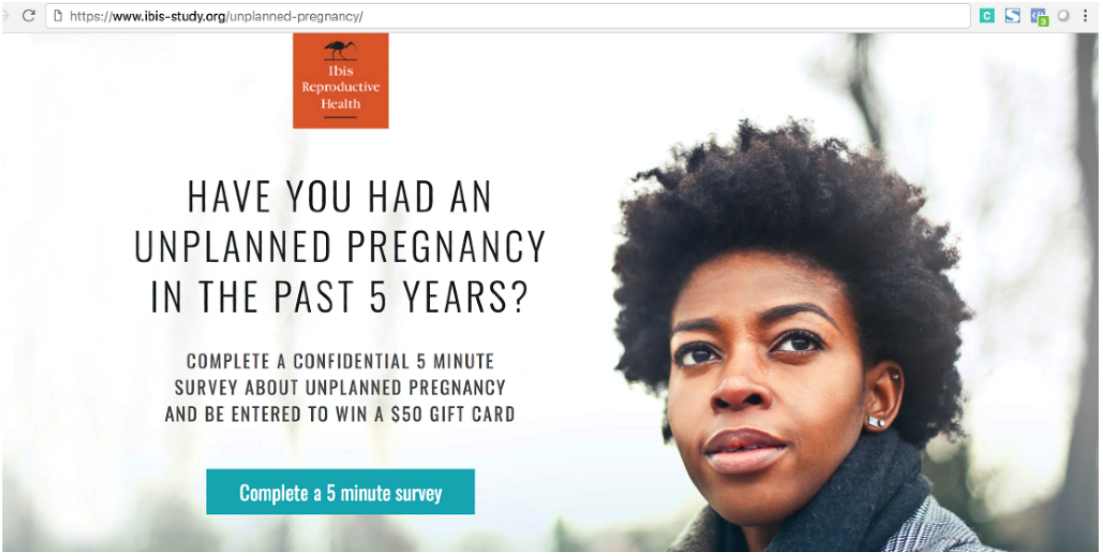


Figure 2. Summary flowchart displaying engagement and response pathways for all study advertisements posted on Facebook. IP: internet protocol.

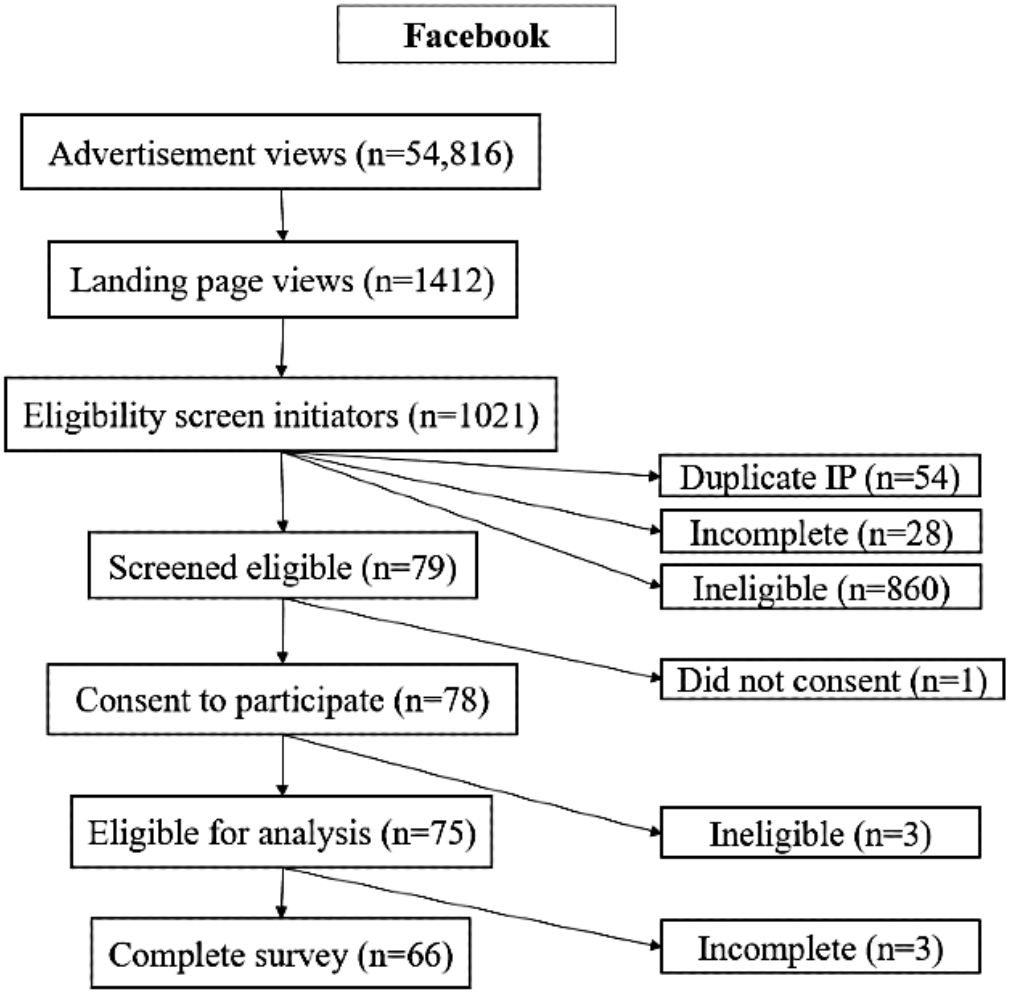


Figure 3. Summary flowchart displaying engagement and response pathways for all study advertisements posted on Google Ads. IP: internet protocol.

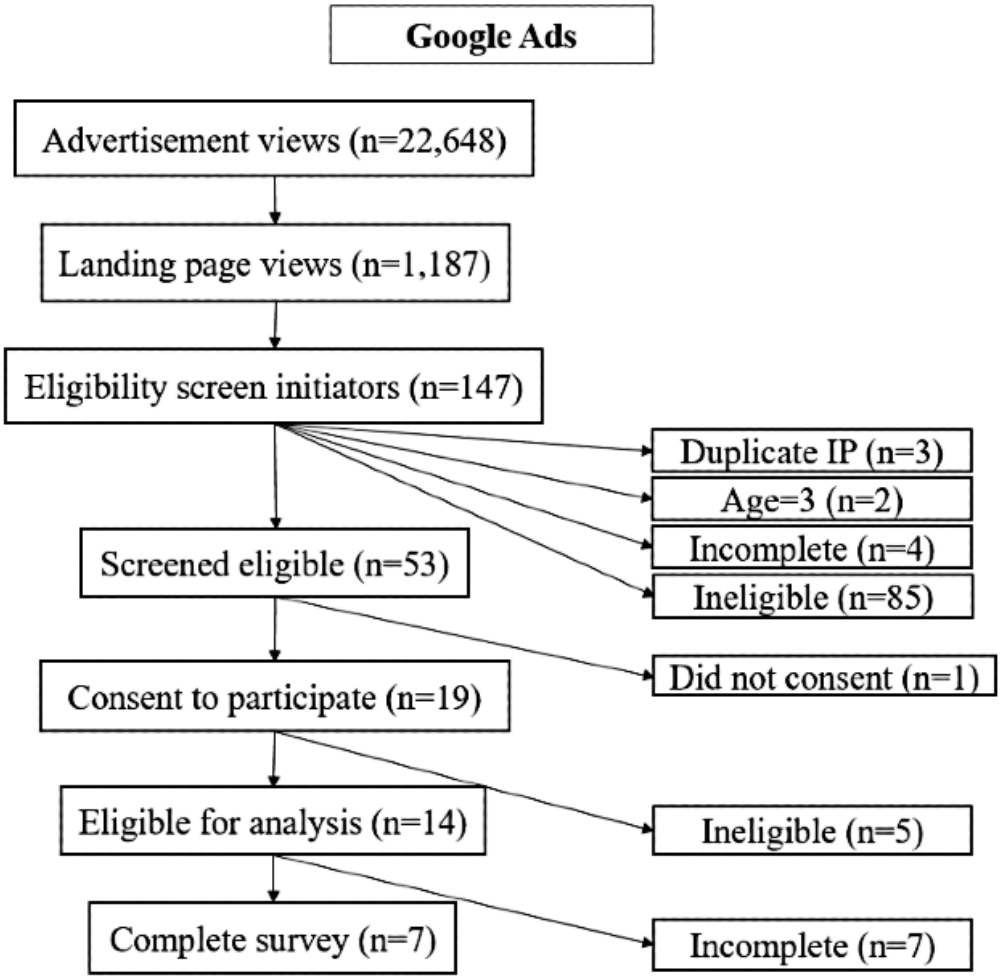
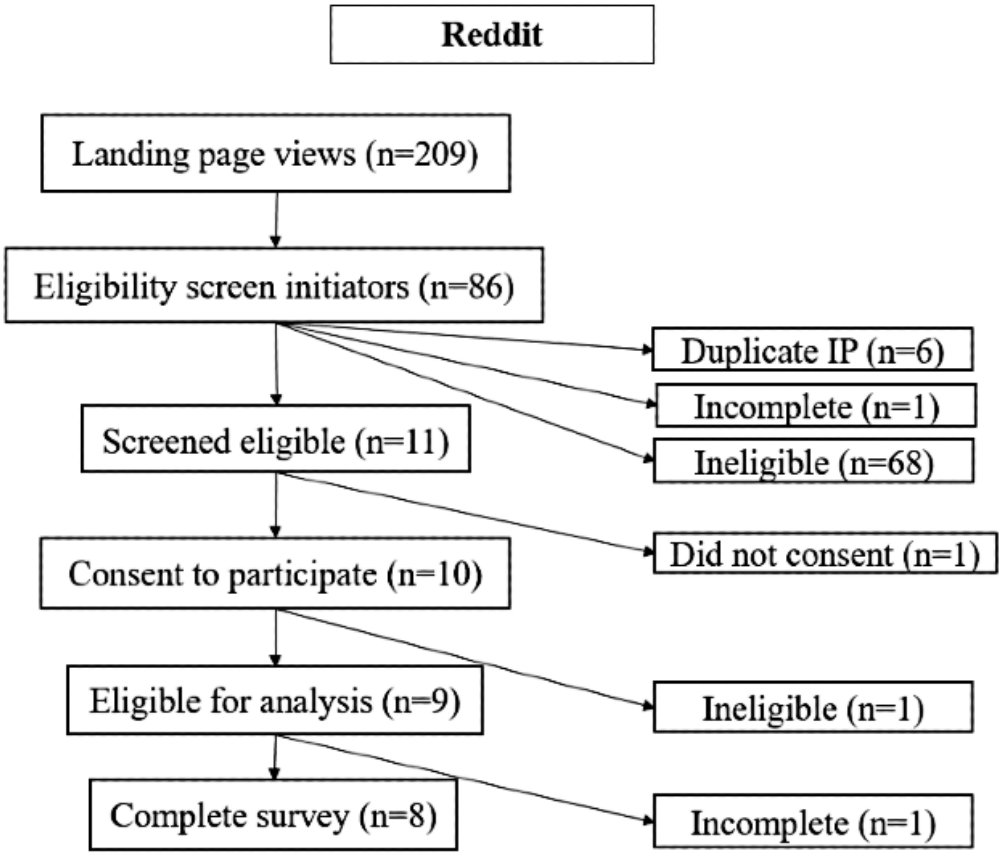


Figure 4. Summary flowchart displaying engagement and response pathways for all study advertisements posted on Reddit. IP: internet protocol.



To understand individual advertisement reach, Facebook provided the most complete data. Table 1 displays information on the number of impressions, reach, and study website conversions for the top 2 advertisements in English (Figure 5) and Spanish (Figure 6). Among the English-language advertisements, the image in Figure 5 garnered the most engagement, whereas among the Spanish-language advertisements, the image in Figure 6 received the most engagement.

Table 1. Impressions, reach, and study website views for 2 study advertisements displayed on Facebook to 2 target audiences of low-income English speakers and low-income Spanish speakers. Models in both advertisements had dark hair and appeared to be aged between 20 and 40 years.

Target audience	Impressions[a] (N)	Reach[b] (N)	Unique study page views, n (%)	Conversions[c], n (%)	Total cost (US $)	Cost per conversion (US $)
Low-income English speakers						
Dark shirt, looking out of the window	22,768	13,973	398 (2.85)	310 (77.9)	216.76	0.70
Light shirt, looking straight-on	16,665	10,157	303 (2.98)	248 (81.8)	155.66	0.63
Low-income Spanish speakers						
Dark shirt, looking out of the window	4266	2572	23 (0.89)	11 (48)	39.08	3.55
Light shirt, looking straight-on	16,614	7840	83 (1.06)	56 (68)	139.57	2.49

[a]Impressions refers to the number of times an advertisement was displayed on the platform.

[b]Reach refers to the number of unique users to whom the advertisement was displayed on the platform.

[c]Conversion refers to the number of people that clicked from the study website to the screener survey.

Figure 5. Screenshot of the study advertisement that received the most engagement of all English-language advertisements posted on Facebook.

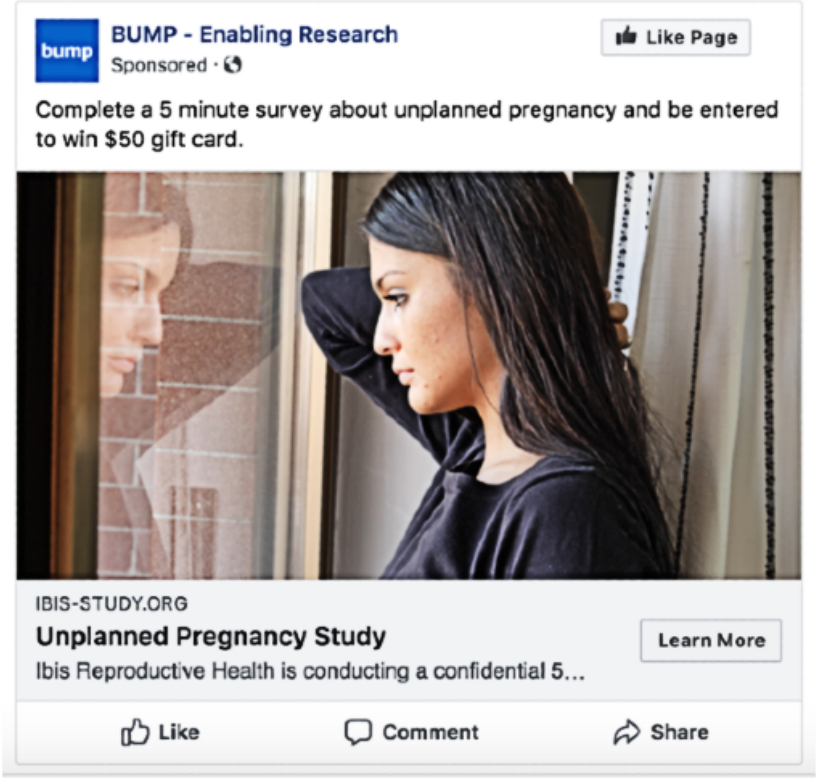


Figure 6. Screenshot of the study advertisement that received the most engagement of all Spanish-language advertisements posted on Facebook.

Eligibility Screen Completions and Eligible Recruits by Platform

Study advertisement views led to 1254 completions of the eligibility screener from 1191 unique IP addresses (63 screeners were submitted from a duplicate IP address). Among those who viewed the study website, 68.48% (967/1412) of Facebook users completed the screening questionnaire, as compared with 11.96% (142/1187) of Google Ads recruits and 38.3% (80/209) of Reddit recruits.

After completing all screening questions, 11.4% (143/1254) of all unique screener initiators were eligible: 7.73% (79/1021) of Facebook recruits, 36.1% (53/147) of Google Ads users, and 13% (11/86) of Reddit users. Among screener respondents, 84.44% (1059/1254) reported that they were currently pregnant or had been pregnant in the last 5 years, and of these, 20.49% (217/1059) said that abortion would potentially have been the best option for one or more pregnancies if it had been accessible. The largest driver of ineligibility among screener initiators was a *no* response to whether the respondent had considered abortion for any of their recent pregnancies, even for just 1 second (605/1013, 59.72% of those who screened ineligible). The second largest driver of ineligibility was a *no* response to the question about whether abortion would have been the best option for any recent pregnancy if it had been available to them (206/1013, 20.34% of those who screened ineligible), followed by having visited a clinic or hospital to learn about options for the pregnancy (104/1013, 10.27% of those who screened ineligible). Age and recent pregnancy were not the major drivers of ineligibility.

In total, 68.5% (98/143) of eligible participants consented and completed at least some of the questions included in the main survey: 95% (75/79) of eligible Facebook respondents, 26% (14/53) of eligible Google Ads respondents, and 82% (9/11) of eligible Reddit respondents. Overall, 56.6% (81/143) of those who screened eligible went on to complete the entire survey (66 from Facebook, 7 from Google Ads, and 8 from Reddit). The recruitment rate was approximately 18 (SD 4) eligible subjects per week from Facebook, 3 (SD 1) per week from Google Ads, and 2 (SD 1) per week from Reddit.

Including staff time, marketing firm fees, and advertisement buys, the research team spent approximately US $5745 on recruitment efforts across all 3 platforms (Table 2). This translated to a total cost per platform of US $3711 for Facebook, US $3723 for Google Ads, and US $1645 for Reddit. The cost per eligible survey translated to US $49.48 for Facebook, US $265.93 for Google Ads, and US $182.78 for Reddit.

Table 2. Funds expended on recruitment efforts, including staff time, marketing firm fees, and advertisement buys, were recorded in 2018 US dollars.

Recruitment expenses	Recruitment platform		
	Facebook	Google Ads	Reddit
Staff time, min	240	210	290
Staff cost, US $	120	105	145
Advertisement buys, US $	791	818	0
Marketing firm fees, US $	2800	2800	1500
Total cost, US $	3711	3723	1645
Cost per eligible survey, US $	49.48	265.93	182.78

Respondent Characteristics

Among the unique screener completions (n=1189), the average reported age was 29 years (SD 6.3; range 14-46 years). Age differed across the 3 recruitment platforms (Kruskal-Wallis $P<.001$); for Facebook, the average age was 30 years (SD 5.8; range 18-45 years); for Google Ads, the average age was 24 years (SD 7.1; range 14-46 years); and for Reddit, the average age was 23.8 years (SD 5; range 16-41 years). The language in which the screener was completed also differed across platforms (chi-square $P<.001$): 7.34% (75/1021) of the Facebook participants completed the screener in Spanish, 32.0% (47/147) of the Google Ads participants completed the screener in Spanish, and Reddit advertisements were posted in English only.

When asked about their social network, survey respondents reported knowing an average of 4 people who wanted an abortion but did not get one and were willing to share information about the study with an average of 2 of these people. Overall, 92.5% (99/107) of the survey participants accurately reported where they saw the study advertisement (Facebook, Google, or Reddit). All 100% (10/10) Reddit respondents accurately reported the referral platform, as did 99% (77/78) of Facebook respondents and 63% (12/19) of Google respondents.

Discussion

Principal Findings

We sought to advance the understanding of recruitment-based methods to address potential selection bias in research on abortion access. To do so, we piloted 3 web-based approaches to recruit a narrowly defined, difficult-to-target, and potentially stigmatized population that has not been included in traditional, clinic-based abortion research—people who self-identify as not having obtained an abortion for a recent pregnancy, despite having considered abortion and feeling that that abortion could have been the best option. We found that it is feasible and cost-effective to use web-based platforms—particularly Facebook, which balances cost and participant recruitment most efficiently—to recruit this specific population.

Limitations

As with all research, this study has strengths and limitations. The recruitment methods tested were identified through a systematic review process to employ the methods most likely to succeed in our target population. To create the conditions for a fair test of each web-based platform's ability to recruit our target population, we recruited through all 3 platforms simultaneously, using the same text for the advertisements where possible; conducted outreach in both English and Spanish; and tested multiple images in the advertisements. A professional social marketing firm assisted our study team, facilitating the creation and implementation of the most rigorous test possible of Facebook and Google Ads; however, nonmarketing professionals (the study team) managed the Reddit campaign. As a result, findings may differ if a marketing professional managed all recruitment streams.

The findings are limited in that we could not pilot the advertisement images before launching the full recruitment campaign. Due to a failure in the embedded tracking code, we could not assess which advertisements converted the most participants, as we could not differentiate participants by advertisement beyond the study website; this issue, however, has been remedied for future studies. We were also limited by a small budget for advertisements on Google Ads and Facebook and by our time frame, and we used only 2 subthreads within Reddit. To streamline the recruitment process, we collected little data on the population that visited the landing page and were screened, limiting our ability to comment on the differences between the individuals who were targeted by our advertisements but were not in our target population. An additional limitation is tied to the fact that we did not create a dedicated Instagram advertisement set or allocate money specifically to Instagram advertisements. Thus, because of low initial engagement, Facebook allocated nearly all of our advertisement dollars to Facebook and not Instagram; this resulted in very few advertisement impressions on Instagram, which limited our ability to assess recruitment performance via Instagram. Furthermore, although coverage of our target population among internet and social media users is estimated to be high, a better understanding of who does and does not use each platform will provide insight into how estimates from these web-based recruited samples should be interpreted. Given the timeline of research, another limitation is that there will always be a delay between when data are collected and study findings are shared—a delay during which the algorithms and systems used by these web-based platforms have continued to iterate, which could potentially shift findings in unknown ways. Finally, based on the decision to keep only the first survey submission from a given IP address, we may inadvertently have lost relevant study information provided in subsequent submissions.

Comparison With Prior Work

Our results are consistent with a large proportion of prior studies that compared web-based recruitment strategies, including among hard-to-reach populations (although never within our specific target population), which found Facebook advertising to be the most effective method in terms of cost and absolute numbers. Exceptions included studies in which a specific platform was organized around a key characteristic of the target population, such as dating apps for gay and bisexual men (eg, Grindr) [24-26]. In a systematic review of 35 studies that used Facebook for recruitment, the average cost per participant was US $14.41 and the median number of participants recruited was 264 over a 3-month period (approximately 88 per month) [27], as compared with an average cost of US $49.48 for the 75 eligible, consented survey initiators recruited over 1 month in this study. Although some studies included in the review overrepresented the experiences of young, White, cisgender women, most resulted in study samples that mirrored national sociodemographic statistics [27], a finding that supports the potential use of Facebook-focused recruitment efforts for future studies.

Studies that used Google Ads, although fewer than those reporting on Facebook recruitment, have returned more variable results, with many recruiting higher numbers of participants than this study. A recent study on self-managed abortion recruited over 1200 participants in a 1-month period [22]. Another study that recruited pregnant people seeking information on abortion providers enrolled approximately 190 participants per month over 9 months [21], compared with the 143 who initiated our screener in that same period. A more recent study focused on those currently pregnant and searching for information on abortion providers reported an average cost (based on advertisement spend) of US $18.85 per completed baseline survey [21], as compared with US $58.43 (based on advertisement spend only, not including staff and social media firm time) for this study. It may be that (1) Google Ads is better suited to target currently pregnant people versus those who have been pregnant in the past 5 years, or (2) the difference could reflect the substantial variance in advertising budgets, or (3) the fact that participants in this study only had the chance of winning US $50, rather than guaranteed remuneration. It is worth noting that in this study, Google Ads recruited more Spanish speakers and younger people (as measured via click-throughs) than Facebook or Reddit. The few studies published using Reddit have returned results similar to our findings, including one that recruited 34 young men who have sex with men in a 2.5-month period [26]. We did not identify comparable cost comparison data from other Reddit studies.

Recommendations

Given the consistency between the results presented here and in the prior literature, Facebook and Google Ads may be promising platforms for recruiting people who consider abortion in the United States but never make it to an abortion clinic. The click-through rates of our advertisements on Facebook and Google Ads were higher than the industry standard for both platforms [28], suggesting a high level of interest and engagement, although costs per eligible recruit were quite high with Google Ads. Our results also suggest that, to some extent, people share the experience of not having a wanted abortion within their social network, as indicated by the fact that 1 out of 5 participants knew someone in their network who had not obtained a wanted abortion in the past 5 years, and of these people, over half would be willing to share information about the study. This finding indicates an opportunity to pilot web-based referral methods to recruit this population.

Additional research, conducted on a larger scale over a longer time frame, is needed to build and expand upon the initial findings of this feasibility study. A larger study that recruits through Facebook and adds a dedicated Instagram-based recruitment arm, with structured incentives to encourage respondent-driven recruitment, could broaden the diversity of age, ethnicity, and level of education reached by the study advertisements. Relatedly, now that this study has established that these web-based platforms can successfully recruit from this narrowly defined population, future research should use these platforms with broader eligibility criteria to recruit people who considered abortion to explore experiences that differ across those who do and do not access abortion facilities. A larger budget (beyond the US $5745 spent for recruitment in this study) might dramatically increase the visibility and reach of the study advertisements beyond what was possible in this feasibility study. We recommend that future work carefully pilot test recruitment advertisement text and images and develop and embed tracking code so that participants can be followed from the initial advertisement view through survey completion and that researchers consider independently funded campaigns for each advertisement to test the performance of individual advertisements in a more controlled manner. Furthermore, researchers can consider the incorporation of complementary, free posts to Facebook groups and pages when relevant groups exist if the content of study messaging is not seen to be overtly stigmatizing or compromising participant privacy.

Conclusions

Without data from people considering abortion (not just those who make it to an abortion clinic), we cannot know if and how our understanding of the scope and magnitude of barriers to abortion care is limited and what the true implications are for abortion-related programs, policies, and clinical practices. Results suggest that as we strive to better understand the full abortion-seeking experience, recruitment via Facebook may be a promising approach to sample from a more complete group of people who consider abortion. Our findings show the potential of web-based recruitment methods to address potential selection bias in research. We encourage researchers who study abortion access and those who work on other sensitive and/or stigmatized areas of population health to further explore and test the use of these methods and to consider how recruitment methods and sample selection may influence the conclusions of our research.

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Conflicts of Interest

None declared.

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Abbreviations

IP: internet protocol

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Original Paper

Co-Designing a Mobile App to Improve Mental Health and Well-Being: Focus Group Study

Felwah Alqahtani[1,2], MCS; Andrea Winn[1], MCS, MEd; Rita Orji[1], PhD

[1]Faculty of Computer Science, Dalhousie University, Halifax, NS, Canada

[2]Faculty of Computer Science, King Khalid University, Abha, Saudi Arabia

Corresponding Author:
Felwah Alqahtani, MCS
Faculty of Computer Science
Dalhousie University
6299 South St
Halifax, NS, B3H 4R2
Canada
Phone: 1 9027892230
Email: Felwah.alqahtani@dal.ca

Abstract

Background: Recent advances in mobile technology have created opportunities to develop mobile apps to aid and assist people in achieving various health and wellness goals. Mental health apps hold significant potential to assist people affected by various mental health issues at any time they may need it, considering the ubiquitous nature of mobile phones. However, there is a need for research to explore and understand end users' perceptions, needs, and concerns with respect to such technologies.

Objective: The aim of this paper is to explore the opinions, perceptions, preferences, and experiences of people who have experienced some form of mental health issues based on self-diagnosis to inform the design of a next-generation mental health app that would be substantially more engaging and effective than the currently available apps to improve mental health and well-being.

Methods: We conducted six focus group sessions with people who had experienced mental health issues based on self-diagnosis (average age 26.7 years, SD 23.63; 16/32, 50% male; 16/32, 50% female). We asked participants about their experiences with mental health issues and their viewpoints regarding two existing mental health apps (the Happify app and the Self-Help Anxiety Management app). Finally, participants were engaged in a design session where they each sketched a design for their ideal mental health and well-being mobile app.

Results: Our findings revealed that participants used strategies to deal with their mental health issues: doing something to distract themselves from their current negative mood, using relaxation exercises and methods to relieve symptoms, interacting with others to share their issues, looking for an external source to solve their problems, and motivating themselves by repeating motivational sentences to support themselves or by following inspirational people. Moreover, regarding the design of mental health apps, participants identified that general design characteristics; *personalization of the app*, including *tracking and feedback, live support,* and *social community;* and providing *motivational content* and *relaxation exercises* are the most important features that users want in a mental health app. In contrast, *games, relaxation audio, the Google map function, personal assistance to provide suggestions, goal setting,* and *privacy preservation* were surprisingly the least requested features.

Conclusions: Understanding end users' needs and concerns about mental health apps will inform the future design of mental health apps that are useful to and used by many people.

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KEYWORDS

mental health; mobile app; focus groups; design recommendation; mobile phone

Introduction

Background

Mobile health technology is considered to be a promising tool to help users engage in their health care. Specifically, the ubiquitous nature of smartphones and other handheld devices makes them ideal tools for delivering mental health interventions. The increasing number of mobile device users has created opportunities to develop mobile apps for delivering health interventions [1]. Moreover, mobile apps can assist people with mental health issues by incorporating self-monitoring, psychoeducation, self-management, and treatment options. These apps can be especially appealing because of their anonymity, ease of access, and ease of use [2].

Consequently, researchers are increasingly using mobile apps as tools for delivering health interventions. However, a key challenge is how to design interventions that are effective and acceptable to people experiencing mental health issues. We believe that the best way to design such apps is to employ the user-centered design (UCD) approach that engages intended users and involves them in the app's design process.

In line with the UCD process, the goal of this paper is to explore the opinions, perceptions, preferences, experiences, and ideas of people who have experienced mental health issues based on self-diagnosis so that we can design a mental health app that would be engaging and effective at improving mental health and emotional well-being.

To achieve this, we conducted 6 focus groups with 32 participants. The results revealed that participants used strategies to deal with their mental health issues: (1) doing something to distract themselves from their current negative mood, (2) using relaxation exercises and methods to relieve symptoms, (3) interacting with others to share their issues, (4) looking for an external source to solve their problems, and (5) motivating themselves by repeating motivational sentences to support themselves or by following inspirational people.

Regarding the design of mental health apps, participants identified 13 unique feature ideas and 32 unique participant-generated sketches of how their ideal mental health app would look and what it should contain. The analysis revealed a core set of features, style preferences, and characteristics considered necessary by participants for a mental health app: (1) general design characteristics; (2) personalization of the app, including (3) tracking and feedback, (4) live support, and (5) a social community; and providing (6) motivational content and (7) relaxation exercises are the most important features users want in a mental health app. In contrast, (8) games, (9) relaxation audio, (10) the Google map function, (11) personal assistance to provide suggestions, (12) goal setting, and (13) privacy were least requested.

This paper contributes to advancing state-of-the-art mental health apps by exploring the preferences, needs, and concerns of mental health app users. It also sheds light on opportunities for future work in this area by offering recommendations for designing mental health apps that meet the unique needs of this population.

Mental Health Apps

Research on mental health and emotional well-being in human-computer interaction (HCI) is rapidly growing. There are different types of mental health and emotional well-being app interventions: (1) mental health apps to predict mental health issues, (2) mental health apps to improve the user's awareness of their mental health symptoms, (3) mental health apps designed based on cognitive behavioral therapy (CBT) or meditations to relieve symptoms, and (4) mental health apps designed based on a game to reduce issues.

Some mental health mobile apps were designed to predict the affective health state of users by collecting mobility and contextual information [3]. For example, Canzian and Musolesi [4] designed a mobile app that collects mobility patterns of the users from GPS data to trace and assess 28 users' depressive moods. They were able to identify a significant correlation between the changes in mobility metrics that were extracted from the mobility traces and the variations in users' depressive mood. Similarly, Boukhechba et al [5] developed a mobile app to passively collect the GPS location and communication data (text messages and calls) from 54 college students over 2 weeks. They examined the correlation between the social anxiety level of students and passively collected data (GPS, text messages, and calls). They found that by using both mobility and communication patterns, they were able to predict the level of social anxiety of the students with an accuracy of up to 85%.

On the other hand, some mental health apps collect the personal data of users manually or passively to improve their awareness and understanding of their mental health issues [3]. Some studies have shown that self-tracking helps users to understand their mental health symptoms and be involved in their mental health management by improving their awareness. Consequently, this type of mental health app facilitates self-tracking by helping users keep track of their mental wellness data; the apps use these data to improve users' awareness. For instance, Bardram et al [6] designed the MONARCA app, which is a personal monitoring app that allows users with bipolar disorder to monitor their mood and other factors. They compared the MONARCA app with paper-based forms and found that the app was easy to use and useful and increased adherence compared with paper-based forms.

There are also some mobile apps designed based on CBT. Bakker et al [7] conducted a study to evaluate a mobile app called MoodMission, which was designed based on CBT strategies for mood and anxiety issues. They found that the app improved mental well-being, the ability to cope, and self - efficacy for people experiencing moderate depression or anxiety.

Moreover, mindfulness apps are especially popular. Laurie et al [8] conducted a study using a previously developed app called HeadSpace to understand how users use and experience mobile-based mindfulness interventions. They found that there are some barriers to using the app, including busy lifestyles, a lack of routine, strong negative emotions, and negative perceptions of mindfulness. Therefore, they concluded that developers should design mobile well-being interventions by

considering people's beliefs, affective states, and lifestyles and should make them adaptable to fit the needs of different users.

In addition, Franklin et al [9] designed a game app called Therapeutic Evaluative Conditioning (TEC) as a tool to increase aversion to self-injurious thoughts and behaviors (SITBs). The game became more challenging as the trial progressed. Users earned points as rewards for faster and more accurate performance. They conducted 3 separate studies for people with a severe history of SITB who were randomly assigned to use the mobile treatment TEC app or a control app for one month. They measured the effectiveness of the TEC app on "the frequency" of self-cutting, nonsuicidal self-injury more generally, suicide ideation, suicide plans, and suicidal behaviors. Across all 3 studies, self-cutting episodes, suicide plans, and suicidal behaviors were consistently reduced but suicide ideation was not.

The UCD Approach

Involving users in the design process is essential to understand and incorporate their needs and preferences into the design. Some studies included intended users in the design processes to be able to design an application that was acceptable and more engaging to users. End users played a consultative role in the area of mental health and well-being intervention designs, such as improving psychological well-being [10-12], screening potential depression and supporting treatment choices [13], a web-based treatment program [14], self-management conditions [15], and a web-based mental health clinic [16].

Peter et al [11] conducted a participatory study to explore workers' perceptions, preferences, and ideas to design a mental health app that would be engaging and effective at improving emotional well-being for workers in male-dominated workplaces. They found that participants considered the available languages, ease of use, visual appeal, and offline mood as important features for a mental health app. Another study found that privacy, feedback, convenience, ease of use, personalization, and control over the amount of information were considered essential features in mental health mobile technologies used by adults [12].

In addition, Kenny et al [10] conducted 5 focus groups to explore adolescents' needs and concerns regarding mental health apps. The results show that participants identified 8 important factors: *safety, engagement, functionality, social interaction, awareness, accessibility, gender, and young people in control*. Similarly, Todd et al [15] conducted 5 focus groups to inform the development of a web-based self-management intervention. Participants highlighted the importance of social activity, exercise, and support with self-management and noted that it would be useful to have advice tailored to their mental health state. Although much work has been done toward understanding users' perceptions regarding the design of mental health apps, this study has mostly focused on the understanding of strategies used by participants who have experienced mental health issues for dealing with mental health issues in their lives, understanding participants' perspectives and opinions in relation to selected mental health apps, and understanding how these strategies and ideas could be leveraged in designing a mental health app, all of which have received little attention in previous studies.

Methods

Study Design

We conducted a focus group study with people who have experienced mental health issues based on self-diagnosis to (1) explore the ways people manage symptoms and overcome their issues; (2) understand their opinions, preferences, ideas, experiences, and needs in relation to 2 selected mental health apps; and (3) engage them in a co-design session.

Participants

We recruited participants by email (in both academic and nonacademic environments) and social networks (Facebook and Twitter). We conducted 6 focus groups, with a total of 32 participants (age range of most of our participants [88%] was 18-34 years; 16 males and 16 females) who had experienced mental health issues based on self-diagnosis. Each group had 4 to 7 participants and lasted 60 to 75 min. A total of 20 participants had used general health apps, whereas only 5 participants had used a mental health app to manage their mental health issues. We had a relatively diverse population in terms of gender, age, education level, and the type of mental health issues (Table 1).

Table 1. Demographics of 32 participants.

Demographics	Values, n (%)
Gender	
Female	16 (50)
Male	16 (50)
Age (years)	
18-24	18 (56)
25-34	10 (31)
35-44	2 (6)
45-54	1 (3)
≥55	1 (3)
Level of education	
High school or equivalent	12 (38)
College diploma	4 (13)
Bachelor's degree	9 (28)
Master's degree	6 (19)
Doctoral degree	1 (3)
Mental health concern	
Stress	22 (69)
Anxiety	7 (22)
Depression	5 (16)
Low mood	3 (9)
Panic attack	2 (6)
Worry	1 (3)
Fear	1 (3)

Producer

We conducted single-sex focus groups as people may not feel comfortable talking about personal issues, such as mental health, in mixed-gender groups. The moderator began the focus groups by asking questions to guide the group through topics related to the research topic while also taking a flexible approach and following unanticipated ideas that emerged during the discussion. The goal of the focus groups was to explore people's mental health issues, needs, and concerns about mental health mobile apps, including discussing users' perspectives on mental health mobile apps using 2 sample apps. The focus group session format was designed to unfold over 3 phases:

- Phase 1: exploring the type of mental health issues that participants have experienced and how they have managed symptoms or overcome the issue
- Phase 2: understanding participants' perspectives, preferences, opinions, concerns, and needs in relation to 2 selected mental health apps
- Phase 3: engaging participants in a co-design workshop

The main goal of this structure was to use the first and second phase discussions to establish common ground by helping participants reflect and discuss different ways of managing their mental health issues and understanding their perceptions. These discussions were then used to spur a co-design session where each participant designed an app to help them overcome or control their mental health issues.

Phase 1: Exploring Users' Experiences With Mental Health Issues

In this phase, we focused on exploring the type of mental health issues that users had experienced and how they dealt with these issues. We asked participants about their experiences with mental health issues and what they usually do to control or manage these issues. We also asked them if they had used a mobile app to help with their mental health issues.

Phase 2: Understanding Participants' Perspectives, Opinions, Preferences, Concerns, and Needs in Relation to 2 Selected Mental Health Apps

We asked the participants to download and use two mental health apps—Happify and Self-Help Anxiety Management—2 days before the focus group session, giving them time to explore and have a sense of how the apps worked by using them before the focus group session. In addition, we gave a demo of the two apps in the focus group before our discussion of the apps. We chose these two apps for the following reasons: the Happify app is complex and comprehensive with a high number of behavior change strategies implemented, whereas the Self-Help

Anxiety Management app is simple and employs fewer persuasive strategies based on previous work [17], and both apps were reviewed by mental health professionals and were published on the Anxiety and Depression Association of America's website [18]. In this phase, we demonstrated the Self-Help Anxiety Management app first because it was the simpler app and asked participants about their initial reaction to the app, the things they liked most about the app, what things they liked least about the app, and the things they did not like in the app. Following this, we demonstrated the second app (Happify), followed by the same questions asked about the first app. Finally, we asked them whether they felt that gender impacted the use of mental health apps.

Phase 3: Engaging Participants in a Co-Design Workshop

In this phase, we provided participants with paper and a pencil. We then asked them to pretend that they were the designers of mental health apps and invited them to sketch their ideas of their ideal mental health app in words or pictures. We asked them to think about what they would like and want to see in their own mental health application. After they finished, we asked each participant to share their design and, as a group, we dialogued about the user-generated designs, discussing what participants liked and disliked in each design.

Data Collection and Analysis

During each focus group session, we gathered data by audio recording the session with participants' consent and through design artifacts (sketches) to better understand (1) participants' personal ways of caring for their mental health issues, including general depression, stress, low mood, and anxiety; (2) their perceptions, opinions, needs, concerns, and ideas in relation to the selected mental health apps; and (3) how they reflected their needs, ideas, and perceptions in their own designs (sketches).

All group sessions were audio recorded and transcribed for coding. We conducted a thematic analysis to analyze our data [19]. Thematic analysis was chosen because it allowed us to analyze a large data set in a systematic manner that uncovered patterns in the text while considering the context of what participants said to more accurately inform our interpretation of the data. We followed the six-phase framework by Braun and Clarke [19] for conducting a thematic analysis: (1) becoming familiar with the data, (2) generating initial codes, (3) searching for themes, (4) defining themes, (5) iteratively reviewing themes, and (6) writing up the results.

Specifically, 2 researchers individually read and re-read all transcripts (iteratively) to identify codes using open coding. Following this, the 2 researchers met in a series of meetings where the codes were expanded, developed, and modified and new codes emerged. For each phase of the study group session format, we wrote each code on a separate sticky note and posted all generated codes on a large whiteboard to help identify the themes. On each sticky note, we wrote the number of times and in which focus group the theme was mentioned (Figure 1). After many iterative reviews, where we identified which themes could be revised or combined, the researchers identified a clear theme (Figure 2). Next, to further refine the themes, we presented and discussed the themes with a group of 12 researchers in the HCI Laboratory who had good knowledge of the research area. On the basis of their feedback and discussions, we generated a final iteration of the themes (the final themes are given in Multimedia Appendix 1). We presented the results of each phase in the sessions and provided quotes as specific examples from each theme within the results. Table 2 shows the frequency of occurrence of each theme that emerged in each phase. We identify participants by number (eg, P1, P2, etc) and which group each participant was associated with (eg, G1, G2, etc).

Figure 1. Codes generated from each phase (1, 2, and 3) in order from left to right.

Figure 2. Themes generated from each phase (1, 2, and 3) in order from left to right.

Table 2. Coding frame detailing the frequency of occurrence of the themes within the data.

Themes	Frequency, n (%)
Phase 1	
Doing something to distract themselves	22 (22)
Relaxation exercises and approaches	20 (20)
Social interaction	14 (14)
Looking for an external source of support to solve the problem	11 (11)
Doing something to motivate themselves	10 (10)
Helpful thinking	7 (7)
Doing physical exercise	7 (7)
Managing their time	6 (6)
Religious practices	3 (3)
Isolating themselves	1 (1)
Phase 2	
The need to enhance the app design	71 (43)
Tracking of personal data	18 (11)
In-app social community	16 (10)
Motivational content	14 (9)
Personalization	11 (7)
Providing feedback from the app	10 (6)
The need for enhanced privacy and security features	8 (5)
The need for relaxation approaches	7 (4)
Providing professional support	4 (2)
Including games for entertainment	4 (2)
Including the Google map function	2 (1)
Participants' perceptions regarding gender differences when using mental health apps	32 (19)
Phase 3	
General design characteristics	27 (16)
Self-tracking of personal data	20 (10)
Providing feedback for the users	20 (10)
Providing live support	18 (10)
Personalizing the app's style and functions	18 (10)
In-app social community	17 (10)
Motivational content	14 (8)
Providing relaxation exercises	10 (6)
Including a Google map function in the app	7 (4)
Including simple games for entertainment	7 (4)
Providing relaxation audio	6 (3)
Personal assistance in the app to help users	5 (3)
Goal setting	3 (2)
Privacy	2 (1)

Results

Users' Experiences With Mental Health Issues

All participants (32/32, 100%) reported experiencing stress, anxiety, depression, panic attacks, and/or low moods at some point in their lives. They reported a variety of factors affecting their mental health. Stress and anxiety caused by *studying at a university* were the most common issues discussed and were reported by half of the participants 53% (17/32). Moreover, *being a mother* (both during pregnancy and in raising children), *money issues*, *losing a job*, *losing friends*, *childhood abuse*, *family or community issues*, and *having a large number of commitments* were mentioned as factors that contributed to them experiencing mental health issues.

Participants shared a variety of ways they had used and were using to deal with and manage their mental health issues. We identified 10 core themes related to the approaches used by the participants: *doing something to distract themselves*, *using relaxation exercises and methods*, *social interactions*, *looking for an external source of support (ie, someone or information) to solve the problem*, *doing something to motivate themselves*, *helpful thinking*, *physical exercises*, *managing their time*, *religious practice*, and *isolating themselves*.

Detailed themes are presented in Multimedia Appendix 1, and sample responses from participants in support of each theme are discussed in detail later.

Doing Something to Distract Themselves

The participants used many strategies to distract themselves from unpleasant feelings. For instance, participants who were usually stressed, anxious, or depressed wanted to *run away* and desperately sought a way out. As a result, they spent time shopping, on social media, sleeping, focusing on work or study, or changing their environment, for instance, by physically going to a new location. All these they did as coping strategies, as illustrated in the sample comments below (comments from participants are included verbatim throughout the paper):

> *Every time I feel down or something, I would go to school just to run away and do something like this.* [G1P1]
>
> *I sleep when I feel down or stress.* [G5P3]
>
> *If I feel stress, I will go out to change the environment.* [G3P5]

In addition, when participants experienced mental health issues, they tried to entertain themselves by playing video games or mobile app games to distract themselves from their current situation, as demonstrated in some sample comments below:

> *I spend a lot of time on video games.* [G2P1]
>
> *I used to play a game when I am stressed to distract myself.* [G5P2]

Some people mentioned that eating to deal with their emotions was a strategy that helped them to forget their stress:

> *If I am depressed...I eat something that I like. I do anything that makes me feel better.* [G5P2]
>
> *When I am stressed, I eat a lot even if I feel I am full.* [G2P1]

Relaxation Exercises and Approaches

Participants mentioned that doing relaxation practices, such as breathing or meditation, via a mobile app, YouTube, or Fitbit assisted them with reducing stress, relieving symptoms of depression, and boosting feelings of joy and well-being:

> *Trying breathing exercise to mitigate the stress.* [G1P2]
>
> *I start to use some application that has some meditation and it works.* [G6P6]

Furthermore, doing CBT over a long period helped participants handle panic attacks:

> *I did CBT for long time...so when attack comes, I know how to handle it.* [G6P3]

Moreover, they mentioned that practicing gratitude before bedtime for about a month assisted them in being more positive and reducing negative thoughts:

> *Before I sleep, I write three things that I am grateful for. For example, I am grateful for having a family...and this change me too much. I became more positive I can control my stress, fear.* [G6P4]

With respect to relaxation exercises employed by our participants, they highlighted that listening to natural sounds and music helped them to reduce their stress:

> *I have tried one app that has natural sounds such as rain which help to sleep better.* [G1P2]
>
> *I usually listen to music. It helps a lot.* [G6P5]

They also reported that strolling or sitting outside in a natural environment were other ways in which they could reduce their stress and anxiety:

> *If I feel depressed or sad...sometimes I like to walk next to the waterfront or in a garden.* [G3P5]

Moreover, making herbal tea to reduce worry and stress was also mentioned by a participant:

> *Sometimes I made herbal tea to relax and overcome the stress.* [G1P3]

Social Interaction

Participants mentioned that talking with their mother, hearing their mother's voice, and knowing their mother was praying for them were some of the most relieving things for them when they experienced mental health issues:

> *I just call my mom and I want to hear her voice and chatting, and she prays for me that is the most relieving thing.* [G1P2]
>
> *Because maintaining my mental health leads to my being appreciated by the people I know.* [G1P12]

Furthermore, spending time with friends and nurturing their partners were also mentioned as ways of reducing depression, stress, and anxiety:

> *I call friend and talk about it.* [G1P1]

> *In order to have a healthy life with your partner, you need to take time with him.* [G1P4]

Moreover, having a person with whom the participant was comfortable and could talk about a troubling issue brought the participant some relief:

> *Talk to a comfortable person, that helps me so much.* [G5P4]

Looking for an External Source of Support to Solve the Problem

Looking for information or people that could help solve their mental health issues and help them feel relieved was another approach used by participants when they felt depressed, stressed, or anxious. Some participants joined a wellness group to share their issues and find someone who could provide them with suggestions or solutions for their issues:

> *I attend one session in the health and wellness center, and they teach us how to manage our stress and fear and how change our mood.* [G6P4]

> *Now I join a wellness group.* [G3P3]

Some participants went to see a doctor, psychologist, or counselor to find a solution for their depression or sleeping difficulties. Some of them used medication to help with their symptoms:

> *I went to my doctor and he said to me we need to talk we need to do something about this and I started some medications which worked for me.* [G3P3]

In addition, people searched for a solution to their mental health issues using Google. However, they stated that this approach was not always an accurate source of health information:

> *The hypochondriac is the most stuff, so I am using Google.* [G6P3]

Doing Something to Motivate Themselves

In this section, participants mentioned the internal and external motivations they accessed when they felt down, stressed, or in the midst of a panic attack. One of the approaches they used was self-talk, which is an internal form of motivation people practice by repeating motivational sentences or affirmations to support them in stopping negative thoughts:

> *Regarding to panic attack, I just try to tell myself this is not real to get myself feel good again.* [G6P7]

Participants reported following inspirational people on the internet and rewarding themselves after hard work as examples of external motivations they used to encourage themselves to be more positive and reduce their mental health symptoms:

> *I also follow some inspirational people in the internet to motivate me.* [G6P4]

Helpful Thinking

Some participants tended to think of the *bigger picture* surrounding their issues to see the benefit of the issue; this strategy helped them to reduce their stress.

> *I think about the overall picture. I am talking about my case for overcoming my stress...helps me so much.* [G4P1]

In addition, some overcame their fear by facing the things that generated that feeling:

> *If I am afraid from something, I do it. I found it very effective just facing your fear.* [G4P2]

Another strategy to avoid feeling depressed was to force themselves to do the thing that generated the depressed mood:

> *So, when I do poorly in school I can go to the depressive episode where I stopped going to class, I just don't feel good. The ways that I have had to deal with it...and force myself to wake up and go to the class.* [G2P2]

Doing Physical Exercise

Participants stated that being physically active improved their mental well-being by reducing anxiety, depression, stress, and negative mood. Hence, they overcame their depressive feelings and anxiety by going to the gym, walking, or dancing. Some played physical games, such as soccer and billiards, which helped to release their negative feelings:

> *I do something I like, such as playing billiard, and soccer.* [G3P2]

> *Dancing at home makes me feel better.* [G1P3]

Managing Their Time

Some participants highlighted that identifying priorities and being more rigid with their schedule helped them reduce stress and depression:

> *I just organize my time at least what I should do for each day to reduce my stress.* [G5P5]

> *I try to be more rigid with my schedule.* [G2P2]

They also mentioned that creating time to do something enjoyable and removing anything that contributed to their stress helped them in dealing with their mental health issues:

> *Stress is only created when you keep things inside you...so I started creating my own time I do what I want to do. I need my me time.* [G1P4]

Religious Practice

Some people stated that reading religious books and praying reduced their symptoms of depression and anxiety and enabled them to cope with stress better:

> *I seek something religious. Do the things I believe in, reading the religious book.* [G3P4]

Isolating Themselves

One person stated that when he experienced mental health issues such as feeling depressed, he preferred to withdraw and isolate himself:

> *I preferred to be isolated.* [G5P4]

Understanding Participants' Perspectives, Opinions, and Preferences in Relation to 2 Selected Mental Health Apps

We identified several themes related to participants' perceptions, needs, and preferences in relation to selected mental health apps. We discuss each of these themes along with the related subthemes that follow.

The Need to Enhance the App Design

Usability

Usability is an essential factor in users' experience of mental health apps.

- Easy to use: most participants highlighted simplicity and ease of use as important in the mental health apps that they really like to use regularly:

  > *The home page is a very complex design. It would be better to design like icons to be easy to use.* [G5P2]

- Easy to navigate: participants liked to be able to find relevant or required information or app components more directly and quickly. "*I feel there are lots of things going on that it takes many steps to go there*" (G2P5).
- Organized and simple home screen: participants liked apps that were organized and had fewer details on the home screen. They preferred that app information be presented in a nonoverwhelming way. "*I liked the layout organize of the app*" (G1P3).
- Tutorial: participants expressed a preference for apps with simple instructions on how to use the app. "*If the app has a little tiny pop-up for each activates to give you brief overview, how it works so it would not be confusing*" (G2P3).

App Content

Participants liked having a variety of activities in the app and felt that this activated their curiosity. They liked apps that have regular content updates, and the information content in the app had to be from trusted sources. Moreover, some participants liked content that shifted their attention away from their current issues:

> *The information they provide looks more trustworthy than the other. There are some links I can check them out.* [G1P3]

> *This app does not have anything that let you remember your stress or depression just play games and read an article which is good.* [G5P5]

> *The app should not show stress or depression as the illness it should show as something normal that we all face in our life.* [G4P2]

Basic Design

Participants highlighted the importance of the app having a clear purpose:

> *Users need to understand the main purpose of the app easily.* [G4P2]

They also mentioned that the app name should be both simple and not include or mention or be related to any mental health issue because they do not want others to know that they are using a mental health app:

> *I like that it is called happify. You are clicking to happify not clicking to anxiety. Even the color is bright and happy.* [G3P5]

Participants preferred the color scheme of the app to be bright and calm. They also liked apps that support different languages:

> *It need to include other languages not only English.* [G5P3]

> *I like the app color. It is calm.* [G2P2]

Tracking of Personal Data

Participants reported 2 types of tracking: *self-tracking* and *auto-tracking*. For self-tracking, participants wanted to make their own notes and track their successful personal solutions. The app should be able to support that:

> *I like taking note so I can know if there is improvement or not.* [G3P1]

> *I really like the anxiety tracker which shows your progress and kind it gives yourself hope that you will get better and you can report in the things that make you up and dawn.* [G2P1]

For auto-tracking, participants wanted their emotions to be tracked based on the auto-tracking data of their sleep, heart rate, and phone use:

> *What if you have something that can track your sleeping time and maybe heart rate and know your feeling based on that.* [G2P1]

> *I do not think users can rate his/her level of anxiety. I prefer sensors to give the rate of my stress like hear-rate.* [G1P2]

Social Community in the App

Participants highlighted their desire to have a social community within the mental health app to interact socially with other users who have the same issues. This would enable them to share issues, give each other advice, and relate to other people's experiences. They also liked anonymous communication in the social community and the ability to post a picture. Including a video calling option in the social community and having a professional monitor in the group was also suggested:

> *I like the community in the app, so you have someone to share with.* [G3P5]

> *Social community will be the main thing I will go for it.* [G4P1]

> *I like you can post the picture to the group.* [G5P3]

Motivational Content

Participants mentioned 2 types of motivation: motivation to encourage participants to be positive and motivation to encourage participants to use the app. Participants emphasized that the app should provide them with inspiring stories and positive news and quotes, pictures, and articles that improve their mental well-being and motivate them to be more positive:

> *I like the positive news. It is good to have it in the apps.* [G5P2]
>
> *If there is an inspiration quote, it will be good.* [G6P1]

Some reported that the app should allow them to gain rewards after each task they have done and compare their points with other users in the app, which would motivate them to keep using the app:

> *I like the points and specially if I can make it competition with other users so I can compare my points with my friends which let me practice more.* [G5P1]

Personalization

The ability to personalize the interface, for example, by customizing reminders, background, color, and music, was attractive to participants. Some also wanted to be able to add personal strategies in their profile, so the app could make personalized suggestions when they experience a crisis. In addition, some participants would like the app to administer an assessment before using the app to personalize the content based on users' answers. However, this assessment must be short. They would also like the app to greet them personally, by their name:

> *I like the level and the assessment in the beginning, it can be used to make the app personalized.* [G1P2]
>
> *Adding personalization in your app like Hi (name), how you are feeling today?* [G4P5]

Providing Feedback From the App

Feedback from the app was divided into 2 types: notifications and suggestions.

- Notifications: participants highlighted that the app should send them periodic notifications to check on them, either randomly or at user-defined times:

> *There is no notification or reminder to remind me to use the app so I will forget it.* [G3P3]

They also highlighted the need for the app to notify them about their feelings based on their tracked personal data:

> *The app could do more work in the background, send a notification and check during the day how's your day today.* [G2P2]

- Suggestions: participants wanted the app to provide helpful suggestions based on auto-sensed data related to their current circumstances. These suggestions could be positive articles, health advice, strategies to overcome the mental health issue, personal strategies that were previously recorded to make users feel better, or advice for the user to contact a doctor:

> *...for example, when you set up your account with the app, they will ask questions, what makes you happy? What is your hope? So, a month later if I feel down, they will suggest that I make a herbal tea for example.* [G1P1]
>
> *There should be a suggestion to contact a doctor.* [G3P1]

The Need for Enhanced Privacy and Security Features

Participants expressed a preference for the option for an individual mode, as opposed to a web-based community mode in which they can make personal notes and express their feelings within the app privately:

> *I will use the private mode first then after a while when I trust the app, I can change it to be community mode.* [G5P4]
>
> *Asking permission to access my photo, contact is good.* [G3P4]

They also preferred the option to use an app without creating an account:

> *Creating an account is something annoying for me. I do not like to create an account.* [G3P5]

Participants also emphasized the importance of the lock feature in mental health apps to protect their collected data and information:

> *There is no locking feature in the app and that increased my concern regarding privacy.* [G1P3]

The Need for Relaxation Approaches

Participants reported the importance of practicing relaxation approaches to reduce unpleasant feelings and feel better. Self-talking and breathing exercises were the strategies that users wanted to have in their mental health apps:

> *I like the breathing exercises in the app.* [G1P2]
>
> *The app should allow users to speak to themselves.* [G6P4]

Providing Professional Support

Participants suggested that the app should provide access to mental health professionals' support by either providing the contact details of doctors, coaches, and a suicide crisis hotline or by providing live therapists who can be accessed to respond to their concerns:

> *If there is icon that you can contact doctor, clinic, it will be good.* [G3P2]
>
> *There should be a hotline for suicide.* [G2P3]

Including Games for Entertainment

Participants reported that apps need to include fun games as a way to reduce stress:

> *The app should have entertainment such as game not only record your notes and mood.* [G5P5]
>
> *I like the game idea it is a kind of entertainment.* [G1P3]

Including Google Map Functionality in the App

It was suggested that mental health apps should have a Google map functionality that shows centers and communities for mental health support that are geographically near the user. Therefore, when users feel down, stressed, or depressed and use the app, they can easily find a physical community for support:

> *If there is icon that show the center or society that help people for example the app has Google map and show the mental health center and society that nearby users.* [G5P4]

Participants' Perceptions Regarding Gender Differences in Using Mental Health Apps

Some participants believed that men would be less likely to use mental health apps because women tend to look for ways to express their feelings, whereas men tend to hide their feelings and pretend that nothing affects them. However, other participants felt that mobile apps could motivate and help men to express their emotions. Others felt that differences in using mental health apps are less gender related and more likely dependent on the personality type of the users:

> *I think women use mental health app more because they are more emotional, and the man can keep his emotion and pretend nothing affects him.* [G3P3]

> *I think all men and women use mental health app but it depends on the personality. There may be some women do not like to use an app and as well as men, so it depends.* [G2P1]

Co-Design Workshop

The co-design workshop produced 32 participant design sketches and an extensive set of app design components, including user-preferred features, functionalities, and characteristics that mental health app users would like to use. The researchers identified 13 major themes from the co-design workshop. We discuss these themes below.

General Design Characteristics

Participants mentioned simplicity and ease of use when explaining their design. They highlighted that this would allow them to learn the app quickly:

> *I kept mine as simple as possible. I was thinking of a person who does not like to be on the phone or just needs the basics.* [G2P2]

In addition, they reported that mental health apps should include a tutorial or instructions for how to use the app.

> *The important thing for me is to show the users how to use the app.* [G5P3]

Participants emphasized that mental health apps could provide (1) credible information in a way that is not overwhelming, (2) a variety of activities, and (3) crisis information support:

> *Any information should be from a qualified person, not anybody can post the information.* [G3P3]

> *I would like to have a variety of activities such as yoga, breathing.* [G1P3]

> *It provides ... emergency and instruction of what users should do.* [G4P4]

Participants highlighted that mental health apps must have a simple name. Others suggested that the app's name must not mention any mental health issues within it:

> *I suggested to name the app 'solve your problem' for example.* [G4P3]

Moreover, it was recommended that the app should show the user's achievements, what they like, and what they dislike in their profile:

...it has a profile of what you like and dislike and activities that make you happy and people that make you happy, things like that. [G2P2]

Some users suggested creating an account within the app to store their information, whereas others disagreed with this idea. Participants found a point of agreement with the idea of making the account optional, and the app could provide more activities and content if the user chose to create an account and formally log in:

> *The app shows the analysis locally that user is using the specific relaxation activities, then it suggests for user that If you log in, you will be able to access more relaxation activities.* [G4P1]

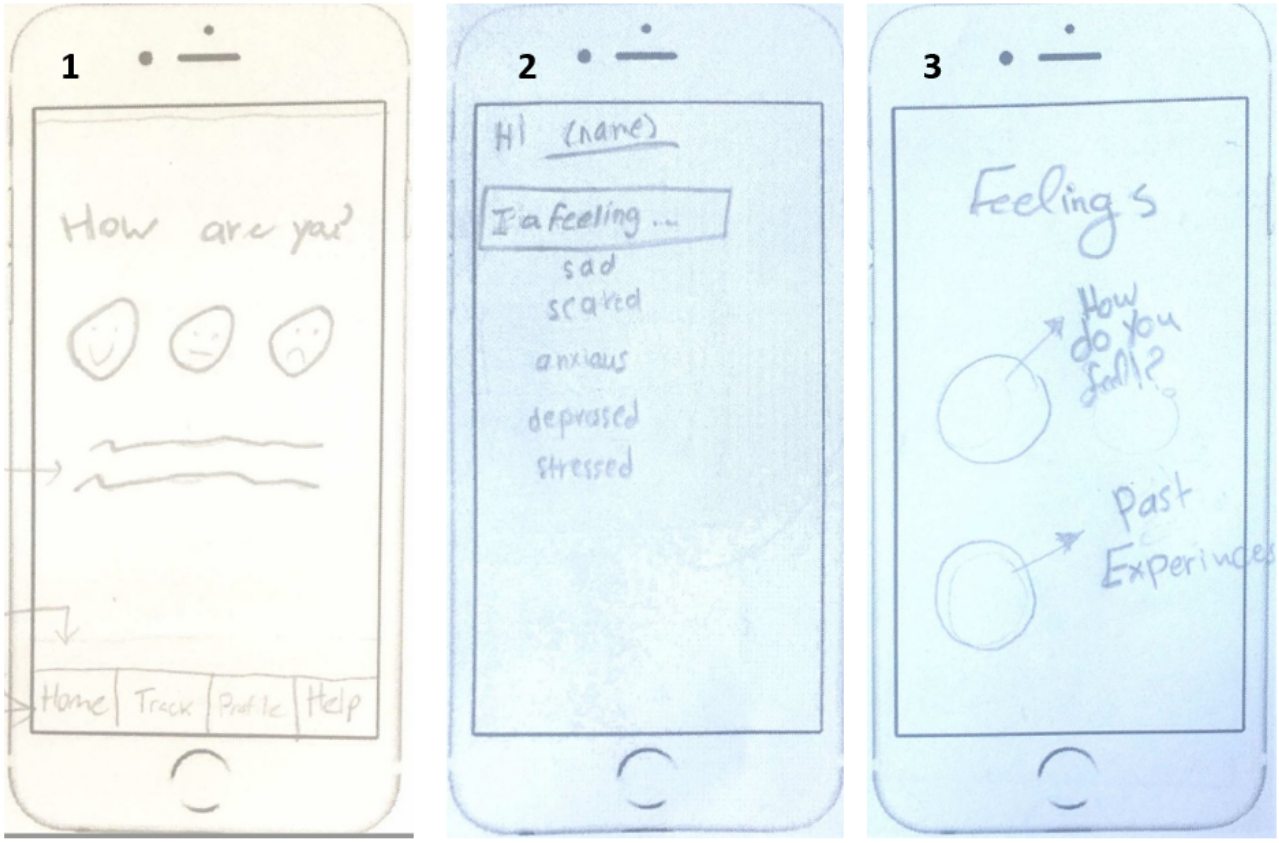
Participants would like to have favorite lists, enabling them to save their favorite videos and activities on the app so they could find them quickly later:

> *You can like the video, article and watch them again.* [G4P3]

Tracking of Personal Data

The tracking feature emerged in all 6 co-design sessions; 63% (20/32) of participants highlighted self-monitoring as an important feature in the app. There were various ways in which tracking was visualized by the participants in the co-design workshop. Specific ideas about how to design the tracker varied, with some participants indicating that they would like to have an auto-tracker to track their sleep time, heart rate, time spent on the phone, and in-app achievements. Moreover, some people suggested that the app could auto-track users' emotions based on their heart rate and breathing. Others suggested that the app should provide the ability to track their mood by using a set of smiley faces or emotion words or by labeling one's emotions in detail to identify the factors that could contribute to mental health issues (Figure 3):

Figure 3. Three implementation ideas of a tracking feature were generated by participants: (1) simple tracker using a set of smiley faces, (2) using a set of emotion words, and (3) labeling one's emotions in detail.



> *The app asks users what they feel and track other problems that may lead to depression such as obesity, social problem.* [G3P1]
>
> *If the app can know your emotions through heart-rate and breathing, it would be great.* [G4P4]

The app could also track users' alcohol consumption rates:

> *The app can track your drink and money to see how you are coping over time.* [G4P6]

Others did not like this idea of self-tracking because of a high probability of error and consistent data input and preferred the app to predict their emotions based on the auto-tracking of their heart rate:

> *It could be auto-tracking for blood pressure, heart-rate and knowing the emotions and providing recommendation based on users' feelings.* [G5P2]

Others suggested that the app should provide the ability to take note of emotions in detail to improve self-awareness:

> *You can track your feeling and write what make you feel down.* [G5P1]

Providing Feedback for the Users

We divided the app feedback into 3 types: notifications, suggestions, and reporting.

Notifications

Participants provided a variety of ideas for notifications and wanted the app to remind them of positive things in general and good things happening in their lives as a way of redirecting their attention away from the negatives:

> *If you feel stress, your app reminds you of the good thing happening to you which can help you to relax.* [G4P3]
>
> *The last thing is reminder to tell me a nice thing, everyone wants to feel good.* [G6P7]

They would like the app to remind them to track their mood and activities. They would also like the app to check in on them to see if they need help, either through auto-track sensing or at random times:

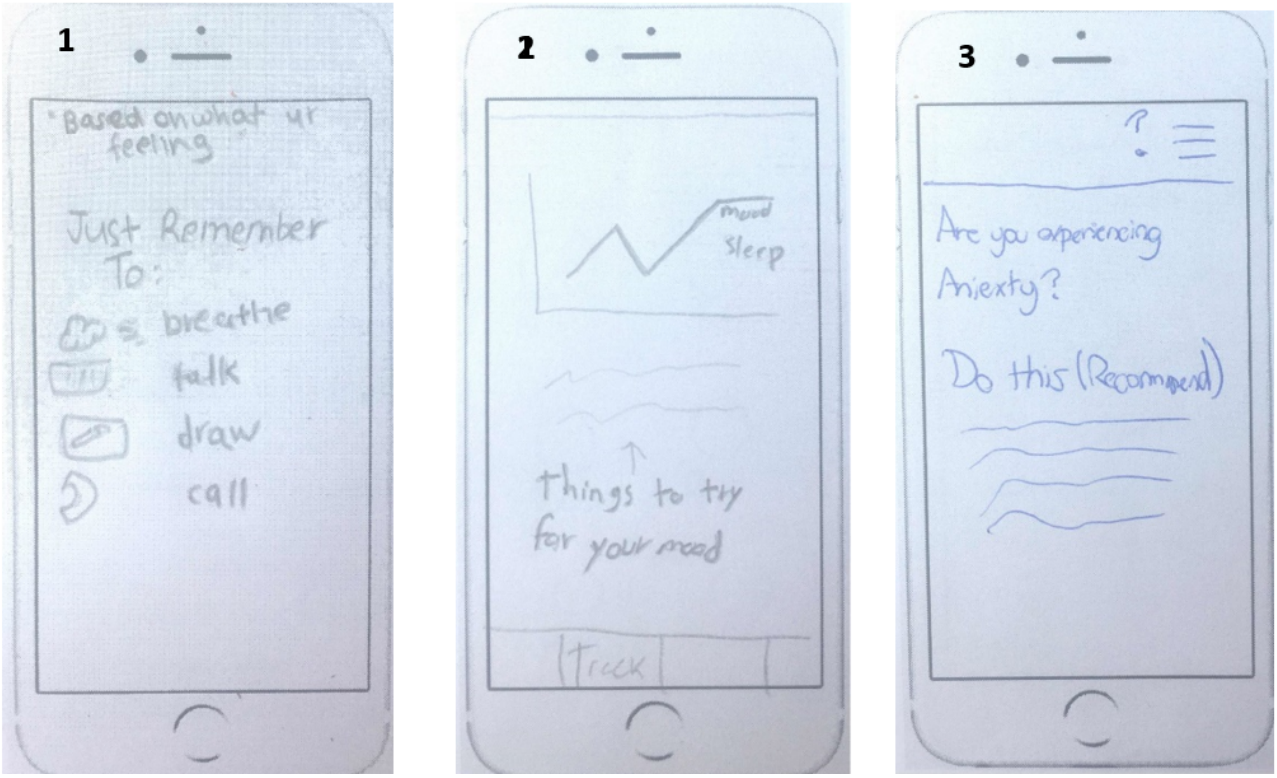
> *I like the notifications because the apps that do not have a notification, are forgotten.* [G4P2]
>
> *App can check me out at random time.* [G6P5]

Participants would like to be notified if they had made progress toward overcoming their mental health issues by showing motivational messages. For example, "*If the app sees you have done good progress toward the anxiety, it says 'Wow, well done!'* [G1P2].

Suggestions

Participants would like the apps to provide suggestions on what to do based on their feelings. The suggestions could be built into the app, things such as reading positive articles, health advice, or news, or could be things users liked or that they entered previously into the app as things that worked for them (Figure 4):

Figure 4. Three implementation ideas of a suggestion feature: (1) suggesting activities based on the moods entered, (2) providing suggestions to improve one's mood based on collected data, and (3) providing general suggestions.



The app can track sleep or mood and immediately diagnosis and provide you with some suggestions on what you can do to feel better based on the data the app has about you. [G2P2]

Reporting

Participants highlighted that they would like the apps to provide a summary report of their data and/or progress that could be shared with their therapist:

The app shows a summary of the results. [G6P6]

The therapist keeps up to date and see how you are progressing or your behaviors. [G2P1]

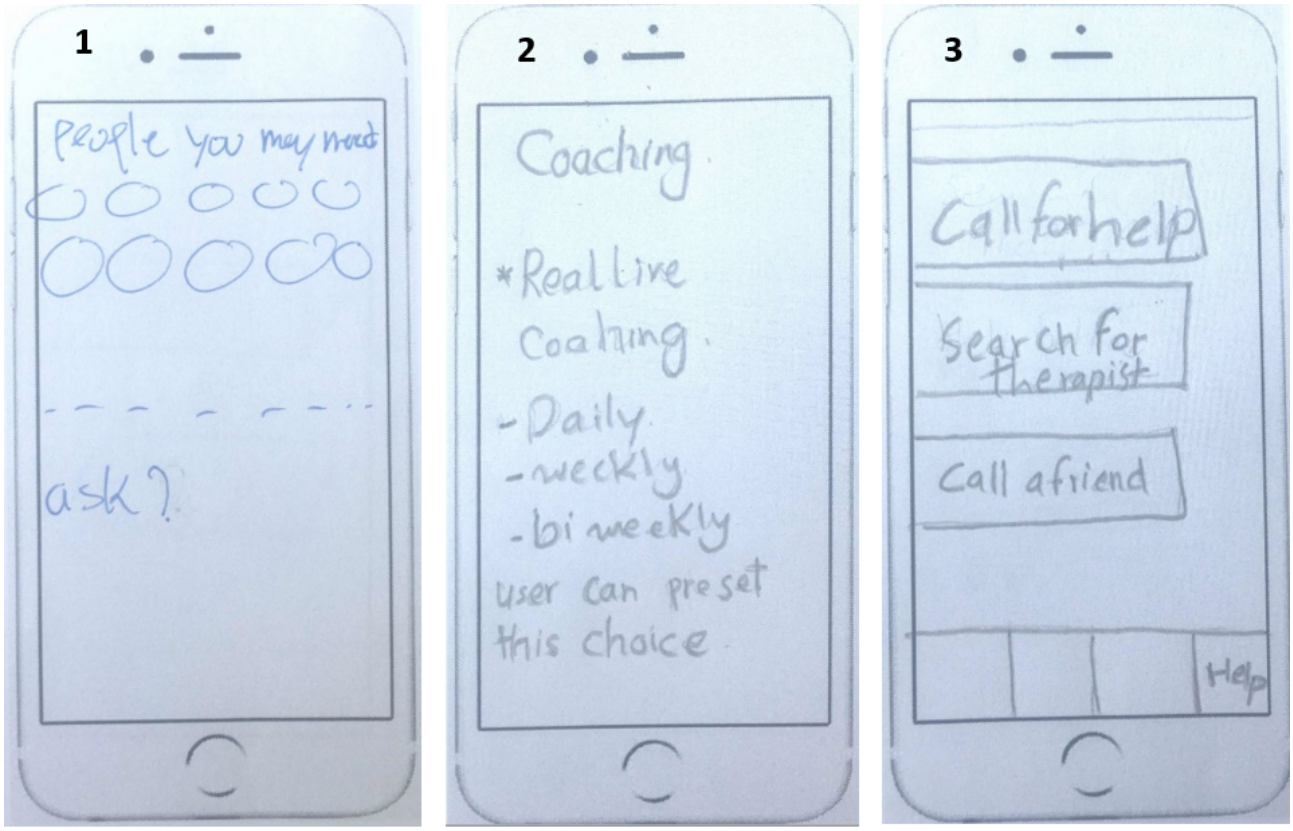
Moreover, some participants expressed that they would like it if their therapist could access their data if they were given permission:

Therapist can access my data if I allow it because I try to take note for each thing, having everything in the app will make it easy to show my doctor. [G3P3]

Providing Live Support

Participants highly valued live support, either personal or professional; 56% (18/32) of participants included live support in their ideal design. Figure 5 shows 3 implementation ideas of a live support feature that were generated by participants.

Figure 5. Three implementation ideas of a live support feature: (1) including therapists that users can contact and the ability to text them; (2) the ability to set up meetings with a live coach, and (3) the ability to call for help, contact a friend, or search for a therapist.



Personal live support allows users to provide contact details for friends and family to contact for support when necessary. It also allows for a way to contact a stranger through the app:

> *The app includes help information: call for help first option, search for a therapist is the second option, call a friend.* [G2P2]
>
> *The app allows users to call a friend or to speak to someone who use the app even a stranger that can help.* [G6P7]

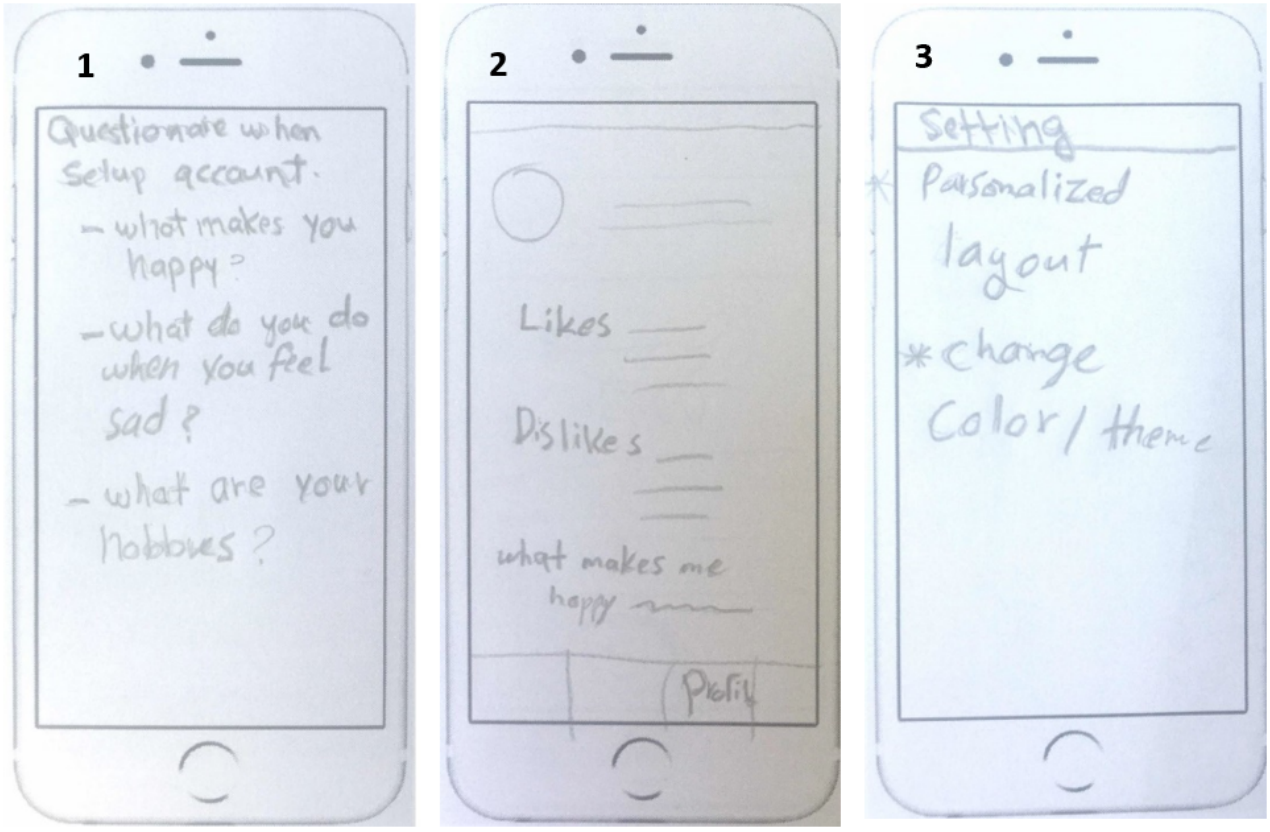
Professional live support allows users to contact a doctor or therapist in their area. It also provides live therapists and coaches who can respond to their concerns. Participants would be willing to pay for sessions with a live therapist when necessary:

> *The last icon is about contact the therapist through online and it could have fees.* [G5P1]

Personalizing the App's Style and Functions

The ability to personalize the app's style and function was attractive to 56% (18/32) of the participants. Figure 6 shows 3 implementation ideas of a personalization feature that were generated by participants. For example, they would like to customize reminders, background, color, and music and create their own personal in-app strategies.

Figure 6. Three implementation ideas of a personalization feature: (1) asking a set of questions when setting up the app; (2) including a profile with users' likes, dislikes, and what makes users happy; and (3) customizing the layout and theme of the app.



Participants would like to have an initial brief questionnaire that could be used to personalize their app experience based on the user's responses to the questions. For example, G1P1 stated, "*The app can have a brief questionnaire to get information to personalize the app*."

Participants also highlighted the need for the app to provide them with solutions based on selected feelings or issues. For example, G4P2 stated, "*The apps provide you with buttons with different issues, you can click on which one that you need help with, and it can direct you where you can find different solutions to the issue*."

Some participants said that it would be nice if the app could greet the user by name:

> *App can say hey with user's name.* [G4P4]

Some participants would like the app to provide music or religious phrases based on what the users are currently feeling:

> *There could be different options for different religions, so I can choose based on my religion and pop-up phrase to inspire me based on my feeling.* [G6P5]

Social Community Feature

Participants reported a desire to include a social community within mental health apps so that they could interact with other users who have the same issues, share their problems, and give each other advice.

The suggested design implementations for the social community were as follows.

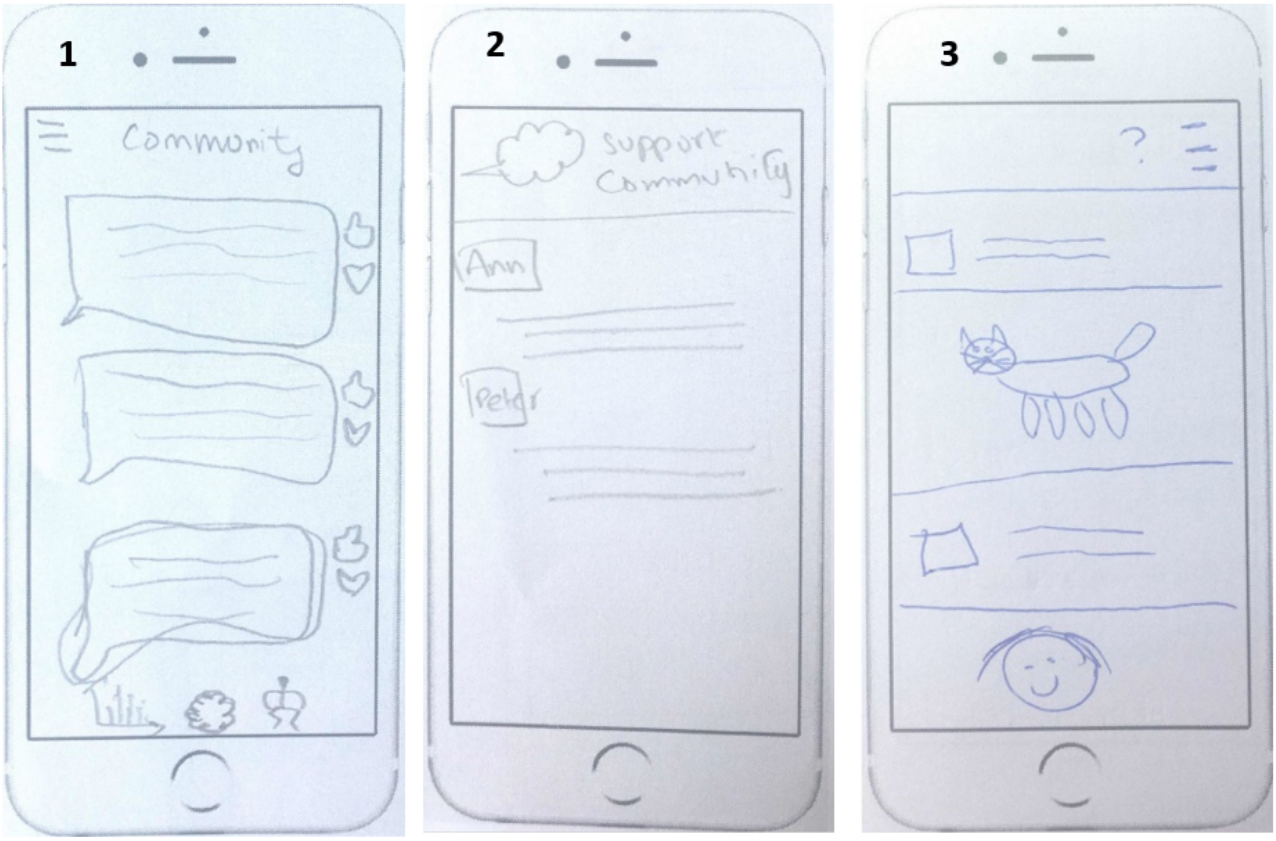
The social community could have different groups created based on mental health or life issues. Users are able to follow any one of these groups by searching for issues they are facing or by answering an assessment questionnaire that directs users to the right group. Moreover, users could create a group for a specific issue and add people to it:

> *In chatting can have different groups and different topics or I can create a group for depression in the school and anyone is interested can get in.* [G2P4]
>
> *The app asks you questions such as what is your issue? and based on this assessment, it takes you to the group which has the same issues, then you can share your issues and do activates together.* [G5P3]

The social community could have one-on-one chatting to talk to a person who has the same issue. The idea is that users can send a request and, if the request is accepted, they can chat together.

The social community could also offer voice calling; however, it should be anonymous. It could also allow users to reply to a comment and upload pictures in the chat room. Figure 7 shows 3 implementation ideas of social community features:

Figure 7. Three implementation ideas of a social support feature were generated by participants: (1) ability to reply to a comment, (2) ability to chat privately, and (3) ability to upload pictures in the chat room.



> *If user finds a person who has the same issue, he makes a match, if the person accepted, then they can do a voice call but it should be anonymous.* [G5P2]
>
> *Enter your issues and the app shows you the people who has the same issues and their solutions.* [G4P4]

Motivational Content

Participants expressed a desire for positive motivational quotes or statements that are updated regularly. They would also like positive news available in different formats (such as text, audio, and video) and religious inspirational quotes in the apps to make them feel better. They also reported that the app giving them rewards after any accomplishment would motivate them to keep using the app:

> *The introduction page has simple motivation statements such as you are the best, be confident. It should be updated every 6 hours or make it daily.* [G2P4]
>
> *Positive news is a good idea to have in the app which helps, and it can be in different format. Reading for people who like to read, video for people who like to watch and audio for people who like to listen.* [G2P1]

Providing Relaxation Exercises

Participants reported that the app could contain approaches for symptom relief, such as breathing exercises, yoga, recording thoughts, a forgiveness feature, and a regret feature. However, some people disagreed about the usefulness of a regret feature, as this could force them to remember unpleasant and depressive experiences and this would not make them feel better:

> *I want to record my thoughts. Sometimes when you have anxiety, you need someone to talk to, so recording something make you feel like you have spoken to someone.* [G6P7]
>
> *I would like to add forgive feature to forgive people who hurt us, and we can do it monthly.* [G6P4]

Including a Google Map Function to Find Clinics Near Users

Participants emphasized the idea of having Google map functionality that shows available therapists and communities for mental health support near the users. In addition, participants wanted a map that shows organizations in need so they could volunteer and improve their feelings by helping others:

> *It can have something like Google map to show the therapists that are near to me. It can pop up and users can select and contact.* [G2P4]
>
> *If the app tells me to help this charity or community by showing them in the Google map.* [G6P3]

Including Simple Games

Participants reported that the content of the app should be fun and interactive; thus, they included games in their design:

> *There are four icons in home page as main categories including an icon for a game.* [G1P2]

Providing Relaxation Audio

Participants highly valued the idea of having relaxation audio such as music, natural sounds, and worship and religious audio clips:

> *The first thing I want is sound or music just to help me calm down.* [G6P7]
>
> *For me personally, I like to hear worship sounds.* [G6P5]

Providing Personal Assistance in the App to Help Users

Some participants reported that using advanced artificial intelligence (AI) technologies in mental health apps could help to improve their mental health issues by providing individualized emotional support, assessment, and advice based on their recorded data:

> *You can click on and talk to your phone and tell it that something happened or that you feel bad. This could be simple or complex information and the app can understand you and give you a quick solution on what to do or suggest that you talk to your friend.* [G4P6]
>
> *Having a voice in the app talk to me and ask question. It is kind of robotic.* [G6P5]
>
> *It could be AI that responds to me and if the situation is serious it could tell me to contact a therapist.* [G5P4]

Goal-Setting Feature

Participants would like to set up their health-related goals. The app could show them how many days they have left to complete their goal, which can motivate them to finish their task and reduce their stress:

> *Goal setting shows how many days left to achieving the goal.* [G2P3]

Privacy Feature

Participants were highly valued when the app requested permission to access the personal data on their phone. Some would like to have a clear privacy policy that shows how their data will be protected:

> *There should be privacy agreement that there is no sharing of users' information.* [G1P1]

Discussion

This study aims to explore the perspectives, preferences, opinions, and needs of those who have experienced mental health issues such as stress, general depression, anxiety, panic attacks, and low mood. Given the well-documented difficulties engaging people in promoting mental health, such perceptions are likely to be pivotal to develop a successful app for mental health interventions.

Our results highlight that people who have experienced mental health issues use existing strategies for dealing with mental health issues in their lives, and these strategies should be leveraged in designing a mental health app.

Participants' ideas were organized into 14 overarching themes showing what they want in a mental health app. Most of the desired characteristics, features, and design implementations emerged in all 6 of the group sessions.

Regarding app design, participants emphasized that essential characteristics for mental health apps are the app being simple, easy to use, and easy to navigate. These characteristics were unsurprising and consistent with those given in previous studies [20].

Moreover, allowing users to customize the app to suit their individual needs and preferences is an excellent way to improve user satisfaction, engage them, and, hence, reduce the currently high attrition rates associated with mental health apps [21,22]. Moreover, in other health domains, personalized health interventions have been found to be more effective than those employing a one-size-fits-all approach [23,24] and, in depressive and anxiety disorders, this is even more important [25,26]. Therefore, it is not surprising that the participants of this study, who have experienced mental health issues, would like to personalize mental health apps to suit their needs so that they can benefit from individualized solutions.

Participants with mental health issues usually look for someone to help them solve their issues without judging or stereotyping them. Therefore, including a social community and access to live support in the app reflects this approach to dealing with their issues in real life, as highlighted by the participants. This finding is similar to that of Alqahtani et al [20], who found that including social support and emergency contacts in a mental health app were appreciated by users. Therefore, sharing issues, advice, and one's solutions with people who have the same issue and the ability to contact professional support, family, or even friends are important for people who have experienced mental health issues. Unsurprisingly, because of the stigma associated with mental health issues, few participants suggested that contacting and talking to a stranger who has no possibility of knowing them is preferred, which would help reduce their issues.

Although participants reported a need for tracking features in mental health apps, their ideas varied. Some participants would like their emotions to be predicted based on the app auto-tracking their vital signs, such as heart rate, blood pressure, and breathing, or based on auto-tracking their phone use as they do not trust their ability to self-track. In contrast, others suggested that the app could have self-tracking to enable users to track their positive emotions, successful personal solutions, and personal notes, all of which can improve their awareness. It is worth mentioning that self-tracking is the most frequently implemented persuasive strategy in the available mental health apps [17].

The feedback theme is a combination of 3 features: notifications, suggestions, and reports. Notifications and reminders are highlighted as very important features to remind users to use the app. Apps without notifications or reminders can be easily forgotten. However, this feature should be customizable so that users can make it random or set up the frequency of reminders; they should also be able to disable it if they do not want reminders. Receiving suggestions based on a current feeling or

progress toward the user's goal is a valuable feature to help users manage their symptoms and motivate them to keep using the app. Moreover, the ability to share a summary of the report with their health provider will save them time and help them facilitate an accurate diagnosis.

Participants stated that they often like to motivate themselves by repeating a motivational sentence, following inspirational people on the internet, or stopping negative thoughts. Therefore, including motivational content, such as positive stories, news, and inspirational quotes in mental health apps will improve users' mental well-being. Moreover, they stated that rewarding themselves after hard work is a way to motivate themselves; therefore, including rewards in the app as a type of motivation is critical.

Playing mobile/video games is one of the strategies that some participants tend to use as a way of distracting themselves from current negative feelings and as a way of entertaining them. Therefore, including simple games in the app is important to entertain users and distract their attention from negative thoughts. In addition, including relaxation exercises and audio clips in the mental health app will bring participants some relief.

Participants have different ways of using mental health apps. Some people prefer to use them only when they are in a crisis: From their perspective, the app should have specific components that help them relax and calm down. Alternatively, others would like to use the app on a daily basis: they suggested a variety of ideas to motivate them to use the app daily, such as reminders and tracking. Textbox 1 shows the implementation ideas that emerged from the focus group study.

Textbox 1. Implementation ideas that emerged from the focus group study prioritize the list numbers for each category based on importance.

- Track personal data to improve mental health
  - Predicting emotions based on the auto tracking of their sleep, heart rate, breathing rate, and phone use data
  - Auto tracking of users' sleep time, heart rate, time spent on the phone, and in-app achievements
  - Tracking of mood and other factors that can contribute to mental health issues
  - Tracking of user's notes and successful personal solutions
  - Tracking users' alcohol consumption rate
- Provide access to a social community group
  - Having different groups created based on mental health or life issues
  - The ability to create a group for specific issues and inviting people
  - The ability to follow any one of these groups by searching for issues users are facing
  - Ensuring and maintaining users' anonymity while communicating in the social community
  - Providing an assessment questionnaire to direct users to the right group
  - Including one-on-one chatting in-app via sending a request and users chatting together in case of acceptance of the request
  - The ability to post a picture in a group
  - The ability to make a video/voice call
  - Adding some basic rules to the community, such as respect and prohibit threats or bullying
  - Adding a block option to block undesirable contacts
- Provide motivational content
  - Including positive news available in different formats, such as text, audio, and video
  - Including positive motivational quotes or statements that are updated regularly
  - Providing religious inspirational quotes and inspirational stories
  - Providing rewards after any accomplishment to motivate users to keep using the app
- Personalize the app's styles and functions
  - The ability to customize reminders, background, color, and music
  - Providing a short assessment before using the app to personalize the app's content based on users' answers
  - A personal app greeting (greeting users by name)
  - Providing users with solutions based on selected feelings or issues
  - Providing music and/or religious phrases based on what users are currently feeling
  - The ability to add personal strategies in their profile so the app can make personalized suggestions when they experience a crisis
- Provide reminders and notifications
  - Sending periodic notifications to check on users, either randomly or at user-defined times
  - Reminding users to track their mood and activities
  - Notifying users about their feelings based on their tracked personal data
  - Reminding users of positive things in general and good things happening in their lives as a way of redirecting their attention from the negatives
  - Notifying users if they have made progress toward overcoming their mental health issues by showing motivational messages
- Provide suggestions for users
  - Providing suggestions on what to do, such as positive articles, health advice, strategies to overcome the mental health issue, personal strategies that were previously recorded to make users feel better, or advice for users to contact a doctor, based on their feelings or auto-sensed data related to their current circumstance
- Allow ability to generate a report
  - Providing a summary report of their data and/or progress that can be shared with their therapist

- Include games to distract and entertain them
  - Including a simple game (such as a puzzle or a focus on positive words) in the mental health app for distracting users' attention from their current (negative) mood and entertaining them
  - Including simulative games such as memory cards, web-based games with other participants
- Provide goal setting
  - The ability to set up health-related goals and show users how many days they have to complete their goal
- Provide relaxation exercises and audio clips
  - Providing relaxation exercises such as breathing, meditation, gratitude, recording thoughts, CBT, forgiveness, and yoga exercises
  - Including relaxation audio such as music, natural sounds, worship, and religious audio clips
- Provide a doctor or therapist, family, and friends as contacts for external support
  - Providing a suicide crisis hotline
  - Allowing users to provide contact details for friends and family to contact for support when necessary
  - Allowing users to contact a doctor or therapist in their area
  - Providing Google Map functionality that shows available therapists and communities for mental health support near users
  - Providing live therapists and coaches who can respond to their concerns
  - Providing users with a way to contact a stranger through the app
- Include personal assistance in the app
  - Providing individualized emotional support, assessment, and advice based on their recorded data using artificial intelligent
- Improve the privacy and security of the app
  - Asking permission to access the user's photos, contacts, and so on
  - Including a clear privacy policy that shows how their data will be protected
  - Offering a lock feature in the mental health app to protect users' collected data and information
  - Offering an option for an individual mode, as opposed to web-based community mode, where they can make personal notes and express their feelings within the app privately
  - Providing users with the option to use the app without creating an account
- General design preferences
- Usability
- Making the app easy to use and easy to navigate
- Including instructions on how to use the app

Making the home screen organized to simplify it

Content

- Providing a variety of activities
- Updating the app's content regularly
- Providing credible information
- Creating app content that shifts users' attention away from their current issues

Basic design

- Making the color scheme of the app bright and calm
- Making the purpose of the app clear
- Including profile and favorite lists
- Making account creation optional or offering a choice to sign up with Facebook or Google account
- Making the app's name simple and not including any mental health issue in the name

Design Recommendations

On the basis of our findings, we offer concrete app design recommendations to improve users' adherence to, engagement with, and ability to benefit from mental health and well-being apps:

1. Developers should formally evaluate their app to ensure that the app is usable. It is also critical that only credible information is presented within the app. These factors are very important for improving users' trust and engagement and reducing attrition rates.
2. Developers should allow users to adapt some app features and functions, such as including a coping strategy that works for them; customizing reminders and notifications; and adapting the font size, font color, background, and layout to suit their preferences. Moreover, they should also be able to personalize the app based on their personal collected data via initial questions and data tracking. This will enhance the overall usability of the app and ensure a personalized experience for each user.
3. The app should provide a form of social support with anonymous communication. In addition, access to professional and personal live support should be provided in case of depression or suicidal feelings.
4. The app should provide motivational articles, news, and quotes to improve mental health and well-being. Tracking and feedback features should be provided in mental health apps. The tracking implementation should match the purpose of the app, specifically whether it should predict emotions based on auto-sensed data or by using self-tracking to improve the user's awareness through self-reflection while encouraging users to add more details about the causes of their emotions.

Limitations

The limitation of this study is that most participants in this study were educated people, meaning their responses may not be generalizable to less educated people.

Future Work

Tracking users' data was the most common feature across users' design sketches. Nowadays, predicting and tracking mental health (eg, anxiety) is possible using wearable electroencephalogram (EEG) devices. Therefore, an interesting area for future work would be to explore the possibility of a wearable EEG that accompanies an app for discovering mental health issues that can be recognized or predicted easily and what type of matrixes can be extracted from raw data to describe mental health issues.

Conclusions

This research is part of a project that aims to develop and evaluate the effectiveness of a mental health mobile app for promoting mental health. Findings from this study generated insight into people's perspectives, opinions, and preferences regarding the use of mobile apps to support mental health and how such apps should be designed.

Through a 3-phase study with 32 participants, which involved the phases of exploring users' experiences with mental health issues; understanding participants' perspectives, opinions, and preferences in relation to 2 selected mental health apps; and a co-designing session, we identified 14 unique feature ideas and generated 32 participant design sketches of an ideal mental health app. Our findings revealed that participants used strategies to deal with their mental health issues: (1) doing something to distract themselves from their current negative mood, (2) using relaxation exercises and methods to relieve symptoms, (3) interacting with others to share their issues, (4) looking for an external source to solve their problems, and (5) motivating themselves by repeating motivational sentences to support themselves or by following inspirational people. Moreover, regarding the design of the mental health app, participants identified the following: (1) usability of the app; (2) *personalization of the app, including* (3) *tracking and feedback,* (4) *live support, and* (5) *social community; and providing (6) motivational content* and (7) relaxation exercises are the most important features users want in a mental health app. In contrast, *(8) games, (9) relaxation audio, (10) the Google map function, (11) personal assistance to provide suggestions, (12) goal setting,* and (13) *privacy preservation* were surprisingly the least requested features. Understanding end users' needs and concerns about mental health apps will inform the future design and development of mental health apps that are usable, useful, accepted, and successfully used by the target audience to promote mental health and emotional well-being.

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Authors' Contributions

FA (the first author) designed and conducted the study and wrote the manuscript. FA and AW analyzed the data. RO reviewed and supervised the study.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Final Themes of each Phase (1, 2, and 3).
[DOCX File , 3199 KB - formative_v5i2e18172_app1.docx]

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Abbreviations

AI: artificial intelligence
CBT: cognitive behavioral therapy
EEG: electroencephalogram
HCI: human-computer interaction
SITB: self-injurious thoughts and behavior
TEC: Therapeutic Evaluative Conditioning
UCD: user-centered design

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Original Paper

Perspectives From Underserved African Americans and Their Health Care Providers on the Development of a Diabetes Self-Management Smartphone App: Qualitative Exploratory Study

Tai Barber-Gumbs[1], BA; Ylva Trolle Lagerros[2,3], MD, PhD; Laura M Sena[4], RD, MSPH; Joel Gittelsohn[4], PhD; Larry W Chang[5], MD; Wayne W Zachary[6*], PhD; Pamela J Surkan[7*], ScD, PhD

[1]Program in Public Health, Johns Hopkins University, Baltimore, MD, United States

[2]Department of Medicine, Karolinska Institutet, Stockholm, Sweden

[3]Center for Obesity, Academic Specialist Center, Stockholm Health Services, Stockholm, Sweden

[4]Department of International Health, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, United States

[5]Department of Medicine, Johns Hopkins University School of Medicine, Baltimore, MD, United States

[6]Starship Health Technologies, LLC, Fort Washington, PA, United States

[7]Social and Behavioral Interventions Program, Department of International Health, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, United States

[*]these authors contributed equally

Corresponding Author:
Pamela J Surkan, ScD, PhD
Social and Behavioral Interventions Program
Department of International Health
Johns Hopkins Bloomberg School of Public Health
615 North Wolfe St
Room E5523
Baltimore, MD, 21205-2179
United States
Phone: 1 410 502 7396
Email: psurkan@jhu.edu

Abstract

Background: Type 2 diabetes mellitus (T2DM) affects approximately 10% of the US population, disproportionately afflicting African Americans. Smartphone apps have emerged as promising tools to improve diabetes self-management, yet little is known about the use of this approach in low-income minority communities.

Objective: The goal of the study was to explore which features of an app were prioritized for people with T2DM in a low-income African American community.

Methods: Between February 2016 and May 2018, we conducted formative qualitative research with 78 participants to explore how a smartphone app could be used to improve diabetes self-management. Information was gathered on desired features, and app mock-ups were presented to receive comments and suggestions of improvements from smartphone users with prediabetes and T2DM, their friends and family members, and health care providers; data were collected from six interactive forums, one focus group, and 15 in-depth interviews. We carried out thematic data analysis using an inductive approach.

Results: All three types of participants reported that difficulty with accessing health care was a main problem and suggested that an app could help address this. Participants also indicated that an app could provide information for diabetes education and self-management. Other suggestions included that the app should allow people with T2DM to log and track diabetes care–related behaviors and receive feedback on their progress in a way that would increase engagement in self-management among persons with T2DM.

Conclusions: We identified educational and tracking smartphone features that can guide development of diabetes self-management apps for a low-income African American population. Considering those features in combination gives rise to opportunities for more advanced support, such as determining self-management recommendations based on data in users' logs.

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KEYWORDS

diabetes; mHealth; type 2 diabetes mellitus; diabetes self-management; mobile app; mobile phone

Introduction

As of 2020, an estimated 34.2 million people (10.5%) had diabetes and it was the seventh leading cause of death in the United States [1]. Non-Hispanic African Americans have a notably higher diabetes prevalence (11.7%) compared to non-Hispanic White people (7.5%) [1]. To avoid complications, living with diabetes involves constant self-management, including exercise, healthy eating, glucose monitoring, and adherence to medications [2]. However, low-income African Americans and other minority populations face structural barriers to self-management, such as transportation-related issues, poor health literacy, and limited access to health services [3,4]. A study of almost exclusively Black and Hispanic participants suggested that individuals living with chronic conditions like type 2 diabetes mellitus (T2DM) have been turning toward technology to help with diet, exercise, and weight loss [5].

Research on the use of mobile health (mHealth) strategies to support individuals with chronic diseases, such as T2DM, has shown promising results, particularly with respect to positive lifestyle changes and self-efficacy [6]. Common features of current diabetes apps include encouraging self-management activities via reminders; collecting, storing, and displaying behavioral data on the user's physical activity, nutritional intake, and medication adherence; offering educational information on diet, nutrition, and lifestyle; and, to a lesser degree, enabling social media connections to other app users. A few make behavioral data available to health care providers, though generally not via the electronic health record [7-12]. Although the effects were small (ie, around a 0.5% change in glycated hemoglobin [HbA_{1c}]), a meta-analysis of controlled trials of diabetes apps found that a range of apps significantly reduced HbA_{1c}, an indicator of average blood glucose level over time [13].

Minority communities have had limited involvement in the development of mHealth interventions or in the comparative assessment of mHealth apps and their relevance to those communities [5]. Diabetes education that is culturally tailored to African Americans with T2DM can enhance self-management of the condition [14]. However, most diabetes apps on the market are not evidence based [11,15] and likely do not reflect the needs of ethnic, minority populations such as African Americans.

A diabetes app, developed in collaboration with an underserved African American community, could serve as a culturally sensitive and cost-effective tool for diabetes self-management. Thus, we aimed to understand from this community what diabetes app features are perceived to benefit people with T2DM or pre-T2DM for diabetes self-management.

Methods

Overview

Between February 2016 and May 2018, we conducted exploratory qualitative research to inform the development of a diabetes management mHealth app, the Diabetes Networking Tool (DNT). Given the wealth of data on social support and its uses in an app, this paper is a companion to a recent separate publication related to desired social support mechanisms in an app [16].

Setting

The study took place in Southwest Baltimore, a low-income neighborhood where almost three-fourths of residents were African American [17]. In 2017, the median household income of the neighborhood was only slightly over half (ie, US $24,946) that of Baltimore City overall (ie, US $41,819). In 2017, the age-adjusted mortality rate for diabetes was 4.4 deaths per 10,000 in Southwest Baltimore, which can be compared to Baltimore City's average rate of 3.0 deaths per 10,000 [17].

Recruitment

Participants were initially recruited at residential buildings, a farmer's market, and a supermarket. Subsequent recruitment was done through snowball sampling. We used stratified, purposive sampling to achieve a distribution by gender and disease status (ie, prediabetes and T2DM versus close friends and family). Providers were recruited from health care facilities in the study area or we recruited those serving similar low-income populations. Nonproviders were incentivized with gift cards of US $40 or US $50, depending on the data collection activity.

The Johns Hopkins Bloomberg School of Public Health Institutional Review Board approved data collection. All participants provided oral informed consent, which included consent that deidentified data might be shared for research purposes.

Study Sample

A total of 78 people participated in this study. Inclusion criteria for nonproviders were being English-speaking adults who self-identified as having either prediabetes or T2DM or being a friend or family member of someone with prediabetes or T2DM, residence in the study community, and owning a smartphone. We included health care providers who served predominantly low-income African Americans with prediabetes or T2DM. Out of the 78 participants, 28 (36%) self-identified as having prediabetes or T2DM, 30 (38%) self-identified as being a friend or family member of someone with T2DM, and 20 (26%) were health care providers (eg, diabetes educators, pharmacists, nurses, and physicians). Upon sign-in at the data collection activities, participants with T2DM and family or friends of persons with T2DM were asked to self-report their

race, whether they identified as Hispanic or not, and whether others in their families had T2DM.

Data Collection

Data were collected in three phases. In Phase I, we held a series of 2- to 3-hour-long in-person interactive forums and interviews with people with T2DM and family or friends, one focus group, and multiple interviews with health care providers. The interactive forums and the focus group discussions were facilitated by public health graduate students, an anthropologist, or a public health faculty member who taught or was trained in qualitative research methods. Forums generally were larger than focus groups and used more interactive aides to guide the discussion, though the topics covered in the guide were very similar. Facilitators used semistructured interview guides and engaged participants in the creative process by asking them to make suggestions, offer ideas, and build on suggestions of other participants. Forums were audio-recorded and transcribed verbatim for analysis. Guides for the semistructured interviews also covered similar content, with the main difference being that they were longer and included more probes. Interviews were mainly carried out when it was logistically difficult to schedule a group session.

From Phase I, we analyzed participants' opinions on design concepts for a smartphone app [18]. In Phase II, we explored reactions of community members and providers to those design concepts through one community forum with people with prediabetes or T2DM and family or friends, as well as through interviews with providers, due to difficulties in organizing providers into groups. Using Phase II inputs, a revised design and prototype were created. Figures 1-3 provide prototype screen examples. Phase III data collection involved two forums that covered community members' perceived usefulness, usability, and learnability of the prototype, supplemented by interviews with 4 participants with T2DM.

Figure 1. Main navigation panel within the app.

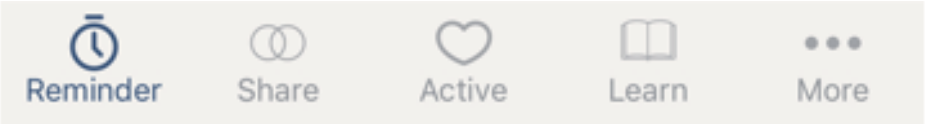


Figure 2. Initial detail screen when "Reminder" is selected from the navigation panel of the app.

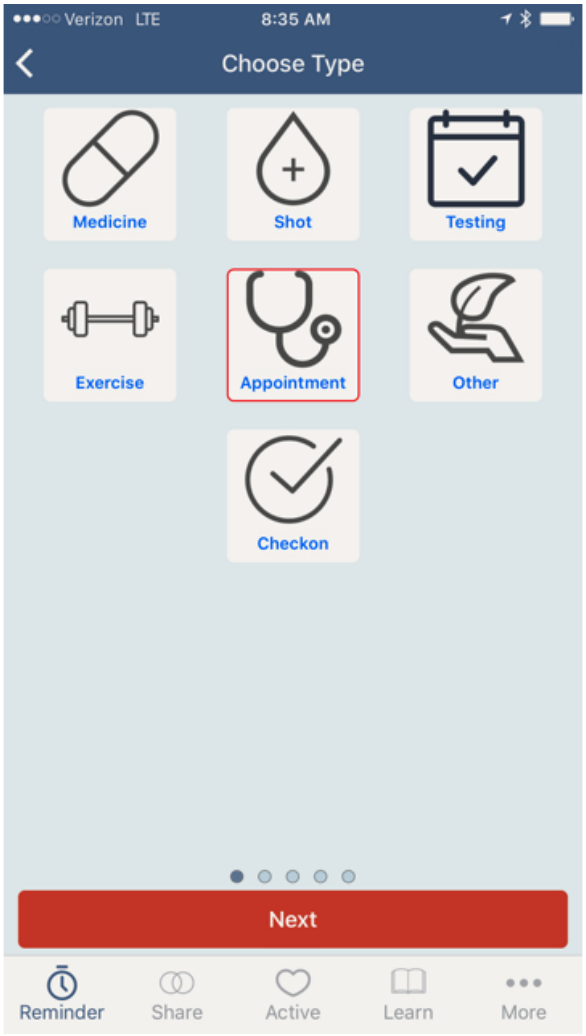
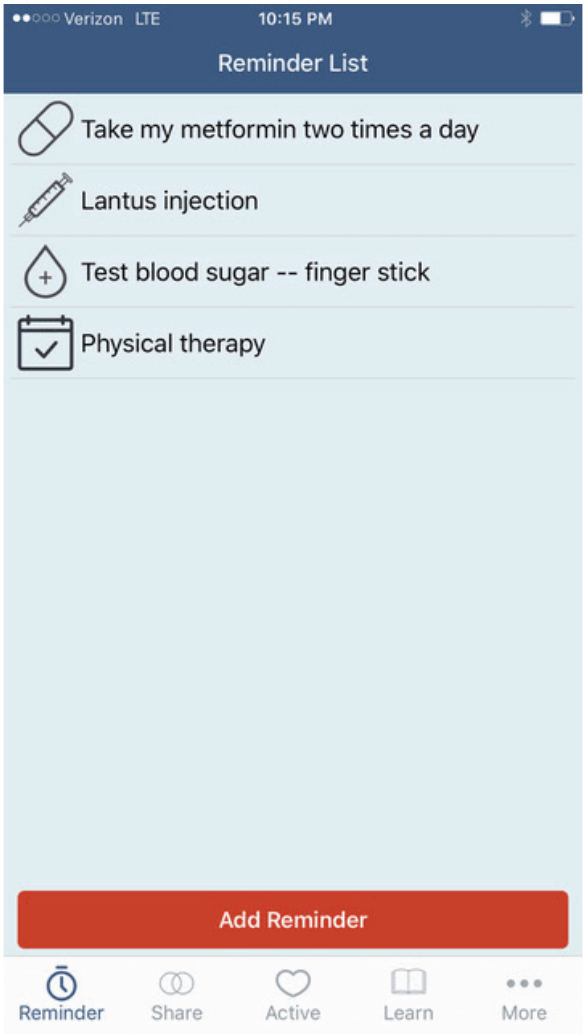


Figure 3. Initial screen when in the process of setting a new reminder in the app.



App Prototype

The results from the Phase I and Phase II data analyses were used to develop design concepts. Afterwards, a preliminary prototype of an app was developed. We presented static mock-ups of specific screens in this hypothetical app to community members in Phase II to receive comments, learn of perceived problems, and get suggestions to improve the design.

Revised designs were then animated to simulate dynamic sequences of app use. We presented this final interactive prototype app to users in Phase III for qualitative discussion and performed a quantitative assessment using the widely used System Usability Scale (SUS) [19,20]. This instrument uses a 10-item Likert scale to measure perceived usability and perceived learnability of a software interface.

Qualitative Data Analysis

Based on the community-generated ideas, we carried out thematic data analysis using an inductive approach to explore ideas about app use in diabetes self-management [21]. An inductive approach entails seeking patterns in the data without using a predetermined theory. Steps in our thematic analysis included the following: (1) reading and rereading transcripts to become familiar with that data, (2) generating initial codes, (3) looking for themes among codes, (4) reviewing these themes, and (5) defining and naming them [21]. Two researchers coded the data (LS and PS). Initial coding was done with the aid of the qualitative software ATLAS-ti, version 7 (Scientific Software Development GmbH), followed sequentially with additional code refinement by another author to further capture the richness of the data (TBG). Memos were used throughout the analysis to facilitate theme development [22]. Data collection and transcription occurred concurrently, and transcripts were reviewed to elicit themes using the constant comparative method [23].

Results

Overview

Table 1 displays participants' demographic characteristics by type and data collection event. Community participants were adults who were evenly split between those diagnosed with T2DM or prediabetes (28/57, 49%) and family or friends (30/57, 53%). The majority of community participants (37/58, 64%) and of all participants (47/78, 60%) were female. A total of 4 people participated in forums across two different phases. No participants self-identified as Hispanic. Table 1 shows the number of unique individuals who participated as persons with prediabetes or T2DM or as family or friends.

Table 1. Participant characteristics and data collection events.

Characteristic	Prediabetes or T2DM[a] and friend or family participants (n=58), n (%)				Provider participants (n=20), n (%)				Total participants (N=78)
	Initial forums (four)	Preusability forums (two)	In-depth interviews	Subtotal	Initial FGD[b] (one)	In-depth interviews	Paired interview (one)	Subtotal	
Total by event	41 (71)	13 (22)	4 (7)	58 (100)	9 (45)	9 (45)	2 (10)	20 (100)	78 (100)
Gender: male	15 (26)	5 (9)	1 (2)	21 (36)	5 (25)	4 (20)	1 (5)	10 (50)	31 (40)
Race: African American	40 (69)	13 (22)	4 (7)	57 (98)	5 (25)	4 (20)	1 (5)	10 (50)	31 (40)
T2DM status: prediabetes or T2DM[c]	15 (26)	10 (18)	3 (5)	28 (49)	N/A[d]	N/A	N/A	N/A	N/A

[a]T2DM: type 2 diabetes mellitus.

[b]FGD: focus group discussion.

[c]One person in the forums did not indicate their T2DM or prediabetes status and was not counted here as having T2DM or prediabetes (n=57).

[d]N/A: not applicable; T2DM status was not applicable to providers.

We identified three main themes that identify desired goals that a smartphone app could help achieve, including help in (1) getting access to health resources, (2) delivering patient education about T2DM, and (3) supporting the diabetes self-management process.

Finding and Accessing Health Resources

All three types of participants reported that accessing care, medication, and testing resources were major barriers to self-managing diabetes. A provider explained the following:

> *They're [people with diabetes] eligible mostly for Medicaid, but for whatever reason they don't have insurance and they don't have funds for their medication. We have a couple of clients who have used the ER [emergency department] for getting their medication...We also see a lot of times people are running into challenges with getting supplies they need—like the glucose monitor, the lancets, the strips.*

Several participants described how an app could make it easier to find free or discounted medication and medical supplies. For example, an individual with T2DM suggested the following:

> *You could talk to the app like, "Hey I lost my medicine, I don't have the insurance to pay for it. Is there some place I can go to get a free meter, a place for free testing strips, a pharmacy that may give out free insulins or medications?"*

An app could also function as an alternative to computers. A patient explained how in the following quote:

> *People [in the study community] don't have access to the computer where they can actually go online and find [the discounts] and then end up waiting until the last minute or say, "Well, I can skip this," and you can't skip a dose. I tried it, believe me. I have been diabetic for over 20 years, and it's in my family. I've seen in my family a lot of missing toes.*

An app could inform people with T2DM and/or their family or friend caregivers about affordable resources, such as free or low-cost medications, testing supplies, and/or healthy foods. Participants agreed that the community does provide resources, but that people with T2DM are not aware that they are available. One provider explained, "It is a city, so the resources are there...it's just being aware of the resources." A patient stated, "If I don't know what's going on, nine times out of ten, I am not going to come out [to access resources] if I don't know."

Some participants expressed how an app could help people with T2DM find free resources to help with self-management. Others thought user posts on social media could help address such resource-finding problems. For instance, "If I wanted to post something, what would it be? I'd post locations for farmer's markets, community gardens." One provider suggested the following:

> *We tell our patients to go to—it's called Baltimore Free Farm on Arch Street—and every Wednesday they literally give away food and there's so many people when they come to their appointment and they say, "I don't have money to eat anything let alone something healthy." So, I think if a careful search is done of those resources and that's included on the app, that would be tremendous.*

Need for More Information About Diabetes

Participants agreed that more information was desired about prediabetes and T2DM self-management and that an app could provide accurate T2DM information in lay terms. T2DM participants expressed how lack of knowledge discouraged them from seeking medical care:

> *I really don't know nothing about diabetes. So, I be like hesitant to go back to the doctor, because I don't want to start taking stuff that I don't know nothing about.*

Some participants with T2DM discussed a need for an app to help fill the information gap:

> *I think if it could be kinda like Siri, if you can talk to it and ask it questions, then that would probably be good too...if you could ask the app questions like*

> *"What happens if I don't take my insulin for two days?"*

Nonetheless, because of concerns about false information being spread on an app platform, participants suggested this information could be based on reliable sources (eg, the State Department of Health and Mental Hygiene).

Active Support for Diabetes Self-Management Tasks and Activities

Overview

The third area in which participants suggested an app could help was in self-management itself, by structuring and automating some repeated care tasks in T2DM (eg, taking medications and tracking blood glucose). Suggestions from all three types of participants fell into two interrelated areas: (1) app support for recording and tracking behaviors and testing data relevant to T2DM self-management and (2) a higher level of structure for self-management, to make it easier to adhere to and keep motivated.

Logging and Tracking Information

Participants expressed that if people with T2DM could track their progress and receive encouragement, then they would be likely to follow through with diabetes self-care plans. Some participants suggested that tracking could allow people to input their diabetes care information, such as HbA_{1c} levels, and to set reminders for care activities, such as when to exercise. A person with T2DM explained as follows:

> *That's how we know who's cheating, and who's not checking their sugars and things like that; in keeping a record, you can see when I did my last finger stick, so I know what it was.*

Likewise, several providers expressed frustration about how patients forget their glucose monitors, yet they noted how most people with T2DM bring their phones to the doctor's office. Providers suggested that if patients registered health data on their phones, it would be easier to track what they were doing. A provider explained as follows:

> *In my last job...they would bring their glucose monitor and it would just link to our computer and we would be able to download all of their data and it would give us a graph and we would be able to see trends and patterns and whether they are truly checking or not...I would like that information* [on an app]

By tracking self-management behaviors, people with T2DM could be held accountable to their health care providers. Friends and family members were also interested in having access to health information stored on an app so that additional support could be given. A friend or family member of a person with T2DM described this view as follows:

> *[The person with diabetes] can share it with me. It's another way you can help them, so when you go to the doctor and you have three months [of tracking], and they are able to send this through the app to the doctor's office and they see this, then they can know what to do to change your regimen.*

In addition to monitoring progress, participants wanted an app that could remind people with T2DM to stay on track with their diabetes care plan. A participant with T2DM explained as follows: "Just something to keep the diabetes in the front of the brain instead of the back of the brain." Moreover, an app that has a reminder function could help people with T2DM remember their appointments or to refill medications. A provider pointed out the following: "We have a really high no-show rate here in West Baltimore, so a reminder for appointments is good."

Encourage Engagement With Self-Management

For persons with T2DM, self-management is a process that requires constant attention. Difficulties with diabetes self-management often lead to psychological distress and decreased adherence [24,25]. Participants suggested that, for the sake of further encouraging people with T2DM to stick with their care plans, an app should incorporate a goal-setting mechanism based on feedback and reward. By setting diabetes-related goals, a friend or family member explained that someone with T2DM could more easily achieve them:

> *The most important things would be to set a goal for them at the beginning—maybe weight loss, maybe HbA_{1c}—so they can follow it and figure out how to get to that goal.*

Then, by providing feedback on those goals via an app, patients would know the steps needed to stay on track with their health management plan. Finally, by setting goals and tracking one's progress toward them, enabled by the data recording and tracking function, an app could help evaluate progress, ideally in conjunction with a health care provider, and give feedback. A provider recommended the following:

> *The app should be able to analyze the data that the patient is putting in there and give them some feedback. "Oh, gee...your blood sugar has been in goal for the last five days—congratulations!"*

This goal-setting, tracking, and feedback structure would enable positive feedback to encourage a person with T2DM to persist with a self-management plan and pinpoint specific problems to work on. Participants suggested that an app could provide, in addition to praise and focused constructive feedback, tangible diabetes-related rewards for people who are doing well. A provider proposed the following:

> *Maybe if they lose five pounds, they can get a discount on their gym membership for a month, or if they keep their blood sugar in control for two weeks, then maybe they get a week's supply of fresh vegetables from the farmers' market...Really, the ultimate reward is going to be that they preserve their health.*

Translation to App Design

Our qualitative data analysis then led to the design of a preliminary prototype app with the following user functions: (1) setting reminders to engage in self-management behaviors (Reminder), (2) sharing information with other users of the app (Share), (3) finding other persons to engage in physical activities as part of T2DM self-management (Active), and (4) learning more about T2DM and related areas (Learn). The navigation

design for the app was realized as a navigation panel of four glyphs at the bottom of the screen that corresponded to these four functions, as shown in Figure 1. The navigation panel also included a *More* glyph that could be used to navigate to a group of settings, as shown in Figure 1. Details on the process of functional and navigation design can be found in Zachary et al [18].

The *Reminder* and *Active* functions correspond directly to one of three themes discussed above, specifically "supporting the diabetes self-management process through the app." The *Reminder* function allows users to create reminders for the self-management activities, while the *Active* function connects users to a local social network of other app users in order to find others to participate, some with whom the user could plan regular physical activity. The *Learn* function was based on the theme of "delivering patient education about T2DM." It takes the user to lists of curated information from health experts, organized into categories of information needs that repeatedly arose in the forums (eg, information on diabetes, nutrition, exercise, and medications). The *Share* function provides functionality for sharing information with other local app users. One key purpose of this function is to share information on access to local health resources and opportunities, thus addressing the theme of "getting access to health resources."

A more detailed example of one function (ie, *Reminder*) begins in Figure 2. It shows the initial page of the interaction once *Reminder* is selected; the user's list of current reminders is shown, as is an option to create a new one. The user can tap an existing reminder to view or change it, or they can tap *Add Reminder* at the bottom of the screen. This takes the user to a palate of glyphs representing different self-management activities, as shown in Figure 3. From there, the user can select the type of reminder and begin the process of setting the details of that reminder.

App Usability Assessments

We collected data on the prototype app's perceived usability through two preusability forums (see Table 1). In each forum, participants were introduced to the DNT concept and exposed to the DNT prototype app via an interactive walk-through of the app. A facilitated discussion followed, which covered the prototype, its perceived match to its purpose, its usability and perceived strengths, its weaknesses, and possible improvements. SUS data were analyzed numerically using algorithms defined by Sauro [20]. Out of 13 participants, 12 (92%) completed surveys were returned, and 2 surveys were discarded because the instructions were not followed. The mean SUS score of the usable surveys was 85.5 (SD 22.5), placing the DNT app above the 90th percentile of all systems assessed with the SUS. While this score was very high, the sample (n=10) was small (ie, N≥12 is recommended for SUS analysis) [26] and the variability was high (SD 22.5). Also, participants did not directly interact with the app but observed its use on the user's phone. Because the participants did not physically interact with the app, we use the term *preusability forum*, rather than usability forum. The high mean score suggests that app functionality and interface design were consistent with the needs identified.

Discussion

Principal Findings

In soliciting perspectives in a high-risk community from people with prediabetes and T2DM, as well as from formal and informal caregivers, we found that an app was desired that could (1) address some problems with access to health resources, (2) provide patient education on diabetes and risk factors, and (3) actively support self-management through tracking and encourage long-term adherence to self-care plans.

While some diabetes apps link patients to health resources and providers [27,28], recent comparative reviews did not include addressing financial barriers to diabetes self-management as a comparison criterion [7-11,29]. Moreover, while many apps focus on tracking of self-management adherence, the comparative review articles also did not cover comparisons of features intended to improve long-term user engagement with the app that would be required for effective long-term tracking. These absences suggest that such features were generally lacking.

Low-income families experiencing stress are less likely to be confident of receiving health care and less likely to receive it regardless of insurance coverage [30]. The problem of limited access to health care for low-income families is substantial in the United States. This could be attributable to the complexity of insurance coverage and the need for out-of-pocket funds to meet co-pays [31,32]. This complexity may explain an inconsistency in our data. The data suggested that participants could perceive health services as being available (eg, reporting having insurance through the publicly funded Medicare and/or Medicaid programs), while also reporting not having access to medications. Medicaid, which insures eligible low-income persons, and Medicare, which insures all persons over 65 and eligible disabled persons, have prescription drug components. However, those programs do not cover the full cost of many medications. Thus, they can levy substantial out-of-pocket costs for patients with chronic illness, such as T2DM patients, who require medications year-round [33,34].

A second inconsistency in our data is less easily explained. Participants reported having a smartphone but not being able to access websites with prescription discounts. It is possible that the participants did not know that they could access those websites from their phones or that their cell connections lacked the bandwidth to easily view those websites. Both would be interesting subjects for further research.

While not able to solve the more structural complex problems of lack of insurance and problems with access, our results suggest that an app with a function that would allow community members to post and share information about discounted or free medication and testing supplies in their area would be useful. Given the existence of primary care interventions where social workers check for social and welfare programs that could cover benefits that people with T2DM are not aware of [35,36], an app including this feature would fulfill this need at a lower cost.

This research points to another underexplored way that a diabetes app could benefit the community—by presenting

curated information about T2DM so that people recognize and understand how to manage symptoms. Low-income, racial and ethnic minority populations underestimate their chance of developing diseases, which is a risk factor for not seeking regular health care [37]. A US study with a 77% non-White sample found that knowledge gaps were pervasive, yet knowledge about diabetes risk was a motivating factor for better management [38]. This underscores the importance of finding ways to disseminate information about T2DM to these populations.

To our knowledge, research has not examined how effective the consumption of health information among people with diabetes who use mHealth apps has been for self-management; however, apps may be superior to other forms of communication (eg, computers and books) for their convenience, mobility, and timely access to information [39]. There has been rapid adoption of smartphone technology in the United States, even among older and poorer segments of the population [40]. Given this, by making information about chronic disease easily accessible, an app might enable people with T2DM to better navigate diabetes management.

This research indicates interest in app features that focus on maintaining the long-term engagement of people with T2DM in self-management. Although long-term engagement is the ultimate goal, Kitsiou et al concluded in their review that they could only comment on short-term diabetes app studies, due to the lack of studies with long-term follow-up [41].

Regarding participants' desires for logging and tracking features, two reviews of 181 and 143 diabetes management apps for a medication reminder feature showed that only 56% and 58% of apps had such a function, respectively [42,43], in spite of the fact that those that did had characteristics identified as likely to be effective [43]. Moreover, logging and tracking are typically applied only to a few aspects of self-management, with logging of nutritional intake and blood-glucose testing being more common, and logging of medication adherence being the least common [12]. This point is particularly relevant given challenges in self-management because of residents' low-income and minority status. Participants valued positive feedback and encouragement that could be enabled by data recording and tracking and automated data analysis, suggesting these two features may be helpful to support self-management. This may be particularly important, because participants often reported not having a consistent primary care provider over time and/or moving among several health systems, meaning that their electronic patient records would likely be incomplete and spread across many different computer systems. In such cases, the self-management log created by the user's app may be the only longitudinal data available to the provider for that patient.

One more enhancement suggested by participants was to get feedback from providers using tracked data [5]. An analysis of existing diabetes apps showed that improvements in HbA_{1c} levels, in conjunction with diabetes app use, were highly related to feedback from health care providers [13]. For example, dietary logs in combination with medication adherence, glucose testing, and physical activity logs could anticipate situations that might lead to degraded glucose management and alert the app user to take preventive actions.

Gamified smartphone apps fulfill a psychological need for satisfaction and feelings of accomplishment [44-46]. Health gamification can be applicable to an array of health conditions, including diabetes [46-48], and could directly extend from the engagement-enhancement features envisioned by our study participants. Gamification can lead to greater engagement and more persistent use. Positive feedback, driven by the app's analysis of recorded and tracked data, can trigger more gamified feedback, such as earning badges and/or setting up challenges with others. Such features can encourage people to persist in self-management by making it fun.

Strengths and Limitations

Multiple perspectives from different types of participants enabled triangulation of the findings. Another study strength was the participatory nature of data collection that incorporated voices of people traditionally overlooked in app development [5].

A study limitation was that most participants with prediabetes and T2DM were African American women, limiting the transferability of these findings. We lacked information on participant age and socioeconomic status, though our impression is that most participants with T2DM were in midlife or older and that they were low-income persons, as they all resided in a disadvantaged neighborhood. Furthermore, unless identifiable by the quote itself based on the audio recordings, we could not always distinguish participants with prediabetes and T2DM versus friends and family.

Finally, the interactive app prototype developed as part of this research did not, and could not, address all the functionality suggested because of the limited exploratory scope of the project. Specifically, it did not attempt to address more complex issues, such as gamification and longitudinal analysis of logged self-management data. Thus, while we identified community-driven ideas for diabetes self-management app features, the feasibility of implementing these features still needs further study.

Conclusions

In conclusion, despite the proliferation of diabetes mHealth apps [49], a dearth of information exists concerning the usage needs of these apps from African Americans with T2DM and the people who help them with disease management. Some needs uncovered in our study have been relatively uncommonly reported in the literature, such as lack of awareness of available social and welfare programs, of affordable health insurance, and of available, affordable, and local sources of healthy foods. Other needs identified correlate with those of T2DM patients in general (eg, support for self-management, encouragement, and engagement). App features should facilitate addressing these needs and consider incorporating, for example, tracking and gamification features. Future research may extend these findings and assess the feasibility of, and test apps with, these features.

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Conflicts of Interest

None declared.

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Abbreviations

DNT: Diabetes Networking Tool
ER: emergency department
HbA_{1c}: glycated hemoglobin
mHealth: mobile health
SUS: System Usability Scale
T2DM: type 2 diabetes mellitus

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Original Paper

Assessment of Patients' Ability to Review Electronic Health Record Information to Identify Potential Errors: Cross-sectional Web-Based Survey

Lisa Freise[1*], BSc, MSc; Ana Luisa Neves[1,2*], MSc, MD, PhD; Kelsey Flott[1], BA, MSc, PhD; Paul Harrison[3], BSc (Hons), MBA; John Kelly[3]; Ara Darzi[1], PC, KBE, FRS, FMedSci, HonFREng; Erik K Mayer[1], MBBS, BSc, MRCS, PhD, FRCS (Urol)

[1]Patient Safety Translational Research Centre, Institute of Global Health Innovation, Imperial College London, London, United Kingdom

[2]Center for Health Technology and Services Research / Department of Community Medicine, Health Information and Decision (CINTESIS/MEDCIDS), Faculty of Medicine, University of Porto, Porto, Portugal

[3]Imperial College Healthcare NHS Trust, London, United Kingdom

[*]these authors contributed equally

Corresponding Author:
Ana Luisa Neves, MSc, MD, PhD
Patient Safety Translational Research Centre
Institute of Global Health Innovation
Imperial College London
St Mary's Campus Queen
Elizabeth Queen Mother Wing
London, W2 1NY
United Kingdom
Phone: 44 (0)20 7589 5111
Email: ana.luisa.neves14@ic.ac.uk

Abstract

Background: Sharing personal health information positively impacts quality of care across several domains, and particularly, safety and patient-centeredness. Patients may identify and flag up inconsistencies in their electronic health records (EHRs), leading to improved information quality and patient safety. However, in order to identify potential errors, patients need to be able to understand the information contained in their EHRs.

Objective: The aim of this study was to assess patients' perceptions of their ability to understand the information contained in their EHRs and to analyze the main barriers to their understanding. Additionally, the main types of patient-reported errors were characterized.

Methods: A cross-sectional web-based survey was undertaken between March 2017 and September 2017. A total of 682 registered users of the Care Information Exchange, a patient portal, with at least one access during the time of the study were invited to complete the survey containing both structured (multiple choice) and unstructured (free text) questions. The survey contained questions on patients' perceived ability to understand their EHR information and therefore, to identify errors. Free-text questions allowed respondents to expand on the reasoning for their structured responses and provide more detail about their perceptions of EHRs and identifying errors within them. Qualitative data were systematically reviewed by 2 independent researchers using the framework analysis method in order to identify emerging themes.

Results: A total of 210 responses were obtained. The majority of the responses (123/210, 58.6%) reported understanding of the information. The main barriers identified were information-related (medical terminology and knowledge and interpretation of test results) and technology-related (user-friendliness of the portal, information display). Inconsistencies relating to incomplete and incorrect information were reported in 12.4% (26/210) of the responses.

Conclusions: While the majority of the responses affirmed the understanding of the information contained within the EHRs, both technology and information-based barriers persist. There is a potential to improve the system design to better support opportunities for patients to identify errors. This is with the aim of improving the accuracy, quality, and timeliness of the information held in the EHRs and a mechanism to further engage patients in their health care.

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KEYWORDS

patient portals; electronic health records; patient participation; medical errors; patient safety

Introduction

With advancing digitalization and focus on patient centricity, sharing of personal health information with patients has gained increasing importance and prevalence worldwide [1-3]. The UK Department of Health and Social Care [4] has emphasized the need for patients to have access to their records and enhanced control over them. Evidence suggests that sharing personal health information positively impacts quality of care across several domains such as safety and patient-centeredness [5-7].

A potential opportunity to improve patient safety can be realized when patients access and read their health records and identify, and even correct, errors within them [3]. Potential errors include incorrect or missing information concerning administrative details, diagnosis, or treatment, all of which diminish the accuracy, quality, and timeliness of the information held in the medical record, which affects care delivery.

Previous studies have explored the potential of sharing medical records with patients for error correction purposes. Ross and Lin's [3] review of patient access to medical records indicated that 11 studies reported a facilitation of error correction. However, the studies were based on paper records and the information in 4 studies was anecdotal while that in the other 7 was purely descriptive [3]. Considering electronic health records (EHRs), Bell et al evaluated the impact of an OpenNotes patient reporting tool focused on safety concerns and found that patients and health care partners reported safety concerns in about one-quarter of the reports included in the study, suggesting that a reporting tool could help engage patients as safety partners [8]. However, in order for patients to fully embrace the potential of using EHRs, and particularly to identify and correct potential discrepancies, EHR platforms must support technology acceptance and usability, thereby enhancing a positive user experience and sustained adoption. Previous studies have identified a range of barriers perceived by patients, including attitude and culture challenges [9-11], privacy concerns [12,13], cost concerns [14], poor digital literacy [15], and interface difficulties [11,16]. In a systematic review by Zhao et al (2017), technical or logistical difficulties with the enrollment process (eg, difficult navigation, lack of information technology support) prevented interested patients from completing registration in 15 studies exploring the use of patient portals [15].

Further investigation and understanding of the extent to which patients can identify errors in the EHR will realize current barriers as well as their impact on patients and the safety of their care. The relatively easier access to EHRs compared with paper records might better support patient-initiated correction of errors, although they will likely be presented with a greater granularity of medically related information, which could impact understanding. In addition, patients will need at least some information communication technology skills to navigate an EHR successfully.

Patients' ability to understand information presented in their EHRs is an essential component for error identification and subsequent correction. If patients cannot interpret information, any proposed advantages of EHR error identification for patient safety will be limited. This pilot study assessed patients' perceptions of their ability to understand the information contained in their EHRs and the main barriers to their understanding. Additionally, the main types of patient-reported errors were characterized.

Methods

Study Design and Setting

A cross-sectional study using electronic survey data collected patients' use of the Care Information Exchange (CIE). The CIE is a patient-controlled EHR portal in North-West London that allows data sharing between patients and their health care professionals [17]. It was initiated in 2014 at the Imperial College Healthcare National Health Service (NHS) Trust funded by the Imperial College Health Charity [17] and integrates data from sources across health care trusts and care settings. From an organizational perspective, a single patient account is created at the service/department that first registers a patient. However, data from all the departments relevant to each patient's care are integrated into 1 account. The enrolment of patients in the CIE is optional. Patient information contained in the CIE includes appointment details, test results, care plans, and information on medications. If a patient's practice has signed up, data such as allergies, medications, and diagnoses will also be visible to them. Clinic letters and discharge summaries can be shared as well. Patients may access their records whenever they wish to review information or when notified about new information such as test results being available. Opportunities and challenges of patient identification of errors within their EHRs were discussed with the National Institute for Health Research (NIHR) Imperial Patient Safety Translational Research Centre's Research Partners Group, a group of lay partners advising researchers on issues surrounding patient and public involvement and engagement.

Participants and Sampling

All CIE users accessing their records during the data collection period were invited to participate in this study. Upon logging in, a message signposting the survey was displayed on the CIE webpage to all users during the time of the study (n=682). Patients were asked to follow the link to complete a short survey, which they could complete at a convenient time.

Data Collection

The survey was open for completion between March 1, 2017 and September 30, 2017. The web-based survey was implemented using Qualtrics (web-based survey software). It contained both structured (multiple choice) and unstructured (free text) questions (Multimedia Appendix 1). Question topics

were selected based on information from the CIE standard operating protocol, which was developed from existing evidence about best practice and the necessary characteristics for EHR systems. Responses to the structured questions provided metrics of the patients' perceived ability to understand their EHR information (ie, "Did you find any information in your record difficult to understand today?") and identify errors (ie, "When using CIE today, did you notice any errors in your record?"). Responses to unstructured questions supplemented these metrics with qualitative data. Specifically, unstructured questions allowed respondents to expand on the reasoning for their structured responses and provide more detail about their perceptions of EHRs and identifying errors within them. This pilot survey was tested and it underwent the relevant approval process at Imperial College Healthcare NHS Trust (Reference: 675796). There was no direct contact between the survey team and the participants during data collection. Replies to individual questions were not mandated. Patients could complete the survey more than once as it was related to their current visits to the CIE platform.

Data Analysis

Data were analyzed using Microsoft Excel 2013. Qualitative data were analyzed thematically using the framework analysis method by Ritchie and Spencer [18]. The 6-stage approach was organized as (1) familiarization, (2) identification of a thematic framework, (3) indexing, (4) charting, (5) mapping, and (6) interpretation [18]. A team of 2 researchers (ALN and LF) with previous experience in qualitative research independently and systematically analyzed the data. Subsequently, both discussed their themes together to develop thematic maps for (1) the barriers to understanding EHR information and (2) the kind of errors identified by patients. Themes were supported by quotes from the patients' free-text survey responses. Data saturation was reached. Results were not returned to participants for comments or feedback. The COREQ (Consolidated Criteria for Reporting Qualitative studies) was used to ensure the study meets the recommended standards of qualitative data reporting [19].

Results

Participant Characteristics

The response rate was 23.5% (160/680). A total of 160 patients confirmed that it was their first time responding to the survey, and 210 survey responses were completed. The additional responses may have been made by patients responding more than once as not all respondents stated how many times they had completed the survey. The average time needed to fill in the survey was 6 minutes. The respondents represented a variety of clinical departments, including Oncology, Colposcopy, Early Intervention Services, HIV Service, Interstitial Lung Disease, Neuro-Oncology, and Renal and Rheumatology. Most responses (134/210, 63.8%) were received from services at 1 out of the 3 acute trusts.

Patients' Perceptions on Their Ability to Understand the Information in EHRs

Participants were asked whether any information in the record was difficult to understand during their use of the system on the same day. A total of 123 of 210 responses (58.6%) indicated that they did not find it difficult to understand information in the record during their use, while 56 responses (26.7%) indicated at least some difficulties based on the barriers outlined in the section below.

Barriers to Patients Understanding Their EHR Information

When asked to specify the difficulties they had in understanding information in their EHRs, patients' replies were classified under 2 broad themes. First, difficulties regarding the information itself and, second, the technology with which the information was relayed to the patients. The presence of difficulties with technology indicates the importance of system usability for its usefulness to patients (Table 1). Concerning the information-related barriers, 2 subthemes of "medical terminology" and "knowledge and interpretation of test results—meaning and significance," were identified (Table 1). Knowledge of medical terminology was considered a necessary prerequisite to understanding the EHR information and therefore a barrier when lacking (Table 1). Furthermore, the interpretation of EHR information in terms of its meaning and significance could be problematic. This was evidenced by patients' concerns regarding their inability to understand the meaning of tests, interpret their results, understand their clinical implications, and decide whether any action was required. Patients are unsure about what impact test results might have on their care and what could or should be done as a consequence (Table 1).

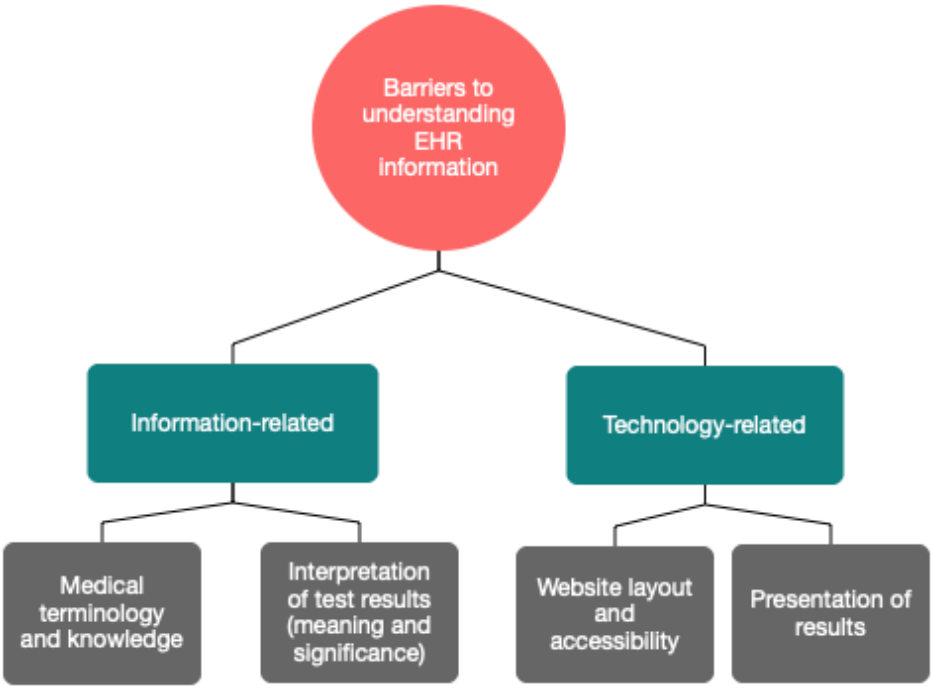
The difficulties in understanding information were further perpetuated by technological issues. In terms of the technology-related barriers to understanding EHR information, the EHR portal layout and accessibility was another dominant theme that emerged. Patients reported finding it difficult to find and access information in their EHRs, even when they had previously been notified by the system that their information had been updated. Finally, the presentation of test results (ie, plots instead of raw values) emerged as a theme and another barrier to patients understanding their EHR information, as it impacted what information they were visibly able to extract from the EHR.

In order to provide an overview of both information-related and system-related barriers to patients understanding their records, the themes derived from the survey (as well as the interactions between them) were used to build a thematic map (Figure 1).

Table 1. Barriers to patients understanding their electronic health record information.

Barriers, themes	Illustrative quote
Information-related barriers	
Medical terminology	*…Plain English needed against various medical terms/acronyms used.* [Patient ID 1]
Knowledge and interpretation of test results	*…I do not understand […] how worried I need to be when test results are out of range.* [Patient ID 204]
	…You obviously need reasonable medical knowledge to understand results. [Patient ID 89]
	…All test results should have an information sheet attached explaining in layman's terms what it means and if any action is required. [Patient ID 94]
Technology-related barriers	
Portal layout and accessibility	*…Having received an email stating that my records have been updated, I cannot find the stated change once logged in.* [Patient ID 136]
	…I do not know how to access information correctly. [Patient ID 81]
	…I received an email telling me that radiology data had been uploaded to my account, but I was not able to find it. It would have been easier if there had been a path finding link. [Patient ID 146]
Presentation of results	*…I would prefer to see [actual] numbers not […] graphs for blood tests.* [Patient ID 100]

Figure 1. Thematic map of information-related and system-related barriers to patients understanding their records.



Types of Errors Identified by Patients Within Their EHRs

While the majority of the responses did not identify any error in the EHRs (160/210, 76.2%), 26 responses (12.4%) did indicate noticing some form of error in their records, while 24 responses showed no replies to that question. From the free-text responses, 2 main information-based themes were identified as accounting for the errors patients identified within their EHRs: (1) incorrect and (2) incomplete information (Figure 2). Incorrect information included the subthemes of contact information, appointment details, and results and measurements. Moreover, errors in results and measurements were further divided into the classification of results and measurements and entirely false results and measurements. A detailed description of the errors identified, evidenced by participants' quotes, is provided in Table 2. The subthemes of incomplete information included information on appointment details and results. Patients commented that not all their appointments or results were visible on the system. While most patients appeared to have at least some information with respect to their appointments on CIE, for some, no information at all regarding their results were accessible, thereby limiting the CIE usefulness for the patient.

Figure 2. Types of errors identified by patients within their electronic health records.

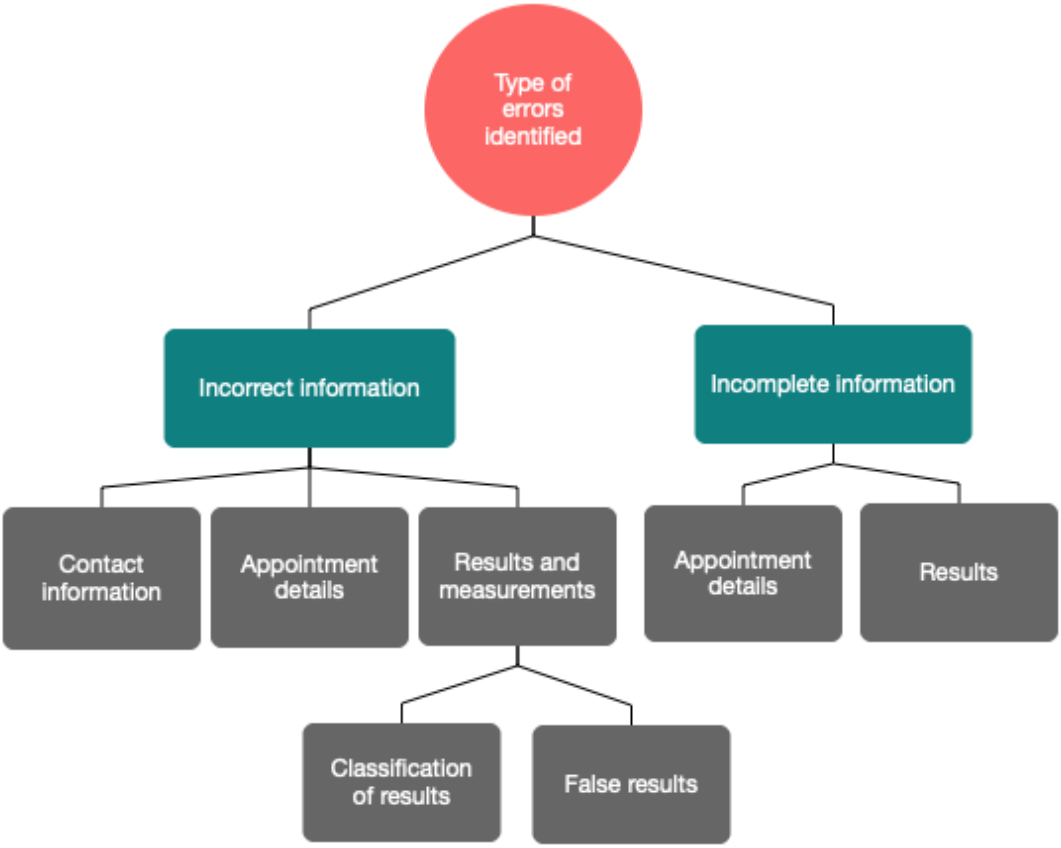


Table 2. Types of errors identified by patients within their electronic health records.

Themes	Illustrative quotes
Contact information (incorrect information)	…*Incorrect address.* [Patient ID 147 and Patient ID 163]
Appointment details (incorrect/incomplete information)	…*Not all my appointments are accurate.* [Patient ID 180] …*My appointment admission and discharge times are not accurate* [Patient ID 140] …*Not all my appointments are recorded so I can't rely on this so I have to keep a separate record myself.* [Patient ID 180]
Results and measurements (incorrect/incomplete information)	…*An x-ray scan […] was recorded as a CT scan.* [Patient ID 186] …*I had an HRCT scan which had been recorded as an X-ray.* [Patient ID 3] …*No information shown on blood test results or anything other than hospital appointments.* [Patient ID 144] …*Blood glucose of another patient maybe with the same name seems to be there.* [Patient ID 199]

Discussion

Summary of the Key Findings

The majority of the survey responses (123/210, 58.6%) reported no problems in understanding EHR information. However, for those reports that did, several difficulties seemed to exist that created barriers to the understanding. These were identified as relating to the information presented (terminology and significance) or to technology-based or system-based issues (layout and result presentation). Furthermore, patients recognized issues of incorrect or incomplete information in a range of aspects, including contact information, appointment details, and results and measurements.

Findings as Compared With Previous Studies

In a high percentage of responses, patients were able to understand their EHR information. These results are consistent with the findings of a previous observational study assessing patients' preferences and perspectives in accessing their records, in which 70.8% of the participants found their records easy to understand [20]. In previous studies, patients reported that they understand notes and that reading notes helps them remember next action points such as tests and referrals [8,21], enables timely follow-up of results, supports family or friend care partners with information [8,21-23], and creates a new mechanism for patients to identify documentation errors [24,25].

The likelihood of patients using EHRs and understanding the information is linked to their digital health literacy, defined as "the ability to search, locate, understand, and use health

information through electronic resources and use this knowledge to resolve health-related problems" [26]. Digital health literacy can contribute to more informed decision making and potentially improve health outcomes [27]. Previous studies found that patients with higher digital health literacy levels have a higher likelihood of being a portal user [28-31]. Holt et al (2019) actually suggest that information about patients' health literacy may provide a better understanding of patients' reasons for not using digital health services, rather than the sociodemographic data [31]. However, similar to other digital health technologies, providing patients with access to correct errors can also increase health inequities, that is, widen the "digital divide" [32]. While patients with higher level of education and better health literacy may want to get more involved in their health care decision making, patients who are less educated may feel that they will not understand the information or may also feel that their doctors know what is best and be less inclined to get involved [33]. Therefore, realizing the potential of patients correcting errors in their EHRs will require broad outreach, engagement, and training for a diverse group of patients of various ages, races/ethnicities, and educational and health literacy levels [34].

As previously found in other studies [35-38], one of the main barriers to understanding medical information was medical terminology and jargon. Acronyms can vary greatly between individuals and specialties, and their understanding can be confusing for clinicians and even more for patients [20]. Strategies to improve readability include efforts to keep usage of terminology consistent [20], minimization of the use of jargon in clinical notes, as well as use of dictionaries as supporting documents in medical records. Other strategies include providing adequate support and training for patients and activities aiming to improve health literacy, that is, patients' knowledge and ability necessary to understand and act upon health information [39].

As in this study, technology-related issues have previously been identified as inhibiting patients' use of health records [40]. The navigation of the system as well as the ease of use have been previously criticized by patients in regard to their EHRs [40]. These findings are consistent with the results of this study showing that patients' ability to use their EHRs effectively is related to the subthemes "user-friendliness" and "website layout." The technology-related barriers are likely to further perpetuate the identified information-related barriers as the way medical information is presented is known to influence patients' ability to interpret its significance and the actions needed as a result [40,41]. There is an opportunity for EHRs to support understanding of health information through user-centered designs in their presentations and provision of linked and easily accessible additional information, to support interpretation of the information shared and to provide guidance for patients on how to use this information for their self-care.

Patients and families have unique knowledge about themselves and their own health care, and their reports have potential for improving both individual and organizational safety [34]. The types of errors identified in our study and in those by Mossaed et al in 2015 and Bell et al in 2020 were similar, including missing test results, medications, and wrong date of birth [20,34]. In our study, the potential severity and impact of the different error types identified varied. While a misclassification of a result (eg, "An x-ray scan […] was recorded as a CT scan") may be inconvenient for finding it on the CIE, this does not necessarily directly pose a threat to patient safety. However, test results from another patient may directly affect future care provision by providing false data to health care professionals and posing safety risks. Hence, as suggested by Bell et al, patients engaging with their EHRs to monitor its contents and flag up potential inconsistencies could enhance quality of care further down the line and offer an opportunity for patients to engage with their health care [7].

In our study, 12.4% (26/210) of the patients identified errors in their medical records. This value is slightly higher than that observed in similar studies published previously, where 7.7% of the patients reported finding errors in their records [20]. In a recent study by Bell et al in 2020, more than 1 in 5 patients perceived mistakes in their notes, with older patients and those with poorer health twice as likely to identify serious errors, suggesting that note sharing may have particularly important safety implications for those groups [34]. As no information on the actual error rate in the patient-controlled EHR was accessible because of patient privacy reasons, the interpretation of the patient-reported error detection percentage could not be explored further.

It is important to note that some patient-reported errors may refer to disagreements between providers and patients and may not necessarily be errors [34]. However, previous evidence suggests that the errors described by patients as very serious usually appeared to have relevant clinical implications [8,34,42], and therefore, patients perceived and reported that error rates remain central to partnering with patients toward the successful and sustainable patient engagement with their EHRs. Future investigations of errors or inconsistencies as identified by patients in contrast to health care professionals may allow for further estimation of the impact of patient EHR review on safety and quality of care.

Consistent with UK policy guidance emphasizing the need to share health information with patients [4,43], a recent initiative has focused on outpatient clinic letters and the style and language used within them to be better "directed" at patients and thereby written in appropriate language [44]. This initiative highlights the political drive to overcome some of the information-related and knowledge-related barriers to understanding information. These approaches may also help mitigate some barriers inhibiting error identification by patients, thus enhancing the effectiveness of future patient-initiated error identification. In addition, receiving clinic letters almost immediately gives patients the means to keep a convenient record of the letters and to ensure that actions advised in these letters are followed through.

Strengths, Limitations, and Future Work

There are several strengths in this study. The triangulation of interpretations among researchers with expertise in qualitative research, clinical research, and cognitive science resulted in a depth of knowledge and inclusion of different perspectives in this study. Another strength of this study was the diversity in the participant sample, including participants from a range of

departments. To ensure the quality of this work, qualitative data were handled with reference to the COREQ checklist, according to best practice recommendations [19]. In order to keep the length of the survey short, encourage responses, and minimize the risk of patient reidentification, the information collected on participant demographics, characteristics, and context of their CIE access was limited. A few demographic factors have been previously identified as playing a role in a patient's ability to understand the information contained in their EHRs, including female gender, younger age (<60 years), and having a higher level of education [20]. Future work will need to investigate how a wider range of demographic, contextual, and social factors, as well as patient activation and health literacy influence patients' perspectives and abilities to identify errors in their EHRs, thereby allowing planning and implementation of quality improvement work to support its posited benefits without causing any disadvantage to any patient group.

Respondents could complete the survey more than once, thereby limiting the aspects of the data interpretation. However, exclusion of responses would have significantly reduced the scope of the data, and we wanted to be sure to capture and use all respondents' feedback, especially when they took the time to provide feedback multiple times. Equally, over time, an individual's feedback could be perceived to become more insightful as their experience with using the patient portal increased. As no information on the scope of errors existing in the questioned patients' records was available, interpretation of the error detection percentage is limited. Future investigation of errors or inconsistencies as identified by patients in contrast to health care professionals may allow for further estimation of the impact of patient EHR review on safety and quality of care. Additionally, it would be important for future research to examine associations between patient-reported errors and safety outcomes [34]. Finally, future work should include methodologically robust quantitative studies focusing on quantifying how different factors influence both the public willingness and ability to correct errors in their EHRs.

Conclusions

EHR systems have the potential to support patient engagement in health care by providing personal health information to patients. While the majority of the patients reportedly understand the information contained within their EHRs, technology and information-based barriers persist. Future implementation of such systems must consider supporting patients in the interpretation of the information presented, in what concerns both terminology and significance, and partner with a diverse group of patients to co-design solutions with appropriate usability. Additionally, organizations will need to develop systematic mechanisms for triaging and responding to patient-reported errors, particularly as EHR transparency increases. At a moment when public demand for data is growing, along with a greater awareness of health care data ownership, these barriers must be addressed and their solutions incorporated in health information systems that support patients and their care providers to together improve patient safety.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Patient survey.
[PDF File (Adobe PDF File), 105 KB - formative_v5i2e19074_app1.pdf]

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Abbreviations

CIE: Care Information Exchange
COREQ: Consolidated Criteria For Reporting Qualitative Studies
EHR: electronic health record
NHS: National Health Service
NIHR: National Institute for Health Research

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Original Paper

Rural Residents' Perspectives on an mHealth or Personalized Health Coaching Intervention: Qualitative Study With Focus Groups and Key Informant Interviews

Nancy Schoenberg[1], PhD; Madeline Dunfee[1], BA, MPH; Hannah Yeager[2], BA; Matthew Rutledge[3], MA; Angela Pfammatter[4], PhD; Bonnie Spring[4], PhD

[1]Department of Behavior Science, University of Kentucky, Lexington, KY, United States

[2]University of Rochester, Rochester, NY, United States

[3]Department of Statistics, University of Kentucky, Lexington, KY, United States

[4]Department of Preventive Medicine, Northwestern University, Chicago, IL, United States

Corresponding Author:
Nancy Schoenberg, PhD
Department of Behavior Science
University of Kentucky
760 Press Avenue
372 Healthy Kentucky Research Building
Lexington, KY, 40536
United States
Phone: 1 859 323 8175
Email: nesch@uky.edu

Abstract

Background: Compared with national averages, rural Appalachians experience extremely elevated rates of premature morbidity and mortality. New opportunities, including approaches incorporating personal technology, may help improve lifestyles and overcome health inequities.

Objective: This study aims to gather perspectives on whether a healthy lifestyle intervention, specifically an app originally designed for urban users, may be feasible and acceptable to rural residents. In addition to a smartphone app, this program—Make Better Choices 2—consists of personalized health coaching, accelerometer use, and financial incentives.

Methods: We convened 4 focus groups and 16 key informant interviews with diverse community stakeholders to assess perspectives on this novel, evidence-based diet and physical activity intervention. Participants were shown a slide presentation and asked open-ended follow-up questions. The focus group and key informant interview sessions were audiotaped, transcribed, and subjected to thematic analysis.

Results: We identified 3 main themes regarding Appalachian residents' perspectives on this mobile health (mHealth) intervention: personal technology is feasible and desirable; challenges persist in implementing mHealth lifestyle interventions in Appalachian communities; and successful mHealth interventions should include personal connections, local coaches, and educational opportunities. Although viewed as feasible and acceptable overall, lack of healthy lifestyle awareness, habitual behavior, and financial constraints may challenge the success of mHealth lifestyle interventions in Appalachia. Finally, participants described several minor elements that require modification, including expanding the upper age inclusion, providing extra coaching on technology use, emphasizing personal and supportive connections, employing local coaches, and ensuring adequate educational content for the program.

Conclusions: Blending new technologies, health coaching, and other features is not only acceptable but may be essential to reach vulnerable rural residents.

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KEYWORDS

rural populations; technology; exercise; diet; community-based participatory research; mobile phone

Introduction

Overview

This paper describes the perceptions of Make Better Choices 2 (MBC2), a multi-component diet and physical activity intervention. Although MBC2 has been shown to improve outcomes in urban population, the program has never been implemented among rural residents [1]. In part, this lack of implementation stems from the assumed limited acceptability of, access to, and use of technology, which forms a core component of MBC2. With the growing use of smartphones and other technologies, rural residents may be well-positioned to benefit from this intervention. The purpose of this study is to better understand the perceived feasibility and acceptability of the mobile health (mHealth) intervention and adaptations that should be made to improve fit among the rural Appalachian community before implementing the intervention. Qualitative approaches are well suited to identify perceptions of feasibility, acceptability, and adaptation needed for mHealth programs [2].

We convened 38 participants in 4 focus groups, complemented by 16 key informant interviews, with peer debriefing through a 10-person community advisory board [3]. Using the Consolidated Framework for Implementation Research (CFIR) [4], we describe participants' overall assessments, including perceived feasibility and acceptability, potential challenges, and required modifications. It should be noted that the program of focus, MBC2, is a multiple-component intervention using mHealth and other elements (health coaching, accelerometers, and incentives) rather than an exclusively mHealth intervention. Although these other components of MBC2 have been successfully deployed and described in this population, mHealth remains under examination among rural residents. Thus, we focus on the personal technology component of the intervention rather than on other components.

Setting and Background

Rural residents, including those from the central Appalachian region (Kentucky, North Carolina, Tennessee, and West Virginia), experience some of the nation's greatest resources and health burdens [5]. Challenging conditions include low personal and community-level resources (eg, minimal public transportation and health care professional shortages) [6]. For example, the median household income (US $33,492) in Appalachian Kentucky is overall US $20,000 lower than the United States (US $53,889) median household income. Nearly three-quarters of Appalachian Kentucky counties are classified as *economically distressed*, with economic indicators in the lowest 10% of all US counties [7]. In addition, in many communities throughout Appalachia, few supermarkets, sparse public health and physical activity programming, and inadequate transportation reduce access to high quality, affordable food and recreational opportunities [8].

Associated with these community and personal resource challenges, rural Appalachian Kentucky residents have among the worst health profiles in the United States [8], including elevated rates of cancer, cardiovascular disease, diabetes, and other leading causes of mortality [5,8,9]. These health conditions are mediated by lifestyle behaviors, including suboptimal diet and physical inactivity [6,10]. As a result of these high rates of risk factors and morbidity, life expectancy in the region has been decreasing over the past two decades. Of the 10 counties in the United States experiencing the greatest decline in life expectancy, 8 are located in Appalachia [5]. This alarming trend of suboptimal and worsening health status requires new and innovative approaches, including leveraging technology that may overcome sparse community and personal resources.

Increasing Use of Technology

The World Health Organization has described mHealth systems as a "medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants, and other wireless devices" [11]. As applied to personal technology, mHealth may refer to "health and medical prevention and treatment supported by exponential technologies, including but not limited to wireless gateways and connectivity, biosensors and wearable personal technology, precision medicine, and of course, patient engagement and empowerment" [12]. Although personal technology approaches to improving lifestyle have been tested in traditionally underserved urban populations, the feasibility and impact of mHealth interventions among vulnerable rural populations have been largely unexplored [13]. In some rural locations, inconsistent mobile phone reception [14], lack of smartphone ownership [15], and concerns about inadequate internet connectivity and costs have been thought to limit the implementation of mHealth interventions.

New evidence suggests that rural residents, including those from rural Appalachia, increasingly use and are favorably oriented toward personal technology [16]. A recent Robert Wood Johnson Foundation, National Public Radio, and Harvard TH Chan School of Public Health poll reported that 85% of rural residents use the internet, nearly 70% of whom use the internet to obtain health information [17]. Although access problems persist—21% and 10% of rural residents indicate that internet connectivity constitutes a problem or a major problem, respectively [18]—the vast majority of rural dwellers view technology as vital to compensate for sparse or absent community resources. Indeed, most people in the region have smartphones (68%), have home internet access, and use the internet (78%) [18].

mHealth offers distinct promise for special populations [2] such as rural residents, including the potential to engage in programs while overcoming the challenges of long-distance travel, sparse community programming, community peer pressure, and few health care professionals. Providing health and wellness services remotely through phone or internet capabilities offers a potentially lower cost option that circumvents limited transportation options [19,20]. At the same time, research suggests that mHealth intervention effectiveness largely depends on tailoring the program to the preferences of the target group [21]. Thus, additional research is needed to establish the optimal fit among resident preferences and community capacity to produce effective interventions [21]. As our intention was to assess the potential feasibility and acceptability—the first step in intervention administration—our findings reflect theoretical and not experiential perspectives with the MBC2 program. Thus, this study aims to obtain insights into the perceived feasibility

and acceptability of mHealth interventions and adaptations that should be made to improve fit among the rural Appalachian community.

Methods

Research Approach

Qualitative approaches have long been used to conduct pilot research on perceived intervention feasibility and acceptability; indeed, qualitative research has become the standard approach to initiating many intervention protocols [22]. Thus, to assess the perspectives of rural Appalachian adults on the acceptability and feasibility of employing mHealth interventions, this qualitative study employed focus groups and key informant interviews. We used both focus groups and key informant interviews because each method has the capacity to reveal distinct insights. During the 4 focus groups, diverse community representatives were shown slides and asked semistructured questions about the multiple-component, targeted lifestyle mHealth program, MBC2. During the 16 key informant interviews, the same slide deck was shown to individuals with specific expertise who were queried about how MBC2 program components might fit with their community and clients.

Setting and Sample

This study was conducted in 6 rural counties in Appalachian Kentucky. The counties were selected because they share many features with the broader group of 54 Appalachian Kentucky counties and Central Appalachia, including access to health and social services, internet and technology use, economic status, and rurality [9]. We used rural-urban commuting area (RUCA) codes to determine the extent of rurality within these counties. Participants resided in counties with RUCA codes ranging from 7 (nonmetro, urban population of 2500-19,999, not adjacent to a metro area) to 9 (nonmetro, completely rural or less than 2500 population, not adjacent to a metro area) [23]. Our campus-community 16-year partnership working in these counties facilitated all aspects of the research conducted.

Focus Groups

To obtain a broad array of perspectives and local relevance, we used convenience sampling [24], overcoming potential limits to inclusivity by employing maximum variation sampling [25]. The focus group participants' personal characteristics (education, income, and lifestyle behaviors) were similar to the central Appalachian population overall and were more likely to be representative of the potential intervention participants, whereas the key informants provided insights based on their specific background and expertise (ie, as a parent, an older adult, a tech sector worker, or a minimal user of technology). Although participants from both groups had a higher socioeconomic status than the average county resident, they were highly representative of potential participants in the intervention [7], which is of greater relevance to this study.

Our local project coordinators contacted community stakeholders in these rural Appalachian counties and requested their participation in focus groups and interviews. These contacts were made informally through their workplaces, churches, and social service agencies. Eligibility criteria included being an adult (age 18 years and above), Appalachian resident, and willingness to participate. Focus groups and key informant interviews were conducted in a wide array of settings (eg, local libraries, the US Department of Agriculture's Cooperative Extension Service, community center, and government building), at various times of the day (to encourage participation by working people, parents, and older adults), and among diverse stakeholders (varied ages and ethnicity or race, both sexes, and differing employment status) to ensure inclusivity across demographic characteristics. The focus groups included 6-10 participants. We conducted 4 focus groups dictated by theoretical saturation [26], known as the point at which adding new data does not substantially contribute to thematic development or insights.

Key Informant Interviews

Consistent with the intention of key informant interviews, we aimed to have special expertise or background represented through our key informant interviews and used purposive sampling [27]. Purposive sampling involves identifying individuals who maintain relevant knowledge or experience on a focal issue and who are willing and capable of engaging in the research [27]. Our key informants included representatives of targeted organizations, including churches, worksites, and community centers. Local project coordinators sought individuals in their personal networks who were more likely to represent the potential intervention participants. In contrast, the key informants provided insights based on their specific backgrounds and expertise (ie, as a parent, an older adult, a tech sector worker, or a minimal user of technology). Eligibility criteria included being an adult (age 18 years and above), Appalachian resident, and willingness to participate. As the MBC2 program enrolls eligible adults of any age, we aimed to explore perspectives from all ends of the age spectrum. Both focus group and key informant interview sample sizes were dictated by theoretical saturation [26], known as the point at which adding new data does not substantially contribute to thematic development or insights. After 16 key informant interviews, we reached theoretical saturation and completed data collection.

Human Subjects Protection

All study procedures were approved by the Institutional Review Board of the University of Kentucky, protocol #4791. Before enrollment in the study, rights and responsibilities associated with this project were explained to each participant. Interviewers, all of whom had successfully completed the Collaborative Institutional Training Initiative in human subjects' protection training, responded to questions or concerns. The interviewer and participant then signed human subject protection documents, and a copy was left with each party.

Data Collection

Upon completion of informed consent documentation, the focus group moderator (a qualitative researcher with 2 decades of focus group experience) described the session, asked an ice-breaker question, and initiated the slide show displaying all program components. Textbox 1 (Note: focus group guides are

similar but brief and more general) shows the questions asked during our focus groups.

These questions were developed according to principles of participatory action research, where stakeholders and researchers work together to develop research protocols [28]. Stakeholders included a community advisory board that was convened for this specific project and included 11 local residents from 4 counties. To establish these questions, the researchers grounded the questions in the domain and constructs of the CFIR. CFIR domains and constructs included the individual (eg, self-efficacy), intervention characteristics (eg, complexity), the outer and inner setting (eg, relative priority, available resources, and incentives), and the process of administering the intervention (eg, champions and engagement). During a community advisory board meeting, we presented questions one at a time to obtain feedback on the wording, clarity, and flow. Once these CFIR-based constructs were transformed into questions by stakeholders (the community advisory board and researchers), the interview guide and the slide show were vetted, pilot tested with 6 new local residents, and revised in vivo. To further ensure fit and cultural consonance, we engaged the community advisory board in a second confirmatory round of reviews and we revised accordingly. Finally, in accordance with the principles of participatory action research, we further revised the interview guide after our first focus group.

The moderator employed prompts and ensured that all of those attending provided input; 2 observers took extensive notes, and the session was audio-recorded after participants provided verbal consent. The focus group sessions lasted 70-90 minutes. For the key informant interviews, upon arranging a mutually agreeable meeting time and location (a participant's home or a community site like a library), interviewers administered informed consent protocols. The interview proceeded with an interview guide based on CFIR but tailored to the particular expertise represented. For example, a technology expert received questions about the standard data use patterns in the region. Each key informant interview lasted 45-60 minutes. For both the focus groups and interviews, participants filled out a pencil and paper questionnaire with standard and validated demographic and relevant health behaviors [29,30] (Table 1). Participants were compensated US $50, a standard honorarium in this region when transportation reimbursement is not provided.

Textbox 1. Sample interview guide for key informant interview based on the Consolidated Framework for Implementation Research. Note: focus group guides are similar but brief and more general.

Intervention characteristics:

- If we train people on the app, can they use it on their own?
- For the personal coaching, who would be best in this role?
  - Trained local people?
- The program takes 6 weeks. You use the app a few times a day, and you use an accelerometer to measure your physical activity. What do you think?
  - Are people willing to do this?
  - Is this too much?
  - Not enough to change people's lifestyle?
- What do you think the main barriers to starting the program would be?
- Why do you think people would drop out?
- Do you think the program would fit into peoples' lives?

Outer setting:

- If people want to eat more fresh fruits and vegetables, where do they go to buy these things?
- Are there programs to help people with lower income afford fresh foods?
- What kinds of physical activities are the most popular? Walking? Biking? Fitness classes?
- Where do people exercise? Inside the home? Gym? Outside (school track or parks)? Churches? Schools?

Internet:

- Are people willing to use their data for this app?
- How often do you think people change their internet provider or phone? Why do people make changes? Is cost a factor?
- Do you think people regularly experience interruptions in service when trying to upload or download data?
- Are there places where people can access free Wi-Fi, like in a library?

Exercise:

- Are fitness club memberships expensive?
  - Are fees determined based on a person's income?
- Are there programs to help people with lower income afford memberships?
- Do places for recreation have childcare?
- Are places for recreation open all the time or are there certain hours?

Inner setting:

- Do you think that we would find people who could be trained as personal coaches? Where? Who would be good?
  - What would be the best approach for training these personal coaches?
  - Are there any logistical issues that we should remember?
- This is a home-based program, so people would not have to travel except for the assessments (baseline and 3, 6, and 9 months).
  - How should we best communicate with our participants? Facebook, email, telephone, and visit?

Individuals' characteristics:

- If we want to get a fuller range of people involved, how can we do that?
  - For example, how do we get men to participate in the program?
- How do we get those people who are not particularly motivated to join?

- How about those people who think they cannot change their lifestyle?

Implementation process:

- How can we make sure that our coaches deliver personal coaching in the same way to all participants?
- How can we make sure that the participants are using the app and accelerometer correctly?
- How should we check in with participants to see how they feel about the program?
- What are your ideas about keeping the program going after the grant ends?

Table 1. Focus group and key informant participants' sociodemographic characteristics and relevant health behaviors (N=54).

Characteristics	Focus group (n=38)	Key informants (n=16)
Age (years), mean (range); SD (4.5)	49.6 (23-78)	44.1 (25-61)
Sex, n (%)		
Male	12 (32)	7 (44)
Female	26 (68)	9 (56)
Marital status, n (%)		
Married	26 (68)	13 (81)
Divorced or separated	5 (13)	—[a]
Never married	4 (11)	3 (19)
Widowed	2 (5)	—
No response	1 (3)	—
Education, n (%)		
Grade 12 or general educational development	4 (11)	1 (6)
College 1-3 years	11 (29)	2 (13)
College 4+ years	7 (18)	4 (25)
Graduate school	16 (42)	9 (56)
Work, n (%)		
Full time	22 (58)	13 (81)
Part time	2 (5)	2 (13)
Student or part time	2 (5)	1 (6)
Homemaker	3 (8)	—
Retired	7 (18)	—
Unemployed or disability	1 (3)	—
Student	1 (3)	—
Financial status, n (%)		
Struggle to get by	6 (16)	1 (6)
Struggle or about enough	1 (3)	—
About enough	13 (34)	5 (31)
More than enough	15 (40)	7 (44)
No response	3 (8)	3 (19)
Fruit and vegetable consumption, servings per day, n (%)		
1-2	17 (45)	5 (31)
3-4	17 (45)	7 (44)
5+	4 (11)	3 (19)
No response	—	1 (6)
Screen time, hours each day not including work or school, n (%)		
None	1 (3)	—
1-2	16 (42)	8 (50)
3-4	14 (37)	4 (25)
5+	7 (18)	3 (19)
No response	—	1 (6)
Exercise, min per week of moderate to vigorous exercise, n (%)		
None	2 (5)	—

Characteristics	Focus group (n=38)	Key informants (n=16)
1-60	1 (3)	—
60-90	14 (37)	6 (38)
91-119	7 (18)	—
120-180	2 (5)	1 (6)
181-240	4 (11)	5 (31)
240+	8 (21)	3 (19)
No response	—	1 (6)
Do you use a smartphone, n (%)		
No	1 (3)	—
Yes	35 (92)	15 (94)
Sometimes	1 (3)	—
No response	1 (3)	1 (6)

[a]Missing data, no response recorded.

Data Analysis

The tape-recorded sessions were transcribed verbatim and immediately subjected to coding to determine the completeness and appropriateness of the questions and to ensure data saturation. Thematic analytic steps include close reading and rereading of transcripts, line-by-line coding, and codebook development [31]. In total, 2 members of the research team read all the transcripts to structure the codebook. During the second reading, 1 reader independently generated a list of codes that were crosschecked with each of the other analysts to produce coherent categories; the senior researcher approved the final codebook. We hand coded all transcripts, which, according to most qualitative standards, is considered more time consuming but just as appropriate as employing a software management system [32]. Moreover, hand coding is particularly well suited when template coding is used [33]. During the process of template coding, memos were developed to identify the relative frequency of the codes and the different contexts in which they emerged [34]. We assessed the relative frequency and variation in thematic presence among participants [35]. Themes that appeared across multiple participant transcripts are presented in the *Findings* subsection, with attention to commonalities across focus groups and key informant interview participants' responses. We followed the steps for thematic analysis by Braun and Clarke [36], first familiarizing ourselves with the data; then embarking upon an iterative coding process for semantic content; and then searching for, reviewing, and naming themes. A second team member reviewed potential themes by checking for coherence with the selected extracts from the original transcripts. The final theme names and definitions were developed by 2 qualitatively trained researchers in collaboration with the first author as the writing process evolved. Research rigor was established via team analysis, prolonged engagement with the subject matter, and reflexivity.

Rigor

We established research rigor through several approaches, including team analytic procedures, extensive reflexivity, peer debriefing, prolonged engagement in the community, and focal issues [36]. We used Lincoln and Guba's conceptualization of qualitative standards of credibility (confidence in the *truth* of the findings, accomplished through prolonged engagement in the research environment and peer debriefing), transferability (whether findings apply to other contexts, established by memoing and case study development), dependability (demonstrating the capacity for the findings to be repeated and remain consistent, accomplished through engaging in inquiry audits), and confirmability (whether participants shape our findings rather than researcher bias or preconception, determined by maintaining an audit trail and engaging in reflexivity among the research team and participants) [37]. Peer debriefing included discussing core themes of the findings with community advisory board members to understand how and in what ways our findings resonated with their experience of community realities [3].

Results

Sample

Focus Groups

Table 1 includes the demographic information for the 38 focus group participants and 16 key informants. The average age (in years) of the focus group participants was 49.6 (range 23-78; SD 4.5). Most participants (26/38, 68%) were female, married (26/38, 68%), and nearly all owned a smartphone (35/38, 92%). Over half (22/38, 58%) of the participants worked full time, and nearly three-quarters (28/38, 74%) of the participants indicated that they have about or more than enough to make ends meet. Only under half (16/38, 42%) of the participants held a graduate degree. Most (22/38, 58%) of the participants reported consuming 1-4 servings of vegetables per day. One-fifth of the participants reported moderate or vigorous exercising 200 minutes per week or more, and over half (21/38, 55%) of the participants reported exercising between 60 and 120 minutes per week. Nearly 80% (30/38) of the participants reported having 1-4 hours of recreational (not related to work or school) screen time per day.

Key Informants

Participants included nearly equal number of males and females, most (13/16, 81%) of whom were married, had at least an associate degree (13/16, 81%), worked full time (13/16, 81%), *had about or more than enough to make ends meet* (12/16, 75%), and owned a smartphone (15/16, 94%). Most (12/16, 75%) of the key informants reported consuming 1-4 fruits and vegetables per day. Half of the participants (8/16, 50%) reported 1-2 hours of daily screen time not related to work or school, with most of the remaining participants reporting more screen time daily. One-third of the key informants (6/16, 38%) reported 60-90 minutes of moderate or vigorous exercise per week, whereas another third (5/16, 31%) reported 181-240 minutes of moderate or vigorous exercise per week.

Findings

Focus Groups and Key Informant Interviews: As qualitative developmental research aims to obtain a holistic understanding of a phenomenon, findings from these 2 data sources are merged to present a cohesive response to the research question. From the focus group and key informant interview analysis, 3 major themes and subthemes emerged pertaining to perceived acceptability and feasibility of mHealth or health coaching interventions within rural communities. These themes were pervasive across focus groups and key informant interviews and included the following: (1) personal technology is feasible and desirable; (2) challenges persist in implementing mHealth lifestyle interventions in Appalachian communities; and (3) successful mHealth interventions should include personal connections, local coaches, and educational opportunities.

Personal Technology Is Feasible and Acceptable

The Appalachian residents in our study considered mHealth interventions feasible and, therefore, promising for 3 main reasons. First, the increased availability and use of smartphones, internet services, and other personal technology in rural areas support mHealth interventions. Participants indicated that most people in Appalachian communities use mobile technology. A fitness studio owner participating in a key informant interview commented on changing patterns of technology use he has noticed in his studio:

> *Fifteen years ago, the parents were watching what was going on the floor and now you can look back there and 80 percent of them are looking at their phones.*

As the use of mobile technology has become more prevalent, awareness of the unique ways mobile technology can support fitness has also spread. For example, in rural areas, where lifestyle guidance can be difficult to find, mHealth interventions may provide personalized information for healthy living. Appalachian residents also recognized unique ways in which mHealth programs encourage personal accountability and awareness. An information technology expert suggested the following during a key informant interview:

> *I think it would be helpful for the app to use the data and encourage them. If the app can collect data, then you know you can set up different sections of communication through the app, so like a pop up in the app to say, "Hey you didn't reach your daily goal."*

Also commenting on how abundant exposure to mobile technology could enhance awareness and support healthy lifestyles, a key informant remarked:

> *This app, it's a great thing because they're always going to be staring (at it) especially if that app has notifications on it. It cues them to say, "Hey look at me for a minute."*

A focus group participant with a community organizing background noted:

> *The program has the potential to change lifestyles. It will make people more aware of screen time and being sedentary.*

Another subtheme of feasibility and acceptability involves changing patterns of interaction that encourage the use of personal technology. Specifically, participants suggested that the app converges with an increasing preference for and ability to engage in programs on their own. A focus group participant explained:

> *Working individually has advantages because working in groups can be intimidating. People are more willing sometimes to do things individually rather than with a group.*

She also noted the benefits apps have in facilitating communication:

> *Social media is a great way to communicate...People have shied away from phone calls.*

A final subtheme of feasibility and acceptability involves enthusiasm for new approaches to lifestyle improvement, making mHealth interventions promising in rural Appalachian communities. Noting growing community awareness of chronic disease threats, participants indicated a greater openness to diverse, new opportunities for lifestyle improvement, including farmers' markets, fitness centers, and personal technology. According to a focus group participant with an entrepreneurial and community organizing background, this openness lends itself to residents trying new approaches if they are locally based. Commenting on the feasibility of the mHealth or personalized health coaching intervention, the participant mentioned the following:

> *People would be very willing to do this. Most people in our area, there is a movement to eat better. The farmers' markets are promoted and there's interest there. People are becoming a lot more conscious of their health. There's been enough national media talking about increases in cancer; people are concerned and would be willing.*

A key informant who has struggled with fitness and diet her entire adult life noted similar perspectives among fellow congregants in her large rural church:

> *People are getting more interested in physical activity and want to do better. Being African American, I know I have many friends who are concerned with blood pressure and diabetes.*

A physical therapist key informant who helps people become more physically active agreed:

> *I think people will be willing (to participate). Many individuals want to get in shape and be healthier, but they don't know where to start.*

Challenges to mHealth Lifestyle Interventions in Appalachia

Despite the potential utility of mHealth lifestyle interventions, participants described numerous challenges that must be overcome to ensure a successful mHealth or personalized health coaching intervention. Participants expressed guarded enthusiasm for such interventions, explaining that challenges exist in the feasibility and acceptability of such innovation at all levels. Consistent with the socioecological framework [38], these challenges include individual-, intrapersonal-, community-, and system-level factors. At an individual level, limited familiarity with healthy lifestyle practices poses a barrier to successful mHealth interventions. Reflecting on her years of teaching youth about healthy eating as a food and consumer science educator, a key informant explained:

> *It is challenging to access a wide variety (of fresh produce), but I find that most people don't even eat the basics. Apples, oranges, bananas...People just don't eat fruit. When I was teaching culinary at the high school, I would do taste tests on fruit. I might have a star fruit and a pomegranate, and I would let kids taste different things and they never knew they liked fresh pineapple. They never knew they liked cantaloupe because they had never tasted or never had it before. So, a lot of times I think it is just the lack of knowledge. And they have never been introduced to that food.*

A focus group member who works in the fitness field voiced a similar concern about unfamiliar food items:

> *People just don't know what to get or how to fix it. I think you have to watch with people in this area about how you present things as well. They are easily made to feel like they didn't know that so they must be dumb.*

In the realm of technology, another focus group participant explained that limited familiarity with technology might pose barriers to successful mHealth programming:

> *Smartphone access is a barrier, especially with elderly participants. Elderly participants will also need extra training on the app.*

Compounding the effects of individual barriers, intrapersonal barriers, including a legacy of unhealthy habits reinforced over generations, may limit the success of mHealth programming among rural residents. A key informant explained that many people:

> *were raised that way just like their parents were raised that way. You know my grandmother...there was more grease in the food than there was food.*

A key informant with a health promotion background emphasized the power of tradition to shape peoples' lifestyle:

> *But if it's been a generational thing. If your parents didn't exercise you don't exercise, you're probably not going to exercise.*

She explained how cultural patterns, shaped in part by the geographical landscape, also limit community members' activities:

> *I think the activity level, especially here in the mountains, people seem to be pretty dormant in winter months is kind of like hibernation and like the bears that hibernate. And as soon as the temperatures start increasing you see more people out like in parks at basketball court, you have little league, basketball and soccer. You just see people out more active, but in the winter months I think that would be a really hard time to be successful with the project.*

In many rural areas, community-level barriers, including cultural traditions of unhealthy choices, intersect with significant and persistent resource scarcity, potentially limiting the success of mHealth or personalized health coaching interventions. A key informant explained:

> *Things like economics, the health issues that we have here in eastern Kentucky are a byproduct of financial burdens. The old joke is nutrition is more expensive than drugs.*

A young father participating in a focus group noted:

> *the closer you get to the poverty line, the less people tend to be worried about their nutrition and health.*

Speaking specifically about the impact of the financial burden on access to technology, the information technology key informant explained:

> *The only concern I would have (regarding mHealth interventions) is that the iPhone is gonna be more expensive for the most part. If you're looking at a Samsung Galaxy S 10 and iPhones they're clearly very compatible. But if you can look at some pretty low-end android phones that are pretty cheap versus you know a brand-new iPhone. So, I don't know if the app is developed for both. I think it would be very helpful if it was.*

Although improving throughout the region, internet access remains another barrier to mHealth intervention success. As the fitness studio owner, a key informant explained:

> *There are some places that have quote unquote "bad spots" in the area. So, yes that could definitely be a hurdle. It seems to be improving but, it's an on-going joke: having a cell phone in Kentucky is an oxymoron because it's useless. It used to be useless about half the time and 80 percent of the time but now it's about 20 percent of the time, so it's getting better.*

An older focus group participant who works with community food access agreed:

> *Access to a smartphone that can handle the app; availability of access to Wi-Fi connection I think that's one of our biggest problems around here is the Wi-Fi connection. There are parts of this county*

> *where you cannot get a signal. Therefore, some of the data may not download. You'd have to go somewhere where it does.*

A key informant added his concerns regarding people's access to cellular phone services:

> *I am not sure if everyone has the cellphone coverage needed to be able to use the app accurately...Cellular reception is terrible here. According to the coverage map we should have coverage, but we don't at our house.*

mHealth Implementation Requires Personal Connections, Local Coaches, and Educational Opportunities

Participants indicated that the implementation of mHealth programming, though challenging, could be made feasible and acceptable by ensuring extensive local engagement and staffing. First, the participants emphasized personal connections to help support each other. Reflecting on her experience coordinating programs to help people live healthier, a focus group participant observed:

> *People do better walking together with someone rather than by themselves. If they have someone to share with, they may help each other along the way.*

Another key informant reflected:

> *When you do it by yourself, most people will fail. But if they have a coach, if they have somebody else to work with and talk to and things like that and that accountability is there where you are not just letting yourself down and you don't let your friend down.*

With novel communication apps continually available, allowing friends to communicate constantly using video, audio, and text, mHealth interventions may increase motivation by "connecting (participants to) others using social media or a member chat within the app. They can give each other feedback and support. If they have a partner, things are much easier and they are given that accountability." This connectivity may be especially important for older adults who are less familiar with technology; however, numerous participants advocated revising the upper age limit (65 years) as an increasing number of healthy older adults embrace this technology.

Participants also viewed local coaches to enhance relational support. A focus group participant explained that program facilitators must "be knowledgeable about the area. Local people will be more effective."

A key informant elaborated:

> *Many people are leery of outside groups coming in and telling them what they need to do or how they need to do it.*

A focus group participant concurred:

> *Nonlocals could be seen as condescending.*

Though she also noted:

> *Locals could be a barrier just by knowing or hearing about them. Locals sometimes have "baggage"...The focus should be on finding the person who can offer the best services.*

According to a key informant:

> *Using local people will get rid of that "outsider" feel.*

Reflecting on his years coaching children and adults, the key informant fitness studio owner shared:

> *I think that there would be a lot of people locally that could be qualified to do so (coach within mHealth programming) with the right training and through understanding how to coach people...If you can get a coach that can look at someone, make eye contact, and see that inner stride inside of them and figure out what it takes to pull that out of them instead of just being a motivational speaker. Yeah, I mean you can do that here as well as you can do that anywhere.*

Finally, reflecting on suboptimal health traditions common in their community, participants considered mHealth interventions that increased participants' knowledge about healthy living practices as the most promising. A key informant explained the importance of providing education with accountability:

> *If you had something to guide them along the way with nutritional facts and just basic physical activities it would be very beneficial. I think people will be more prone to go through with it. A lot of people are too scared to start. By getting the one-on-one alone time it will help people to not give up and they will be more likely to follow through. Calorie intake and information that can be given through the app will be helpful as well.*

A focus group participant also shared how learning about positive results would motivate him to maintain a healthy lifestyle:

> *Understanding that OK well if I feed my body properly and I get some calories burned in the right way, I may see some improvements in the way I look physically, or I may be influenced in the way I feel physically. Just knowing that there are benefits to it and understanding those benefits to it.*

Discussion

Principal Findings

We examined Appalachian residents' perspectives on the feasibility and acceptability of a mHealth intervention that promotes healthy diet and active lifestyle. We specifically focused on the mHealth component of the intervention because other components (personalized health coaching, accelerometer use, and economic incentives) have been extensively described and characterized in this population. Focus groups and key informant interviews revealed that rural Appalachian residents consider such interventions promising, although persistent resource scarcity raised some concern about feasibility. Below, we discuss 3 insights emerging from this work and their implications for future research.

First, participants described the untapped but vast potential of mHealth programming in rural contexts, noting that most of

their neighbors have sufficient access to and experience with using app-based programming to support the implementation of mHealth lifestyle interventions. It is important to emphasize that MBC2 consists of elements other than simply the technology; for example, participants expressed strong support for personal health coaching, which is likely the most critical part of the program. Our results corroborate previous studies in Appalachia demonstrating widespread internet access [16] and the feasibility and acceptability of mHealth [39].

Second, despite the study participants' enthusiasm for and comfort with using app-based programming, sparse resources remain a barrier to all lifestyle intervention success. Specifically, study participants described how limited access to material goods (eg, fruits and vegetables and physical fitness venues) pose barriers to the potential success of lifestyle interventions in rural communities. Although the use of the internet is common among most rural adults (78%), and 66% of rural adults have a smartphone [16], access to smartphones varies greatly by age, socioeconomic status, and geographic region [15]. It is possible that scale-up of the MBC2 or other mHealth or personalized health coaching interventions may provide less benefit to the most vulnerable populations in the region. However, given the widespread and pernicious health inequities, improvement across all population segments, even the relatively well resourced, is warranted. Moreover, given that over half the population currently uses personal technology and rates of use are increasing, it seems provident to begin testing and improving this intervention in preparation for greater technology saturation.

Third, although mHealth interventions may provide rural Appalachia residents access to advice and guidance for living a healthy lifestyle, limited access to high quality, affordable foods, and physical activity resources impede rural residents' ability to act on this guidance and support [6]. As participants acknowledged these barriers, they also provided nuanced guidance for tailoring mHealth interventions for success in vulnerable rural communities. Participants desired mHealth or personalized health coaching interventions that emphasize personal connections with friends and locally appropriate personnel, organizations, and lifestyle guidance. Consistent with other multiple health behavior interventions, most of our participants preferred lifestyle interventions that combined in-person and technology-based methods [14]. For example, many participants advocated for face-to-face group-based activities, a departure from MBC2. Additional recommended adaptations included local health coaches and integrating local organizations and resources into this mHealth or personalized health coaching intervention. These recommendations do not require dramatic modification and converge with Appalachian traditions of self-reliance and mutual aid and support [5,8].

Limitations

Although this study identified important findings regarding the acceptability and feasibility of a mHealth or personalized health coaching intervention in rural communities, we acknowledge several limitations. First, this study was conducted solely in Appalachia; thus, the findings of this project may not be applicable to other contexts. Second, with the rapid advancement of technology, these findings will require frequent updates. We suspect that our findings will be increasingly relevant as more Appalachians use personal technology. Third, our participants had higher incomes, more education, and tended to engage in physical activity more than others in the region. Although our participants' socioeconomic status is likely to be similar to that of future intervention participants, such differences may raise questions about accurately characterizing the entirety of the local community. We would counter that given the close integration and connection among community members, even participants with slightly higher socioeconomic status and more optimal health behaviors have health profiles and behaviors that would be improved by this intervention and thus have relevant perspectives. In addition, purposive sampling of key informants necessarily involves more professionals, who may slightly differ in their backgrounds from the general population. Finally, the modest sample size precludes generalizability and diversity.

Despite these limitations, this study provides insights into the promising potential of mHealth or personalized health coaching interventions to support healthy lifestyle among residents of underserved rural communities. Future studies are needed to determine ideal strategies for enhancing lifestyle programming through connections to community-based resources.

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Conflicts of Interest

None declared.

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Abbreviations

CFIR: Consolidated Framework for Implementation Research
MBC2: Make Better Choices 2
mHealth: mobile health
RUCA: rural-urban commuting area

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Original Paper

Prevailing Outcome Themes Reported by People With Degenerative Cervical Myelopathy: Focus Group Study

Danyal Zaman Khan[1*], MRCS; Siobhan Mairead Fitzpatrick[2*], BA, MSc; Bryn Hilton[3], MD; Angus GK McNair[4], PhD, FRCS; Ellen Sarewitz[5], MA; Benjamin Marshall Davies[1], BSc, MRCS; Mark RN Kotter[1,6], PhD, FRCS; AO Spine Knowledge Forum Spinal Cord Injury[7*]

[1]Academic Neurosurgery Department, University of Cambridge, Cambridge, United Kingdom

[2]Department of Psychology, University of Warwick, Coventry, United Kingdom

[3]Colchester Hospital University, East Suffolk and North Essex NHS Foundation Trust, Colchester, United Kingdom

[4]Centre for Surgical Research, Bristol Medical School: Population Health Sciences, University of Bristol, Bristol, United Kingdom

[5]Goffin Consultancy, Cambridge, United Kingdom

[6]Wellcome Trust & MRC Cambridge Stem Cell Institute, University of Cambridge, Cambridge, United Kingdom

[7]AO Spine, Davos, Switzerland

[*]these authors contributed equally

Corresponding Author:
Mark RN Kotter, PhD, FRCS
Academic Neurosurgery Department
University of Cambridge
Box 167
Cambridge Biomedical Campus, Addenbrooke's Hospital
Cambridge
United Kingdom
Phone: 44 122 333 6946
Email: mrk25@cam.ac.uk

Abstract

Background: Degenerative cervical myelopathy (DCM) arises when arthritic changes of the cervical spine cause compression and a progressive injury to the spinal cord. It is common and potentially disabling. People with DCM have among the lowest quality of life scores (Short Form Health Survey–36 item [SF-36]) of chronic disease, although the drivers of the imapact of DCM are not entirely understood. DCM research faces a number of challenges, including the heterogeneous reporting of study data. The AO Spine Research Objectives and Common Data Elements for Degenerative Cervical Myelopathy (RECODE-DCM) project is an international consensus process that aims to improve research efficiency through formation of a core outcome set (COS). A key part of COS development process is organizing outcomes into domains that represent key aspects of the disease. To facilitate this, we sought to qualitatively explore the context and impact of patient-reported outcomes in DCM on study participants.

Objective: The goal of the research was to qualitatively explore the patient-reported outcomes in DCM to improve understanding of patient perspective and assist the organization of outcomes into domains for the consensus process.

Methods: Focus group sessions were hosted in collaboration with Myelopathy.org, a charity and support group for people with DCM. A 40-minute session was audiorecorded and transcribed verbatim. Two authors familiarized themselves with the data and then performed data coding independently. Codes were grouped into themes and a thematic analysis was performed guided by Braun and Clarke's 6-phase approach. The themes were subsequently reviewed with an independent stakeholder with DCM, assisting in the process of capturing the true context and importance of themes.

Results: Five people with DCM (3 men and 2 women) participated in the focus group session. The median age was 53 years, and the median score on the modified Japanese Orthopaedic Association scale was 11 (interquartile range 9.5-11.5), indicating the participants had moderate to severe DCM. A total of 54 codes were reviewed and grouped into 10 potential themes that captured the impact of the disability on people with DCM: acceptance of symptoms, anticipatory anxiety, coping mechanisms/resilience, feelings of helplessness, financial consequences, lack of recognition, mental health impact, loss of life control, social reclusiveness and isolation, and social stigma.

Conclusions: This qualitative analysis of the perspectives of people with DCM has highlighted a number of prevailing themes currently unmeasured in clinical research or care. The determinants of low quality of life in DCM are currently unknown, and these findings provide a novel and so far, unique perspective. Continued inclusion of online communities and use of targeted digital software will be important in establishing a consensus-based COS for patients with DCM that is inclusive of all relevant stakeholders including people with DCM.

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KEYWORDS

cervical; myelopathy; spondylosis; spondylotic; stenosis; disc herniation; ossification posterior longitudinal ligament; qualitative; thematic analysis; core outcomes set; consensus; Delphi; patient perspectives

Introduction

Degenerative cervical myelopathy (DCM) arises when arthritic changes of the cervical spine cause compression and a progressive injury to the spinal cord [1]. This is the most common cause of spinal cord dysfunction worldwide [2]. Sadly, most patients are left with life-changing disability, despite treatment. A recent study has shown people with DCM to have among the lowest quality of life scores (Short Form Health Survey–36 item [SF-36]) of chronic disease, although the drivers for this are not entirely understood [3,4]. Research advances are clearly required.

Currently, however, DCM research faces a number of challenges [5]. This includes the heterogeneous reporting of study data, making it difficult to synthesize or compare research [3,6]. AO Spine Research Objectives and Common Data Elements for Degenerative Cervical Myelopathy (AO Spine RECODE-DCM) is an international initiative in response to this to provide tools that can support research progress [7]. This includes the formation of a core outcome set (COS).

COS development starts with the development of a long list of outcomes that is put through a consensus process to decide which outcomes are most important and should be included in the COS [8]. An important aspect of forming COS is to ensure representation among all stakeholder groups, including those living with the condition. This latter aspect is argued to be essential to supporting meaningful research [9]. This is exemplified in DCM by the recent valuation of people with DCM recovery priorities [10], which identified pain as the overall priority despite its infrequent representation in DCM research [3,6].

There are a number of different methods for involving people with DCM in the formation of a long list of outcomes [8,11]. One is to undertake qualitative interviews and undertake content analysis, which we have recently performed [12]. One of the limitations of this method is it fails to measure the significance or context of an outcome. While this will be mitigated during the Delphi survey, the information would be helpful to support the rationing of an outcome list (to reduce the number of outcomes listed in a survey and respondent fatigue) and the formation of domains (categories of outcomes). The selection of domains is an important step, as each category will expect representation and therefore it should reflect a key aspect of the disease [11].

Thus, the purpose of this study was to qualitatively explore descriptions of people with DCM and the impact of DCM on their lives to identify prevailing themes and their significance. These themes could aid our understanding of the perspective of people with DCM and assist the organization of outcomes into domains for a Delphi process.

Methods

Overview

The objective of this process was to explore the individual impact of the outcomes reported by people with DCM using qualitative analysis techniques. More specifically, we sought to understand the context and implications of DCM outcomes on the psychosocial aspects of the lives of people with DCM. We referred to the Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist for guidance throughout [13] (Multimedia Appendix 1).

Focus Group Workshops

Attendees of a Patient and Public Involvement Day at Cambridge University Hospital on September 21, 2017 hosted by Myelopathy.org, a charity and support group for people with DCM, were invited to participate in a focus group. Convenience sampling was employed, with the event advertised to registered members of Myelopathy.org. As previously described, this group consisted of DCM patients and their supporters [12]. A focus group style was chosen, facilitating in-depth insight into participant perspectives through principles such as social constructivism [8,14].

Focus groups were initially conducted as separate stakeholder groups (supporters and people with DCM), during which field notes of potential outcomes were generated (reported elsewhere [12]). This list was used to guide the main focus group session consisting of both supporters and people with DCM. During this main session, an initial open question—"How does DCM affect you?"—was posed, followed by discussion focusing on outcomes and their significance. This discussion concentrated on the experiences of people with DCM and was semistructured, with the interviewers intermittently reorienting dialogue onto the target topic and field notes when necessary (see Topic Guide in Multimedia Appendix 2). The session was halted when data saturation was perceived to have been reached (no further outcomes or outcome impacts emerging from the discussion) [15]. All sessions were facilitated by two interviewers (BMD and MRNK) and recorded for subsequent analysis.

Ethics and Consent

The survey was granted ethical approval by the University of Cambridge Human Biology Research Ethics Committee with informed consent received from all participants. Participants were briefed on the purpose of the focus group and intended use of the data transcript. All transcripted data was anonymized, and participants were permitted to withdraw at any time.

Data Analysis

The 40-minute session was audiorecorded and transcribed verbatim (Multimedia Appendix 3) separately by two authors (DZK and SMF) who were not present during the interviews and had no access to any notes taken from the interview. DZK is a medical professional with prior knowledge of qualitative research methods, and SMF is a clinical psychology MSc graduate with qualitative research experience. Any transcription discrepancies were settled by discussion and mutual agreement.

Two authors (DZK and SMF) familiarized themselves with the data and then performed data coding independently. Data coding was done using NVivo software version 10 (QSR International Pty Ltd). Open codes were used (and therefore were not preset and amenable to refinement during the coding process) [16,17]. After independent coding, authors met to discuss codes and group them into themes, a theme being defined as a pattern that captured an interesting or important aspect of the data [16,17]. Thematic analysis using a phenomenological approach was then performed guided by the 6-phase approach of Braun and Clarke [16]. Of note, a predominantly theoretical or top-down approach was adopted, our analysis being driven by the research question [16]. This thematic analysis was performed to a semantic level, identifying themes at the surface level and attempting to understand their significance and context [16,18]. The themes were subsequently reviewed with a stakeholder with DCM (ES), who assisting in the process of capturing the true context and importance of themes.

The above processes produced a list of themes presented as detailed analytical notes. Within these notes, square brackets containing three dots [...] indicate short sections of omitted speech when quoting extracts from the transcript.

Results

General

Five people with DCM (3 men and 2 women) attended the focus group session. Three supporters (all women, 2 identifying as partners and 1 as a close friend) accompanied the people with DCM. The median age of participants with DCM was 53 years. One person was awaiting surgery, and 4 participants had undergone surgery for DCM—3 within the last 2 years and 1 over 2 years ago (Table 1). All attendees identified as White. Participants with DCM underwent brief assessment using the modified Japanese Orthopaedic Association scale (mJOA), a validated clinical measure of disease severity scored from 0 to 18. The median mJOA was 11 (interquartile range 9.5 to 11.5), indicating the participants had moderate to severe DCM [19].

Table 1. Characteristics of study participants.

Participant number	Age	Gender	Occupation	mJOA[a]	Surgery
1	45	Male	Unemployed[b]	11	ACDF[c] (C4-C7)
2	54	Female	Unemployed	9	Awaiting
3	65	Male	Retired	11	Yes (unspecified)
4	53	Male	Employed	12	ACDF (unspecified)
5	48	Female	Unemployed[b]	10	ACDF (C6-C7)

[a]mJOA: modified Japanese Orthopaedic Association scale.

[b]Unable to work due to disability.

[c]ACDF: anterior cervical discectomy and fusion.

Thematic Analysis

Thematic analysis initially yielded 54 codes (Textbox 1), highlighting the self-reported impact of DCM on the lives of participants. These codes were mapped to 10 overarching themes (Textbox 1) that captured the perspectives of the participants on DCM outcomes and their psychosocial impact. The 7 themes felt to be predominant and most frequently expressed during the discussion were explored in detail and presented in the analytical notes below, arranged in no particular order. These raw themes formed the foundations for the refined themes presented in the text.

Textbox 1. Raw themes and constituent codes.

Diminishing sense of life control:

- Impact on independence and ability to care for self and family
- Inability to plan day to day because of disease unpredictability
- Decreased ability to earn
- Unable to manage pain or disability
- Unable to travel or drive

Feelings of helplessness:

- Irreversible nature of degenerative cervical myelopathy (DCM) is overwhelming
- Progressive disability is overwhelming
- Limited treatment options
- Decreasing autonomy due to disease
- Feelings of needs that are not met by society or health care

Lack of recognition:

- Societal misconceptions and misunderstandings about DCM
- Invisible illness
- Poor appreciation for unpredictability of DCM and symptomology
- Lack of knowledge in general around the debilitating and disabling nature of DCM
- Misconceptions by people with DCM about their disease and its course
- Poor support from welfare services and disability services

Social stigma:

- Lack of recognition of DCM and the resultant disability
- An “invisible” illness
- Misconception of the unpredictability and unreliability of DCM
- Anticipation of stigma from public service workers
- Lack of support from health care professionals

Financial consequences:

- Inability to work
- Difficulty accessing social welfare and disability allowance
- Financial burden of health care
- Accessing private health care for quicker progress
- Debt to compensate for lack of income or support

Social reclusiveness and isolation:

- Disruption to social functioning
- Unpredictability of symptoms affects ability to commit and socialize
- Inability to continue hobbies and pastimes
- Societal stigma and beliefs
- Fear of accidents or incidents
- Unable to travel or drive

Mental health impact:

- Frequent feelings of anxiety and fear about disease

- Feelings of frustration
- Depression
- Suicidal ideation
- Inability to exercise exacerbates mental health difficulties
- Decreased social interaction exacerbates mental health difficulties
- Familial and carer suffering, watching loved ones deteriorate, accessing mental health services
- Feelings of guilt and burdening of carers
- Decreased confidence and self-esteem

Anticipatory anxiety:

- Anxiety from previous experiences of accidents, falls, exacerbation of symptoms affecting activity levels, or ventures*
- Pain avoidance and disability from avoidance
- Unwillingness to leave comfort zones
- Anxiety regarding symptoms makes symptoms worse
- Anxiety regarding future life with disease

Coping mechanisms and resilience:

- Continue day-to-day living despite symptoms
- Commitment to new hobbies
- Working through mental health difficulties
- Persistence despite symptoms and progression

Acceptance of symptoms:

- Accepting chronic nature of symptoms
- Understanding irreversible symptoms
- Adapting lifestyle to symptoms
- Anticipating symptoms and planning for them

Diminishing Sense of Life Control

DCM had a substantial negative impact on participants' sense of control, both physically and socially. Impediments on day-to-day living were clear.

> *One day you can walk, one day you can't.* [Participant 2]

Disability affects control over many bodily functions, including bowel and bladder function and sexual function.

> *Incontinence products...I'm not proud of it but that's what I have to do!* [Participant 5]
>
> *...having a fulfilling sex life... quite difficult.* [Participant 5]

Participants spoke of losing their autonomy and the negative impact this has on their psychosocial well-being.

> *I think we could sum it up in three things here. The frustration, uhhh frustration, depression and physical infirmity.* [Participant 2]

This understandably affects employment, vocation, and socialization.

> *You can't do that physical exercise because you're physically not fit enough, there's a big gap in your life.* [Participant 2]

Daily tasks and activities are contemplated and often impossible to do due to "bad pain management" [Participant 4], meaning psychological protective factors such as exercise, socializing with friends, and family and hobbies see a decline. This extends to working and making a living, consequently "your ability to earn" was a major concern.

> *If you're not confident in your finances and what you can provide for your family and that's a frustration in itself.* [Participant 2]

Focus group members stressed that this inability to retain control of occupational elements of life was related to feelings of depression.

> *This is what terrifies me, the fact that I'm going to end up y'know with Tesco online sort of bringing me everything I need and then I'd be so afraid to go out of the house, you're going to end up clinically depressed.* [Participant 2]

Additionally, a sense of helplessness was expressed and related to lack of life control due to progressive disease.

> *I was...shocked when he said "I can't repair ya."* [Participant 4]

There is widespread recognition of the irreversibility of DCM and a paucity of treatment options, which one participant linked to subsequent suicidal thoughts.

> *When they told me that I wasn't going to get any better, as I said I was devastated, and I actually ended up feeling suicidal.* [Participant 5]

An important factor is the receptiveness of society to DCM, which is also believed to influence one's sense of control. There is a widespread experience of hopelessness in regard to welfare accessibility and entitlement due to the lack of recognition of DCM. Participants mentioned the difficulty they face when undergoing assessment for welfare; the unpredictability of their symptoms and presentations result in inaccurate recognitions of ability and eligibility. One participant linked a positive societal experience regarding her DCM to the familiarity of the disease.

> *She had a sister-in-law who suffered from cervical myelopathy, so the minute she saw my form she knew exactly what I was talking about and I was fine.* [Participant 2]

Lack of Recognition and Social Stigma

As mentioned briefly above, participants described widespread misconceptions among fellow people with DCM, society, and professionals, resulting in further difficulty for those with DCM. For example, some participants themselves were perplexed that the issue itself lay in their neck, particularly when their most noticeable symptoms were elsewhere.

> *I said "what's wrong with me neck"..."what you x-raying my neck for, it's my legs is what's wrong"* [Participant 4]

Similarly, societal misunderstanding is a common experience shared by the participants. The spectrum of presentations, day-to-day variability, and misconceptions about DCM mean that people with DCM are regularly being viewed as fine in society regardless of their symptoms.

> *Yes it looks like I can walk more than 20 meters or more than 50 meters, I can't do it reliably, I can't do it repeatedly* [Participant 5]

The lack of recognition of DCM's disabling nature is frustrating and distressing.

> *You get the DWP [Department for Work and Pensions] saying that "oooh you're not disabled, you can do this you can do that"... I ... I mean I've lost my DLA [Disability Living Allowance], I've been given zero points for PIP [Personal Independence Payment], I've lost my Motorbility Car, I've had to buy it, I've had to go into more debt than I'm already in* [Participant 5]
>
> *I've lost my blue badge! Even a simple thing like a blue badge cos' the council won't accept that.* [Participant 5]

People with DCM receive inadequate support and have no choice but to endure the disabilities or go through lengthy and complicated repeal tribunals.

> *Yeah it's a big problem now disability wise, they don't recognize it do they... I had to fight for mine as well because in 2014 they wouldn't give me disability at all* [Participant 1]

Furthermore, this lack of recognition is related to the sense of stigmatization people with DCM experience in society. The relatively invisible nature of the illness was noted to propagate societal misconceptions.

> *You look perfectly fine, you talk perfectly fine and all of a sudden y' you're on your back on the pavement and you can't get up again...and people think you're drunk, people think you're off your face.* [Participant 2]
>
> *You feel like you're walking out with a... sort of a... a beacon on your head, with the way you move things.* [Participant 1]

Finally, lack of recognition by health care professionals is a source of feelings of helplessness and frustration.

> *You feel like banging your head against a brick wall trying to get people to understand you.* [Participant 5]

Some people with DCM also expressed frustration toward professionals for the follow-up support they've received in treating the features secondary to DCM such as depression.

Financial Consequences

The financial burden of DCM was mentioned in various forms. Inability to work and "your ability to earn" was a major concern.

> *If you're not confident in your finances and what you can provide for your family and that's a frustration in itself and it's going to make you depressed and angry and down, and that in itself is not good for your general wholesome health.* [Participant 2]

Moreover, some participants lacked social welfare support.

> *In 2014 they wouldn't give me disability at all, because I hadn't had surgery or anything ... they sent it back saying "no you can't have it."* [Participant 1]

The cost of health care was also mentioned as participants describe long waiting times for diagnostic work-up.

> *I pay for the scan, just to get it through quicker.* [Participant 4]
>
> *I'm sick of this.* [Participant 4]

Social Reclusiveness and Isolation

The multitudinous impacts of DCM culminate in profound social disruption. The day-to-day unpredictability of DCM emerges as a major culprit.

> *You don't know until you wake up, whether you'll be able to walk or not.* [Participant 3]
>
> *You miss social engagements... there is no part of your life that you can say I will definitely be at point*

> *A tomorrow or point B tomorrow because you just don't know.* [Participant 2]
>
> *This is the central core of all these issues, be it finance, family, future, your social circle, you cannot plan. There's no consistency, one day you can walk, one day you can't, one day you can travel, one day you can't.* [Participant 2]

Inability to socialize results in isolation and loss of community

> *That's something that got me down... all my mates are still drinkin' and so on, so... it puts you y'know the things into a different perspective then.* [Participant 1]
>
> *And when you can't do that physical exercise because you physically not fit enough, there's a big gap in your life... what do you fill it with?* [Participant 2]

Mental Health Impact

Members of the focus group emphasized the impact DCM has on their mental health, speaking openly about depression, suicidal ideation, anxiety, frustration, and guilt.

> *It's going to make you depressed and angry and down, and that in itself is not good for your general wholesome health.* [Participant 2]
>
> *I actually ended up feeling suicidal.* [Participant 5]

This is intimately related to physical disability.

> *I was a very physically active person, and it's very difficult this part of the depressive cycle because when you... part of physical activity makes you feel good, it gives you endorphins, exercise is good for you.* [Participant 2]

Moreover, guilt was felt as participants placed further reliance on their supporters and their relationships with family members were affected.

> *It's had a massive impact on my 11-year-old, ... he's currently going through CAMHS [Child and Adolescent Mental Health Services] at the moment because he's struggling 'cos he's got now two disabled parents... I might get upset now.* [Participant 5]

Impacts on mental health appear to act synergistically with physical manifestations of DCM due to its potentially huge life impact and the disability it causes.

Anticipatory Anxiety

Participants expressed that the anticipation of pain and disability impacted considerably on their daily living. Many expressed anxieties about leaving their home due to fear of falling or exacerbation of pain when attempting to engage in activities of daily living.

> *Anxious if you're going to leave your own four walls... you know that oooh I've gotta... travel... I've gotta do this and it gets your stomach all mmmm...* [Participant 3]

In fact, anxiety around the symptoms, particularly pain, was emphasized as strongly as the actual pain itself. Pain and discomfort are often consequential to taking control and continuing with daily activities. and participants conveyed the frequent dilemma in deciding whether to sacrifice comfort over control.

> *So, I either get out there and do them and I run the risk of a fall, which makes me anxious, blood pressure goes up and you're shaking and that makes simple things difficult. So what's you're other option, housebound?* [Participant 2]

Similarly, this anxiety often aggravates physical symptoms such as shaking, therefore making tasks more difficult and potentially impossible. Understandably, participants referred to it as a vicious cycle.

Adaptive Coping Mechanisms and Resilience

In spite of the above, people with DCM in the focus group described adjusting lifestyles and taking up new hobbies that were manageable with their symptoms.

> *I have become...the library's best customer...I have gone through 6/7 books a week.* [Participant 2]

Participants were determined to continue with their daily activities and to not succumb to disability.

> *I force myself to go out, even if it is only to the shops and back.* [Participant 2]

There is acceptance of symptoms and alterations that inspires the focus group members to be resilient and partake in activities.

> *I'm just gonna carry on doin' it because I know I'm going to suffer but I just accept it.* [Participant 4]

This is supported through active coping mechanisms such as adaptation and self-acceptance, which further ameliorate the effects of DCM on one's life, allowing for retention of control.

> *I can tell you where all the toilets are in the town center.* [Participant 3]
>
> *When you're going out you're thinking where's the toilets first of all or start planning.* [Participant 4]

The strength and power of positive support systems were made apparent by the participants. Many discussed the indirect or subtle motivation that connections such as children, partners, and even pets provided them.

> *I got a dog to get me out and that's the reason I go out, not because I have... I should do, but because I have to. I have to obviously with having depression I really struggle to motivate myself.* [Participant 5]

However, reflecting on these connections revealed feelings of guilt that appeared to be overpowered by the participants' sheer determination to retain their caregiving roles.

> *I've got the kids to look after, I've got dog and bunnies to look after... And so it's... it's really important for me to keep...as clear as I can.* [Participant 5]

Discussion

Principal Findings

Qualitative analysis of the perspectives of people with DCM and their supporters has revealed an array of emotive themes relating to the psychosocial impact of living with DCM. We have identified a number of psychosocial implications of DCM, such as loss of control, secondary mental health impacts, external misconception, and anticipatory anxiety and fear. The absence of DCM-specific evidence is in keeping with experience from other chronic disease.

The focus of current DCM literature is on the biological consequences of the disease [3], but psychosocial consequences are also important to people with DCM and their supporters. In a review of reported outcomes in 108 DCM studies, biological outcomes were reported relatively frequently—function was reported in 90% of studies, complications in 52%, imaging in 55%, and pain in 27% of studies [20]. Of note, only 29% of studies reported quality of life (QoL) outcomes, with 80% of these studies using the SF-36 [3]. Although the SF-36 captures, briefly, the impact of depression and anxiety on the physical and social functioning of the individual, it does not capture other emotions, the relationship of people with DCM with the disease, and the social context of DCM (as highlighted in our themes) [21]. Indeed, people with DCM often tend to focus more on the effects of disease on their life (eg, the impact of unpredictable variations in disease) and wider aspects of health, as opposed to the disease process itself [22]. Indeed, there may be discordance between perspectives of researchers and people with DCM on the important outcomes in DCM [3,10]. Studies that have measured the quality of life impact of DCM using the SF-36 show that DCM encompasses among the lowest scores [4]. In the mental component score (covering energy levels, mental health, emotional role functioning, and social functioning), DCM is second only to that of back pain/sciatica [23]. Similarly, DCM scored low on the physical component score (PCS) of SF-36, second only to heart failure [3]. Interestingly, there is discordance between the severity of physical symptoms and general quality of life measures and mental health scores [24], and the determinants of QoL are unknown.

Moreover, exploration of the psychological impact of other chronic illnesses in general adds context to our findings. Anticipatory fear and anxiety is emphasized in the fear-avoidance model of chronic pain [25]. This details the disabling cycle that can occur when an individual experiences pain-related fear. To avoid this fear, individuals become hypervigilant which can lead to further isolation, disability, and often, depression. However, positive coping mechanisms such as acceptance of symptoms (eg, acceptance of chronic pain) predicts positive mental well-being beyond actual severity of pain [26]. Acceptance facilitates more engagement with activities of daily living and may empower feelings of cognitive control over symptoms [26]. Indeed, members of our focus group display this psychological flexibility, understanding some aspects of life are now permanently different and therefore adapting their focus into manageable activities such as reading. This principle of acceptance of symptoms and acceptance of anticipation is fostered in acceptance and commitment therapy, which has shown promise as a psychological intervention for patients with chronic disease [27].

Emotional and psychological dimensions of DCM appear similar to those of other chronic diseases. Disruption of one's lifestyle, career, and goals leads to protracted states of emotional distress, increasing the risk of psychiatric sequelae such as depression and anxiety [28]. Of note, the relationship between depression and anxiety and chronic disease may be interrelated as described above or independent, whereby the two conditions have separate origins but inevitably exacerbate each other [29]. Notwithstanding, the presence of psychiatric disturbances further exacerbates negative physical outcomes and increases disability, resulting in a cyclical disruption in psychosocial health [28].

Lack of life control is an established factor in the development of negative well-being states such as depression and anxiety [30-32]. Similarly, feelings of guilt by people with DCM with chronic disease can contribute to and worsen depression and anxiety [29]. In our focus group, the source of guilt was the perceived impact of the disability on the supporters of the participants. Indeed, in chronic illness, family members may suffer adverse psychological and emotional effects, such as worry, frustration, and stress [33]. It is important for the clinician to consider the mental health of the individual and their supporter network when managing people with DCM.

Finally, societal misconceptions about chronic diseases can have a significant impact on individual psychosocial health. Incorrect perceptions of one's disease have been equated to a feeling of one's reality being questioned—this reality including suffering not understood by others [34]. This societal stigma may adversely affect the doctor-patient relationship, as people with DCM are less open in anticipation of discrimination or stereotyping. Indeed, stigma and the anticipation of stigma results in lower treatment satisfaction and, more broadly, less social support and lower quality of life scores [35]. Raising awareness for DCM and promoting support groups for people with DCM (such as Myelopathy.org) are potential ways to address this.

Clearly, further investigation is required to confirm the determinants of quality of life in DCM, but the experience from this study and the broader literature is consistent. It is likely that a multidisciplinary approach to ameliorate the wide array of difficulties presented by DCM may be the answer in improving the QoL of people with DCM.

Limitations

The selection of participants was based on pragmatic sampling—all participants were White, and the sample size is small (although this size is within acceptable ranges for focus group or style sessions) [36]. Importantly, the age of participants and their level of disease severity matched the average among high-quality clinical series [37]. There was also representation of nonoperative DCM (with one participant not yet having undergone surgery) and their close supporters. Additionally, the qualitative analysis style will be susceptible to variance depending on the researcher performing the analysis [38]. The

interpretation and extraction of themes from the data are shaped by the researcher's perspectives, personal biases, and style of language [38]. We attempted to address this with 2 independent analyses that were merged, and by using researchers independent to the original interview process. Finally, although supporters were engaged in initial parts of this qualitative process, the session highlighted above focused predominately on the lived experience of people with DCM. Further studies would ideally assess the differing views of supporters of people with DCM on the life impact of DCM.

While these aspects may limit the confidence for generalization of findings, in terms of the COS process, this will be mitigated via the involvement of a larger and broader people with DCM and supporter group and the presence of open questions for the first round of the Delphi survey. Specifically, the COS forms a component of the large, international multistakeholder initiative AO Spine RECODE-DCM [7]. Domains (categories of outcomes) will initially be agreed by the AO Spine RECODE-DCM management group, with reference to the Outcome Measures in Rheumatology framework, the literature [3], and the findings of this study. This will be used to categorize individual outcomes identified by people with DCM and the literature to form the first round of an internet Delphi survey. As mentioned, the survey will contain open questions to allow further suggestions for outcome measures not already identified. Consensus will be achieved via further survey rounds and a face-to-face consensus meeting. Digital technologies will be crucial in implementing the next steps of the Delphi process. Recruitment into the process will require wider advertisement through online health communities (eg, Myelopathy.org and AOspine.org), dissemination via computerized survey (eg, SurveyMonkey), and data processing via analytical software (Nvivo [QSR International] and Excel [Microsoft Corp]). Moreover, in an era where social distancing is paramount for safety, committee and consensus meetings will be reliant on online conference calls.

Conclusions

This qualitative analysis of people with DCM perspectives has highlighted a number of prevailing themes currently unmeasured in clinical research or care. The determinants of low quality of life in DCM are currently unknown, and these findings provide a novel and so far, unique perspective. These will be used to inform the formation of a COS, in particular their domains, as part of AO Spine RECODE-DCM. The continued inclusion of online communities and use of targeted digital software will be essential to achieving a consensus-based core outcome set for DCM, which is inclusive of all relevant stakeholders, including people with DCM.

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Conflicts of Interest

MRNK is a trustee of Myelopathy.org.

Multimedia Appendix 1
Consolidated Criteria for Reporting Qualitative Research checklist.
[PDF File (Adobe PDF File), 805 KB - formative_v5i2e18732_app1.pdf]

Multimedia Appendix 2
Topic guide.
[DOCX File , 15 KB - formative_v5i2e18732_app2.docx]

Multimedia Appendix 3
Interview transcript.
[DOCX File , 60 KB - formative_v5i2e18732_app3.docx]

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Abbreviations

AO Spine RECODE-DCM: Research Objectives and Common Data Elements for Degenerative Cervical Myelopathy
CAMHS: Child and Adolescent Mental Health Services
COREQ: Consolidated Criteria for Reporting Qualitative Research
COS: core outcome set
DCM: degenerative cervical myelopathy
DLA: Disability Living Allowance
DWP: Department for Work and Pensions
mJOA: modified Japanese Orthopaedic Association scale
NHS: National Health Service
NIHR: National Institute for Health Research
PCS: Physical Component Summary
PIP: Personal Independence Payment
QoL: quality of life
SF-36: Short Form Health Survey–36 item

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Original Paper

Central Auditory Tests to Track Cognitive Function in People With HIV: Longitudinal Cohort Study

Christopher Niemczak[1], AUD, PhD; Abigail Fellows[1], MA; Jonathan Lichtenstein[1,2], PsyD, MBA; Travis White-Schwoch[3]; Albert Magohe[4], MD; Jiang Gui[1], PhD; Jed Wilbur[5], MS; Odile Clavier[5], PhD; Enica Massawe[6], MD; Ndeserua Moshi[6], MD; Michael Boivin[7], MPH, PhD; Nina Kraus[3], PhD; Jay Buckey[1], MD

[1]Geisel School of Medicine at Dartmouth, Dartmouth College, Lebanon, NH, United States

[2]Dartmouth-Hitchcock Medical Center, Lebanon, NH, United States

[3]Department of Communication Sciences and Disorders, Northwestern University, Chicago, IL, United States

[4]Dar Dar Programs, Dar es Salaam, United Republic of Tanzania

[5]Creare LLC, Hanover, NH, United States

[6]Muhimbili University of Health and Allied Sciences, Dar es Salaam, United Republic of Tanzania

[7]Department of Psychiatry, Michigan State University, East Lansing, MI, United States

Corresponding Author:
Christopher Niemczak, AUD, PhD
Geisel School of Medicine at Dartmouth
Dartmouth College
One Medical Center Drive
Lebanon, NH, 03755
United States
Phone: 1 603 650 6012
Email: christopher.e.niemczak@dartmouth.edu

Abstract

Background: The development of neurocognitive deficits in people infected with HIV is a significant public health problem. Previous cross-sectional studies have shown that performance on central auditory tests (CATs) correlates with cognitive test results in those with HIV, but no longitudinal data exist for confirmation. We have been performing longitudinal assessments of central auditory and cognitive function on a cohort of HIV-positive and HIV-negative individuals in Dar es Salaam, Tanzania to understand how the central auditory system could be used to study and track the progress of central nervous system dysfunction.

Objective: The goal of the project was to determine if CATs can track the trajectory of cognitive function over time in people diagnosed with HIV.

Methods: Tests of peripheral and central auditory function as well as cognitive performance were performed on 382 individuals over the course of 3.5 years. Visits were scheduled every 6 months. CATs included tests of auditory temporal processing (gap detection) and speech perception in noise (Hearing in Noise Test and Triple Digit Test). Cognitive tests included the Montreal Cognitive Assessment (MoCA), Test of Variables of Attention (TOVA), and subtests from the Cogstate battery. HIV-positive subjects were divided into groups based on their CAT results at their final visit (bottom 20%, top 20%, middle 60%). Primary analyses focused on the comparison between HIV-positive individuals that performed worse on CATs (bottom 20%) and the overall HIV-positive group (middle 60%). Data were analyzed using linear mixed-effect models with time as the main fixed effect.

Results: The group with the worst (bottom 20%) CAT performance showed a difference in trajectory for the MoCA (P=.003), TOVA (P<.048), and Cogstate (P<.046) over the course of the study period compared to the overall HIV-positive group. A battery of three CATs showed a significant difference in cognitive trajectory over a relatively short study period of 3.5 years independent of age (bottom 20% vs HIV-positive group).

Conclusions: The results of this study support the ability for CATs to track cognitive function over time, suggesting that central auditory processing can provide a window into central nervous system performance. CATs can be simple to perform, and are relatively insensitive to education and socioeconomic status because they only require repeating sentences, numbers, or detecting gaps in noise. These tests could potentially provide a time-efficient, low-cost method to screen for and monitor cognitive decline in patients with HIV, making them a useful surveillance tool for this major public health problem.

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KEYWORDS

HIV; central auditory function; auditory perception; cognitive dysfunction; testing; cognition; cognitive function; neurocognitive deficit; longitudinal; auditory; nervous system; screening; monitoring; surveillance

Introduction

Even with advanced antiretroviral therapy, people infected with HIV can develop neurocognitive deficits [1]. This consequence of HIV infection produces a lifelong reduction in quality of life and poses a major public health concern. The ability to track HIV-associated central nervous system (CNS) effects is critical for studying, assessing, and treating this serious complication of HIV infection. However, detecting emergent neurocognitive problems is challenging, particularly in the developing world where most HIV cases exist. Neurocognitive test batteries can take considerable time to administer (approximately 2 hours for the National Institutes of Health toolbox); require trained personnel; and depend on accurate, culturally/linguistically appropriate normative data for interpretation. Deploying these tests is difficult, particularly in the developing world where clinician time is limited, few trained personnel are available, and normative data often do not exist. Improved surveillance methods for cognitive decline are needed, particularly in those with HIV.

We have been examining the use of central auditory tests (CATs) as an approach for tracking cognitive function in HIV-positive individuals. Our earlier work established that performance on CATs in HIV-positive individuals is strongly related to cognitive test results [2]. This suggests that central auditory testing evaluates aspects of brain function, and could potentially be used to screen and monitor neurocognitive dysfunction in HIV-positive individuals. However, to date, there has not been a longitudinal study of CATs and cognitive function in HIV-positive individuals. Therefore, the goal of this study was to track cognitive and CAT results over time, and examine the relationship between the two measures.

The central auditory system provides a window into brain function because processing complex auditory information is a neurologically demanding task [3,4]. After the cochlea converts sound waves into nerve signals, the brain must quickly filter out noise, extract timing information, distinguish relevant frequencies within the signals, and determine the meaning of the content. This involves neural pathways throughout the brainstem and into the cortex that integrate with linguistic and cognitive systems, which depend on adequate processing speed, working memory, and attention [5-7]. In addition, previous studies have shown that HIV-positive individuals develop signs of central auditory processing that cannot be attributed to peripheral hearing loss [4,8,9]. Even with normal peripheral hearing sensitivity (eg, normal pure-tone auditory threshold test results), HIV-positive individuals show degraded results on tests of speech perception in noise [10] and auditory gap detection [4].

Problems with central auditory processing often manifest as difficulty understanding speech, particularly in the context of background noise. Accurate speech perception requires complex processing in the auditory midbrain and cortex [7,11,12]. Speech perception in background noise challenges the listener and stresses the central auditory system, requiring the listener to attend to the speech signal, match what is heard to stored knowledge, and derive meaning [13-16]. Most people can attest that understanding a conversational partner in a crowded, noisy room is a common yet difficult task, even for those with normal hearing. This process takes place within milliseconds, and requires high-level cognitive functions such as working memory and executive function [17,18].

To test central auditory processing, we have assembled a battery of behavioral CATs that measure the system in two critical ways: temporal auditory processing and speech perception in noise. Temporal processing refers to the precise perception of time alterations on audible acoustic events [19]. Deficits in temporal processing have been associated with attention problems [20,21] and overall difficulty encoding brief relevant auditory stimuli needed for accurate speech perception [22]. Speech perception in background noise is a broader functional test that involves listeners attending to the auditory signal within noise, performing acoustic analysis, mapping the signal to phonemic categories, temporarily storing acoustic information in memory for further processing, and finally mapping phonemes to meaning [15]. Cognitive factors such as attention, working memory, and speed of processing contribute significantly to both speech perception in quiet and in noise [14,23]. For example, Humes [24] found that part of the variance in speech recognition in noise can be accounted for by nonperipheral factors, including cognitive functions. Using structural equation modeling, Anderson et al [25] showed a strong influence of cognitive factors on speech-in-noise perception, whereas peripheral hearing ability was not a significant contributor.

CATs have several practical advantages over cognitive assessments: they do not require literacy or a high level of education to complete; they are short and easy to explain; and some tests can even be administered remotely, by phone or internet. Thus, these tests could be a major advance for following HIV-positive patients, particularly in the developing world. If performance on CATs can track or provide an early marker of CNS dysfunction in HIV infection, detecting these changes in clinical practice could lead to appropriate adjustments in HIV treatment. CATs could be used to identify CNS comorbidities or to track treatment effects. Antiretroviral drugs differ in their ability to penetrate the CNS to treat HIV, and resistance to particular antiretrovirals can develop over time [26-28]. For example, a change in antiretroviral drug regimen [29], rehabilitative auditory training [30], or signal enhancement approaches [31] might prevent further deterioration in CAT performance. As degraded speech perception and overall degraded hearing have been linked with social isolation [18],

it is also important to identify these individuals and assist in rehabilitation efforts as quickly as possible.

This study was designed to ascertain how longitudinal performance on CATs relates to neurocognitive performance in a cohort of HIV-negative and HIV-positive individuals. We hypothesized that the diffuse white matter disease associated with HIV infection would affect central auditory processing progressively [4,32,33]. This suggests that the effects of HIV on the CNS could be tracked with CATs, which are quantitative, time-efficient, and repeatable. If CATs have reasonable sensitivity and specificity for detecting concurrent cognitive problems, they would offer an effective surveillance metric to follow individuals with ongoing HIV infection, and could perhaps change how HIV patients are medically monitored. This would provide valuable public health information to monitor, track, and potentially predict cognitive decline due to HIV.

Methods

Recruitment

We recruited participants in this study from a unique cohort of approximately 670 HIV-positive and HIV-negative individuals in Dar es Salaam, Tanzania, who have been performing central auditory, peripheral auditory, and cognitive testing at approximate 6-month intervals for the last 4 years. The research protocol was approved by the Committee for the Protection of Human Subjects of Dartmouth College and the Research Ethics Committee of Muhimbili University of Health and Allied Sciences. All participants provided written informed consent.

Study Procedures

Subjects completed a series of questionnaires, and performed cognitive and auditory tests at the Infectious Disease Center in Dar es Salaam, Tanzania. The questionnaires gathered data on the participants' self-reported hearing ability (hearing status questionnaire) and general health (health history questionnaire). The questions covered noise exposure, tinnitus, ear drainage, ear infections, chemical exposure, and balance problems. The questionnaire also asked about past or current tuberculosis treatment; HIV treatment; gentamicin exposure; and the use of antimalarials, aspirin, and diuretics. All participants completed testing at approximately 6-month intervals; not all participants adhered to the schedule and some dropped out of the study during this time.

To ensure accuracy of longitudinal analysis, and control for variables that could affect central auditory and cognitive function tests, we used a series of data selection techniques. First, individuals were excluded if they only completed 3 or less visits. Second, data from visits beyond 3.5 years were excluded to limit bias from the subset of subjects with longer follow up (ie, a few subjects with long follow-up times could have greater leverage in the model). Third, individuals were excluded if they had abnormal hearing sensitivity (>25 dB HL from 0.5 to 4 kHz) or abnormal middle ear function. Fourth, individuals were also excluded if they had a positive history of ear drainage, concussion, significant noise or chemical exposure, neurological disease, mental illness, ototoxic antibiotics (eg, gentamycin), or chemotherapy. This selection technique resulted in a final sample of 382 individuals.

Peripheral Auditory Tests

Peripheral auditory tests included tympanometry and audiometry after otoscopy with cerumen removal as needed to ensure a clear ear canal. A Madsen Otoflex 100 system (GN Otometrics, Denmark) was used to perform tympanometry at 226 Hz. Measurements of ear canal volume, static admittance, tympanometric peak pressure, tympanometric width, and tympanogram type (A, A_s, A_d, B, C) were collected. Type A tympanograms (including A_s and A_d) were required for inclusion in this study, with pressure limits from –100 to +50 daPa and static admittance limits from 0.3 to 1.7 milimho.

Pure-tone air conduction thresholds were measured at frequencies of 0.5, 1.0, 2.0, and 4.0 kHz using a Békésy-like tracking procedure as previously described [33]. Pulsed tones with a duration of 250 milliseconds, a rise and fall time of 20 milliseconds, and an interstimulus interval of 500 milliseconds were used. When the button was pressed, the tone decreased in 4-dB steps until the first reversal, and then 2-dB step decreases were used. Upon releasing the button, the tones increased in 2-dB steps. A total of six good reversals were counted to identify the threshold. Normal peripheral hearing sensitivity (<25 dB HL from 0.5 to 4 kHz) was required for all subjects.

Audiometry and all behavioral audiometric testing were completed using a Creare LLC wireless automated hearing test system (WAHTS) controlled through a laptop. The WAHTS allowed for testing in rooms with minimal background noise, as the device speakers are mounted in the ear cups. The attenuation provided by this headset is on par with a portable sound booth as measured by an independent laboratory according to the relevant American National Standards Institute standards [34]. This technology provided a platform to complete high-quality audiometry and CATs in a resource-limited setting. In addition, the WAHTS included Kiswahili language versions of the CATs.

CATs

CATs included the Hearing In Noise Test (HINT), Triple Digit Test (TDT), and gap detection test (GAP). The HINT was administered in four test conditions: noise front, noise right, noise left, and quiet. In each HINT, a different list of 20 sentences was presented in random order in the presence of the masking noise spectrally matched to the long-term average of the target material. The presentation level of the noise remained fixed at 65 dB (A-weighting), and the test instrument adjusted the level of each sentence adaptively depending on whether the test administrator indicated that the previous sentence was repeated correctly. The presentation level of the sentence was reduced if the previous sentence was repeated correctly and was increased if the previous sentence was repeated incorrectly. This adaptive procedure was used to determine the presentation level of each sentence in the list. The average presentation level of all sentences after the first four sentences defined the speech reception threshold for the test condition expressed as a signal-to-noise ratio (SNR). The WHATS displayed and recorded the SNR for each test condition. A composite SNR of

all three noise conditions was calculated and used as the primary variable of interest for the HINT.

In the TDT, recordings of natural productions of three-digit triplets such as 3-5-9 (spoken as "tatu-tano-tisa" in Kiswahili) were used as target stimuli (Kiswahili numbers below 10 have the same number of syllables). All digit triplets were produced and recorded by a male speaker in a soundproof booth. Triplet digit recognition was tested in the presence of competing Schroeder-phase masking noise. The test included 30 total presentations of pseudorandom triplet digits with six practice presentations. Presentations were delivered in pairs of positive- and negative-phase maskers. Each pair was presented at the same SNR, and the order of the masker was randomized for each pair. The test started at a 0 dB initial SNR with the masker fixed at a 75 dB sound pressure level. SNRs were then adjusted after each presentation or pair of presentations by varying the target level; a 1.5 dB sound pressure level was added to the target level for each incorrect digit and a 1.5 dB sound pressure level was subtracted for each correct digit from the previous positive-phase presentation. The speech reception threshold was calculated as the SNR of the last 14 positive-phase presentations, which was used as the primary variable of interest.

We also implemented an adaptive GAP test to evaluate temporal auditory processing. The adaptive gap detection algorithm applies a single staircase and has been used extensively in our previous studies [4,33,35]. In the algorithm, the gap length is shortened when the subject correctly identifies two gaps in a row. If the subject misidentifies two gaps in a row or three gaps overall, the staircase "reverses," and the gap length increases. In this way, the staircase algorithm converges to the subject's gap threshold. The subjects received training in the GAP test with both a training video and a screen that provided both auditory and visual feedback. The operator presented gaps to the subject until the subject comprehended the task.

Cognitive Tests

We used three cognitive tests: the Montreal Cognitive Assessment (MoCA), the Tests of Variables of Attention (TOVA), and selected subtests from the Cogstate battery. The MoCA was used to assess the participants' general cognitive abilities and screen for potential cognitive impairment [36]. Questions on the MoCA focus on the areas of visual-spatial abilities (cube and clock drawing), executive function (trail making, verbal abstraction, and word fluency), learning and delayed recall, attention (target detection, serial sevens subtraction, and forward and backward digits), language (sentence repetition and verbal fluency), and orientation to time and place [36].

The TOVA (TOVA Company, Los Alamitos, CA, USA [37]) was used as an objective, computer-based series of tests that measure the attention and speed of processing to visual stimuli [38]. In the developed world, these measurements are compared to previously established norms; however, we used the HIV-negative group as the source of norms for the test. The TOVA has several advantages, including the use of visual stimuli, measurement of response times precisely (±1 millisecond), is language- and culture-free, and has a history of use in resource-challenged areas [38]. The visual component was used for this study, since this complements the auditory results from CATs. This attention component was important because the CATs (GAP, HINT, TDT) require sustained attention, and poor performance on these tests could be due to either difficulty in processing sound or a general difficulty in maintaining attention. Individuals who have difficulty with both the visual component of the TOVA as well as CATs may have a more generalized cognitive dysfunction related to processing speed or attention. For this project, we used the total mean response time (to the correct responses across the entire test), total exponentially modified Gaussian (ExGaussian) μ (mean response time of the correct responses modeled using the ExGaussian distribution), and attention comparison score (a composite score comparing the subject's performance to a study of independent individuals diagnosed with attention deficit hyperactive disorder). Mean response time and ExGaussian μ were chosen to provide a direct measure of speed of processing. Particularly, ExGaussian μ provides a more precise distribution of response times to better assess processing speed [39,40]. Response times do not follow a normal Gaussian distribution due to factors such as fatigue and sequential effects [41]. Instead, response time distributions rise rapidly after stimulus presentation and have a long positive tail. This type of distribution is similar to the ExGaussian distribution [42], which is a mixture of a Gaussian and an exponential distribution that has been shown to fit response time distributions accurately [40]. The attention comparison score was chosen as a broad measure of inattention and impulsivity related to response time, omission error, and commission errors. Adults suffering from attention deficit hyperactive disorder or other cognitive disorders generally show variable processing speed with increased inattention (omission errors) or impulsivity (commission errors) [43].

The final cognitive test battery, the Cogstate battery [44], was chosen because it uses culturally neutral stimuli (eg, playing cards) to ensure that the assessment is not limited by a participant's level of education. Card games are popular in Tanzania, and therefore the card-playing approach was familiar to the cohort. The Cogstate tasks are computer-based and designed for repeated administration. The Cogstate battery has been used to assess cognitive function in patients with HIV and has been shown to correlate well with standard neuropsychological test batteries [45-48]. For this project, we used the tests for visual learning and memory (One Card Learning Task, Continuous Paired Associate Learning Task, and Groton Maze Learning Test-with Delayed Recall) and attention/working memory (One Back Test). The One Back test also assessed processing speed. These tests were chosen to assess a broad range of executive functioning related to latent cognitive decline in HIV [32,38,46] and central auditory processing [10,17,18].

Study Groups

To test the applicability of CATs to track cognitive function over time, we created four experimental groups. The first group consisted of HIV-negative individuals. We used this group to create normative values for each central auditory and cognitive test. To divide the HIV-positive group on the basis of CAT performance, we used a combination of transformed *z*-scores

(using the scores of HIV-negative subjects as the standard) from the three CAT measures. That is, the HIV-negative group served as a normative reference for CAT performance for the HIV-positive group. Using the three CAT measures also ensured that those with poor central auditory function were identified accurately and not misclassified based on an outlier from an individual test. This combination score was based on the CAT results from the last visit (ie, the latest visit over the course of 3.5 years). The last visit was chosen since this should yield the greatest reductions in cognitive function due to time. We also noticed a learning effect across both cognitive tests and CATs over the course of the study (ie, scores improved over time). Therefore, identifying CATs at the last visit helped to mitigate this learning effect in the data analysis. In other words, by the last visit, subjects would have had ample time to learn the test; therefore, if the test results were still poor, we could interpret that as a deficit in central auditory processing.

Three groups were created based on the combination CAT score. One group included HIV-positive individuals whose performance on the GAP, HINT, and TDT combination *z*-score was in the top 20% (0.80 quantile, designated "TopCATs") and the other group included HIV-positive individuals in the bottom 20% (0.20 quantile, designated "BottomCATs") of the entire cohort at the time of their last visit. We hypothesized that those in the bottom 20% at the time of their last visit would be subjects with poor central auditory processing and cognitive function. The final group was created by simply taking all of the HIV-positive individuals that did not qualify in the TopCATs or BottomCATs category (HIV-positive group). This preliminary analysis resulted in four study groups: (1) HIV-negative, (2) HIV-positive, (3) TopCATs, and (4) BottomCATs.

Statistical Analysis

Analyses were conducted using linear mixed-effects models with MATLAB 2020a (Mathworks, Natick, MA). Response variables included measures from the TOVA, Cogstate, and total score on the MoCA. Fixed effects included group (HIV-negative, HIV-positive, TopCATs, BottomCATs), age at last visit, and time between tests. Random effects included individual subject result variation over time. Using age and time as fixed effects allowed for analyses of cross-sectional age differences between subjects and longitudinal changes within subjects across time. This approach was developed by Laird and Ware [49] to study longitudinal epidemiological changes [50] and even changes in hearing loss [51].

We calculated *z*-scores for individual TOVA variables and Cogstate subtests using the HIV-negative cohort as the reference sample. We then calculated global scores of executive function, speed of processing, and central auditory scores from the *z*-scores using an approach similar to those proposed by Kamminga et al [48] and De Francesco et al [52]. These global scores allowed us to better understand the key domains of cognition, executive function, and speed of processing. The global executive score was calculated by combining all of the Cogstate subtest scores except the One Back Test (subtest of attention and processing speed) into a single variable of cognitive function. The global speed score was calculated for the TOVA subtests and One Back Test. The global hearing score was calculated from the GAP, HINT, and TDT. The primary hypothesis testing focused on the difference in the longitudinal change of cognitive variables between groups (interaction of time and group with age included in the model), specifically between the HIV-positive and BottomCATs groups, to better understand and track those with developing cognitive dysfunction due to HIV.

Results

Table 1 shows the demographic characteristics of the overall cohort and for each group. BottomCATs were significantly different in age and pure tone average (PTA; average audiometric thresholds of 0.5, 1.0, 2.0, and 4 kHz) from the other groups. The BottomCATs group was about 1.3 years older than the HIV-positive group. Although all audiometric thresholds were <25 dB HL for all groups, the BottomCATs group showed worse PTAs in both ears (about 1.15 dB in each ear) compared to the HIV-positive group. Years of education did not significantly differ between the HIV-positive and BottomCATs groups. However, MoCA scores were significantly different between these two groups. In general, the HIV-negative group was about 15 years younger than the HIV-positive group, and comprised more men than the other groups. TopCATs were 4 years younger and comprised more men compared with the BottomCATs. Years of education was also significantly different between TopCATs and BottomCATs (with about 1.1 more years of education in the TopCATs), and between the HIV-negative and HIV-positive groups (the HIV-negative group had about 1.4 more years of education).

Table 1. Demographic information.

Characteristic	Overall Cohort (N=382)	HIV-negative (n=90)	HIV-positive (n=164)	TopCATs[a] (n=53)	BottomCATs[b] (n=75)	*P* value[c]		
						HIV-negative vs HIV-positive	TopCATs vs BottomCATs	HIV-positive vs BottomCATs
Gender, n (%)								
Male	130 (34.0)	44 (49)	44 (26.8)	32 (59)	17 (23)	N/A[d]	N/A	N/A
Female	239 (62.7)	46 (51)	119 (72.6)	21 (41)	58 (77)	N/A	N/A	N/A
Age (years), mean (SD)	37.8 (14.8)	25.9 (11.8)	40.8 (13.6)	38.1 (12.8)	42.1 (8.4)	<.001	.001	.001
PTA[e], mean (SD)								
Right ear	7.62 (6.1)	3.93 (6.8)	7.25 (5.2)	5.06 (5.2)	8.42 (8.2)	<.001	.001	.02
Left ear	6.43 (6.6)	3.53 (7.2)	6.87 (5.9)	5.88 (5.0)	7.29 (6.1)	<.001	.001	.03
Education (years), mean (SD)	9.01 (2.7)	10.23 (2.6)	8.83 (2.6)	9.7 (2.3)	8.62 (2.8)	<.001	.001	.34
MoCA[f], mean (SD)	27.6 (3.0)	28.2 (3.4)	27.2 (3.1)	27.9 (2.8)	26.7 (3.3)	.009	.01	.04

[a]TopCATs: in the top 20% of central auditory test results for HIV-positive individuals.

[b]BottomCATs: in the bottom 20% of central auditory test results for HIV-positive individuals.

[c]Based on two-sample *t* tests.

[d]N/A: not applicable.

[e]PTA: pure tone average (0.5, 1.0, 2.0, 4.0 kHz).

[f]MoCA: Montreal Cognitive Assessment.

Table 2 shows the results of the linear mixed models examining the β estimate of time (ie, slope), interaction of age and group, and interaction of time and group on CATs and cognitive variables of the MoCA, TOVA, Cogstate, and global scores. The comparison of HIV-positive and BottomCATs over time (time×group interaction) was of interest to analyze the longitudinal change in cognitive variables over time. HIV-positive was selected as the reference variable and HIV-negative was omitted from the model results, as the HIV-negative group was significantly younger than the HIV-positive group. The main effects of age and time are also omitted in the table (although age was included in the model) as they generally showed significant effects across all models due to the age difference in the HIV-negative group (younger HIV-negative subjects generally performed better over time). The interaction of age and group was of interest due to the significant difference between the HIV-positive and BottomCATs groups. That is, if the interaction of age and group was significant between the HIV-positive and BottomCATs groups, this effect could have mediated the interaction of time and group. Results of the interaction of age and group showed no significant differences between the HIV-positive and BottomCATs groups across all experimental variables, although the TOVA response time did approach significance (*P*=.057). Overall, the results are consistent with BottomCATs displaying a significant difference in trajectory over time compared to the HIV-positive group (interaction of time and group) in multiple cognitive subsets and derived global scores. Individual *P* values indicating a difference in slope are shown in Table 2 (β estimate of time) and are discussed below for CATs (Figure 1), cognitive subtests (Figure 2), and global scores (Figure 3).

Table 2. Results of linear mixed effect models.

Variable	Time estimate (slope, β)			Age×group *P* value			Time×group *P* value		
	HIV+	Top[a]	Bottom[b]	HIV+	Top	Bottom	HIV+	Top	Bottom
CATs[c]									
Gap detection threshold (ms)	-4.22×10^{-4}	-7.01×10^{-4}	-5.33×10^{-4}	Ref[d]	.54	.45	Ref	.03	.43
HINT[e] (SRT[f])	-4.68×10^{-4}	-5.61×10^{-4}	-4.10×10^{-4}	Ref	.53	.16	Ref	.17	.89
TDT[g] (mean SNR[h])	-8.93×10^{-4}	-9.01×10^{-4}	2.16×10^{-4}	Ref	.32	.92	Ref	.99	<.001
MoCA[i] (total score)	15.5×10^{-4}	12.5×10^{-4}	-1.96×10^{-4}	Ref	.19	.99	Ref	.56	.003
TOVA[j]									
Response time (mean)	5.70×10^{-4}	4.91×10^{-4}	2.19×10^{-4}	Ref	.63	.06	Ref	.47	.007
ExGaussian[k] μ (mean response time)	3.55×10^{-4}	1.01×10^{-4}	0.942×10^{-4}	Ref	.47	.23	Ref	.08	.048
Attention comparison score	4.50×10^{-4}	3.42×10^{-4}	4.08×10^{-4}	Ref	.72	.29	Ref	.09	.13
Cogstate battery tests									
Groton maze learning (moves per second)	1.05×10^{-4}	0.721×10^{-4}	0.511×10^{-4}	Ref	.84	.69	Ref	.18	.046
Groton maze learning (total errors)	13.8×10^{-4}	11.3×10^{-4}	6.15×10^{-4}	Ref	.24	.16	Ref	.45	.03
One Card Learning (accuracy)	3.86×10^{-4}	2.95×10^{-4}	0.761×10^{-4}	Ref	>.99	.71	Ref	.78	.08
One Back Test (reaction time)	13.2×10^{-4}	9.12×10^{-4}	10.9×10^{-4}	Ref	.62	.18	Ref	.06	.16
Continuous paired associate learning (accuracy)	4.44×10^{-4}	2.98×10^{-4}	4.05×10^{-4}	Ref	.28	.08	Ref	.16	.07
Global executive score[l]	9.61×10^{-4}	8.62×10^{-4}	7.31×10^{-4}	Ref	.47	.21	Ref	.30	.02
Global speed score[m]	3.04×10^{-4}	3.00×10^{-4}	0.511×10^{-4}	Ref	.35	.07	Ref	.89	.006
Global CAT score	3.59×10^{-4}	4.21×10^{-4}	0.540×10^{-4}	Ref	.45	.23	Ref	.58	.01

[a]Top: HIV-positive individuals in the top 20% of combined central auditory test scores.

[b]Bottom: HIV-positive individuals in the bottom 20% of combined central auditory test scores.

[c]CAT: central auditory test.

[d]Reference for comparison.

[e]HINT: Hearing In Noise Test.

[f]SRT: speech reception threshold.

[g]TDT: Triple Digit Test.

[h]SNR: signal-to-noise ratio.

[i]MoCA: Montreal Cognitive Assessment.

[j]TOVA: Tests of Variables of Attention.

[k]ExGaussian: exponentially modified Gaussian distribution.

[l]Combination of speed-of-processing subtests.

[m]Combination of executive functioning subtests.

Figure 1 shows the GAP, HINT, and TDT scores over time for each experimental group. Overall, the BottomCATs group showed poorer scores over time compared to all other groups. BottomCATs showed similar parallel trajectories in the GAP and HINT compared to the HIV-positive group. The TDT showed a significantly worse trajectory in the BottomCATs group compared to that of the HIV-positive group. This is consistent with BottomCATs neutralizing the learning effect seen across variables, exhibiting worsening scores over time.

Figure 2 shows the significant MoCA, TOVA, and Cogstate trajectories over time for each experimental group. Overall, these results are consistent with a trend of BottomCATs

displaying a difference in trajectory of cognitive variables over time. However, the Attention Comparison Score, Continuous Paired Associate Learning, One Back Test, and One Card Learning trajectories were not significantly different from those of the HIV-positive group (Table 2). Trajectories showed an overall improvement in scores in the HIV-negative, HIV-positive, and TopCATs groups, presumably due to a learning effect. Interestingly, the BottomCATs group exhibited a nearly flat trajectory over time and showed significantly different slopes compared to those of the HIV-positive group on the MoCA, TOVA response time, and ExGaussian μ (Table 2). The Cogstate Groton Maze Learning subtest showed similar results, displaying a significant difference in trajectory between HIV-positive and BottomCATs in moves per second and total errors (Table 2). That is, HIV-positive individuals who scored in the bottom 20% of CATs at the time of their last visit showed a difference in trajectory of cognitive results over time compared to the overall HIV-positive group in measures of both executive function (Cogstate Groton Maze Learning) and speech of processing (TOVA response time and ExGaussian μ).

Figure 3 shows the global scores derived from the TOVA and Cogstate subtests. Each global score showed a difference in trajectory between the HIV-positive and BottomCATs groups in the global executive score (derived from Cogstate subtests), global speed score (derived from TOVA subtests and One Back subtest from Cogstate), and global CAT score (derived from the GAP, HINT, and TDT) (Table 2). Particularly, the global speed score showed a nearly flat trajectory over time, which was similar to the MoCA trajectories.

Figure 1. Trajectory of central auditory tests over time. Time 0 is the first visit in the study. Subjects were tested at roughly 6-month intervals thereafter. The blue dashed line shows the slope of the HIV-negative group, the red line shows the slope of the HIV-positive group, the magenta line shows the slope of the TopCATs group, and the black line shows the slope of the BottomCATs group. GAP, HINT, and TDT scores were used in combination to create the TopCATs and BottomCATs groups. The lines were fit to the data using linear fitting procedure in MATLAB. CAT: central auditory test; TopCATs: HIV-positive individuals in the top 20% of CAT scores; BottomCATs: HIV-positive individuals in the bottom 20% of CAT scores.

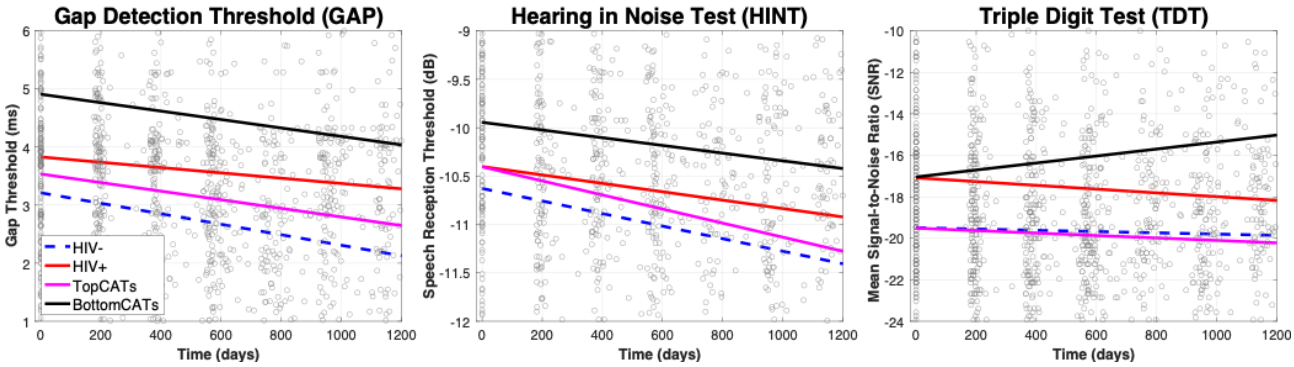


Figure 2. Trajectory of MoCA, TOVA, and Cogstate measures over time. The color scheme of lines for each group is the same as that in Figure 1. Cognitive measures of the TOVA and Cogstate were all transformed to z-scores using the HIV-negative group as normative values (the MoCA was not transformed). MoCA: Montreal Cognitive Assessment; TOVA: Test of Variables of Attention.TopCATs: HIV-positive individuals in the top 20% of central auditory test scores; BottomCATs: HIV-positive individuals in the bottom 20% of central auditory test scores.

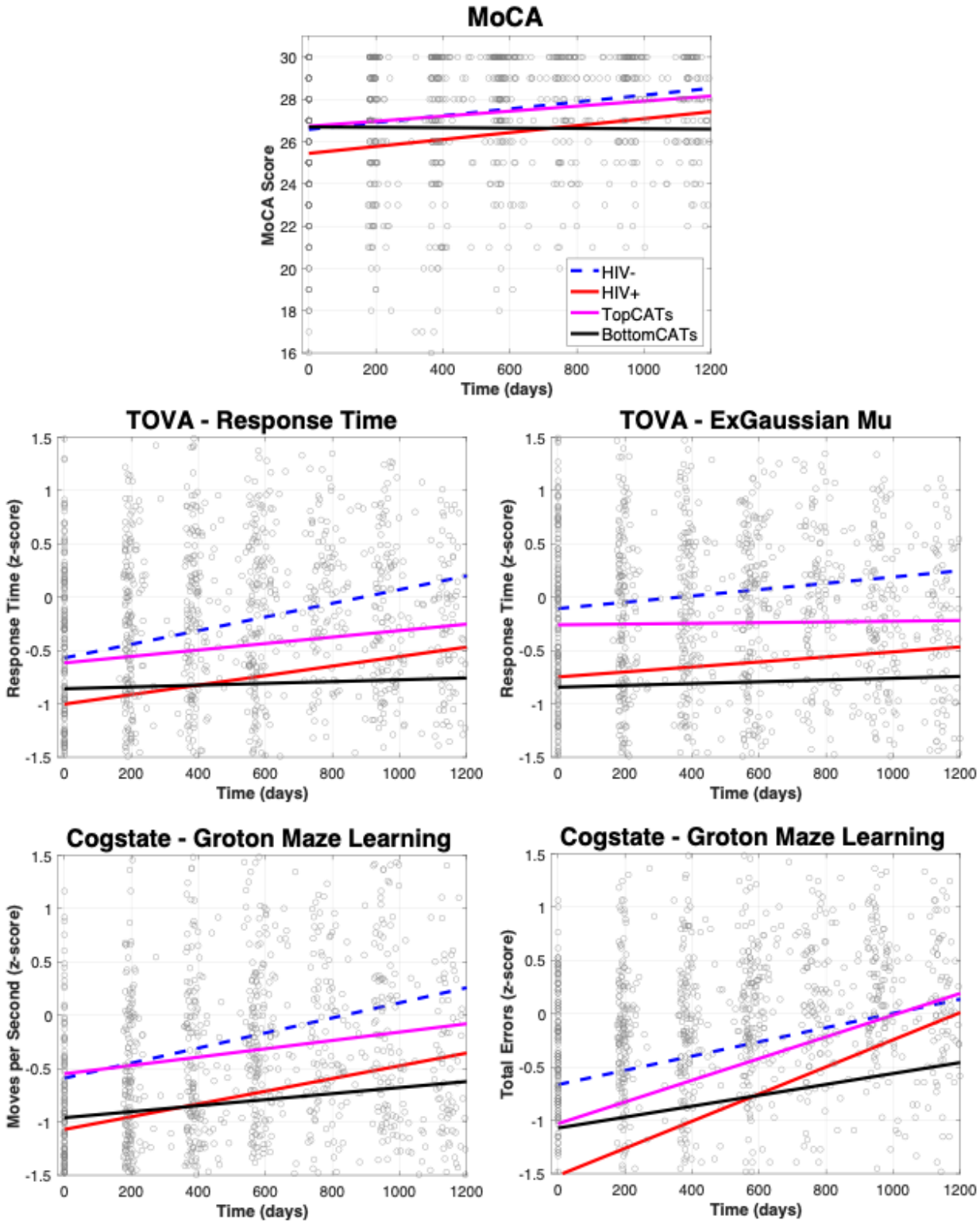
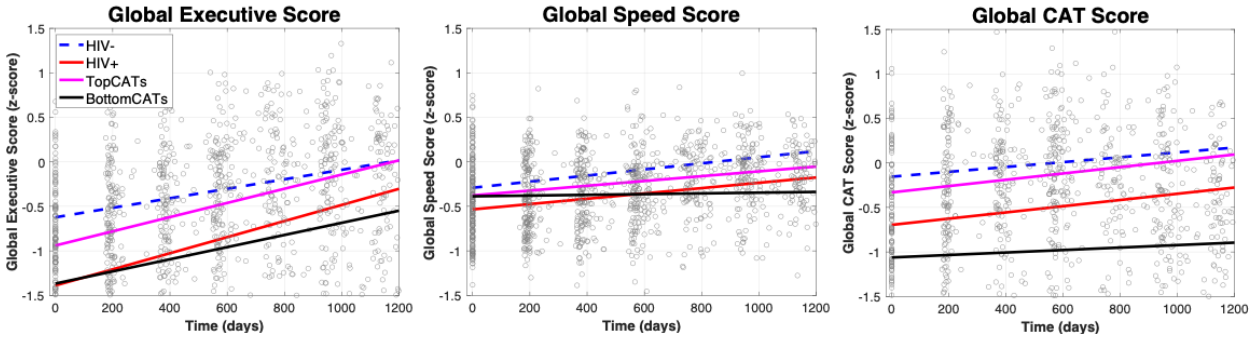


Figure 3. Trajectory of derived global scores over time. The color scheme of lines for each group is the same as that in Figure 1. CAT: central auditory test; TopCATs: HIV-positive individuals in the top 20% of central auditory test scores; BottomCATs: HIV-positive individuals in the bottom 20% of central auditory test scores.



Discussion

Principal Results

Among HIV-positive individuals, the trajectory of cognitive performance over time differed as a function of CAT performance. Over the time period studied, those individuals with HIV that fell in the bottom 20% on a combination of CATs either worsened or improved more slowly than the other groups. In contrast, both HIV-negative patients and HIV-positive patients with good CAT performance improved in their cognitive performance, potentially reflecting learning effects on the tasks. This suggests that CAT scores in those diagnosed with HIV are correlated with a worsening trajectory or failure to improve on measures of cognitive function.

Results from this study suggest that CATs may be a useful way to provide surveillance for the development of neurocognitive problems in people with HIV. Previous studies have suggested that HIV-positive individuals develop signs of central auditory processing deficits [8,33,53,54]. These deficits could reflect CNS damage from HIV infection or treatment. Even with advancing antiretroviral therapy, HIV-positive individuals may potentially develop neurocognitive deficits [1]. We aimed to build on this premise and have provided longitudinal evidence relating performance on a battery of three CATs to cognitive function in HIV-positive individuals. This study is the first to show that HIV-positive individuals with poor CAT performance (despite normal peripheral hearing) have a worse trajectory or fail to improve on measures of cognitive function over time compared with HIV-positive individuals with typical CAT scores. Since this is occurring despite otherwise normal hearing sensitivity up to 4.0 kHz, the changes in cognitive function over time may be explained by deficits in central auditory processing.

Results of this study also suggest that the main problems of CATs are in the domains of executive function and processing speed. This is evidenced by significant results on the MoCA, TOVA, Cogstate, and global scores. The MoCA displayed the strongest interaction (P=.003) and also showed a negative trajectory over time (slope -1.96×10^{-4}) for the BottomCATs group. The MoCA has been shown to be a relatively sensitive measure of cognitive dysfunction in HIV-positive individuals [55,56]. TOVA and Cogstate subtests also showed a significant difference in the trajectory of cognitive variables over time, but one TOVA subtest (Attention Comparison Score) and three Cogstate subtests (Continuous Paired Associative Learning, One Back Test, One Card Learning) did not show the same pattern. This could have been due to various factors such as variability of the subtests, elevated learning effects, or that these subtests are not sensitive to cognitive dysfunction in the experimental HIV cohort. By contrast, global scores, which included these nonsignificant variables, resulted in significant differences in trajectories over time. With the combination of speed and executive variables in global scores (global executive, global speed), the correspondence of cognitive performance to BottomCATs as an indicator of neurocognitive dysfunction became more robust. These global scores emerged as strong between-group trajectory differences between the HIV-positive and BottomCATs groups beyond the individual variability, to which singular cognitive measures are particularly susceptible. The combination of MoCA, TOVA, Cogstate, and global scores further supports the interpretation that CATs are sensitive in the detection of a cognitive dysfunction in those diagnosed with HIV.

HIV-positive individuals with poor central auditory function also showed degradations in processing speed on a variety of cognitive subtests over time. For example, the mean response time and ExGaussian μ on the TOVA, moves per second on the Groton Maze Learning, and the global speed score showed significant differences in trajectory of those with poor CAT scores over time. Although age could undoubtedly have an effect on processing speed, the interaction between age and group was not significant in any of the linear mixed effect models. Processing auditory information quickly is essential for accurate communication, and the link between cognitive processing speed and CATs has been extensively studied [57-59]. Speech perception, specifically in background noise, places a substantial burden on processing speed, attention, and working memory. Unlike written text, speech processing is carried out in real time, with words coming in at a rapid rate of 120 to 180 words per minute, without opportunity for the listener to go back and review previous material [18]. In background noise, this complex process places even more demands on cognitive processing speed.

One interpretation of our results could be that some individuals with HIV experience an accelerated aging process. That is, HIV could be associated with accelerated cognitive aging such that a subset of people with HIV in their 40s and 50s are functioning with a cognitive processing speed typical of that found in people

in their 60s and 70s. Cognitive and central auditory deficits in adults with HIV may result from additive effects of the pathophysiological mechanisms of aging (ie, the "common cause" hypothesis [60]) and HIV [61]. Previous longitudinal studies on HIV have shown significant interaction effects of HIV and age [62,63], suggesting that these mechanisms may be associated. For example, Seider et al [51] showed that older adults with HIV exhibited significant memory decline over the course of 1 year, but no decline was seen in younger adults with HIV or in HIV-negative controls regardless of age. Although problems with learning and memory are more typically reported in those with HIV [1,32], previous studies have also found deficits in processing speed [64-66]. If we interpret subjects in the BottomCATs group as those with accelerated aging, then the results are consistent with the aging and central auditory processing literature [57,67,68]. For example, robust effects of age on auditory temporal processing have been revealed when using complex tasks or stimuli [57,69]. Furthermore, robust age-related differences in gap detection have been observed when the markers surrounding a silent gap are shorter than 10 milliseconds [70] and when the location of the gap falls near the onset or offset of the stimuli, or is varied randomly [71]. These previous results in combination with this study suggest that accelerated aging due to HIV as evidenced by degraded cognitive speed-of-processing tests may be revealed by central auditory processing.

Future studies should seek to examine executive functioning and speed of processing in the central auditory pathway in HIV-positive individuals to improve upon surveillance of this public health concern. Declines in general cognitive processing speed have been considered a hallmark of the aging process, beginning in young adulthood and continuing nearly linearly across the lifespan [58]. However, it may be that the process in HIV-positive individuals has an altered slope or is nonlinear. It may also be that changes to neurocognitive function—and thus central auditory processing—are attributed to changes in earlier or automatic levels of processing, causing a cascade of degradations along the pathway. Neuroimaging research has confirmed age differences in brain activity related to processing speed, particularly in areas of the prefrontal cortex [72], as well as hearing-related differences in patterns of brain activation [73]. The exact links remain to be determined, but such structural and functional changes provide a mechanism for linking sensory and cognitive changes with age and HIV [54]. Finally, a more difficult central auditory task may be more sensitive to detecting HIV-related neurocognitive disorders with age. Although the CATs used in this study are not simple, adults with HIV may compensate for declines in early stages of auditory processing by exerting increased cognitive control or attention [74,75]. Consistent with this hypothesis, Alain et al [63] observed age-related differences in event-related potential amplitudes during passive listening in a simple gap detection task, but not with active listening, which may reflect a decline in automatic processing of temporally modulated stimuli compensated by attentional processes [63].

Limitations

This study has limitations. The main limitation in interpreting the cognitive variables accurately over time was an overall learning effect. Although previous results have shown minor learning effects on these cognitive variables [76,77], we observed an overall trend for cognitive scores to improve over time. This could have been due to two factors. First, the subjects were learning how to execute the tests more accurately every time they came in for a visit. Even though 6 months between visits could be considered a long enough time to limit learning effects [9,78], we observed a general improvement over time in all cognitive tests. Second, the test administrators may have improved at conducting the tests. As stated previously, cognitive testing typically requires trained personnel to administer the tests. Although the test administrators were well trained at the onset of the study, it is possible that they became more proficient in explaining and instructing the cognitive tests over time. Nevertheless, the data show that examining the trajectory of cognitive change over time is important, rather than cross-sectional analysis.

Another limitation is that this study was conducted over a 3.5-year period, which is not an exceptionally long time to develop cognitive decline due to HIV. These data were from an ongoing project in Dar es Salaam, Tanzania. More time is needed for more individuals to complete multiple visits and for deterioration in neurocognitive performance to develop to fully answer the question of whether CATs can predict future cognitive decline. This study was only able to show the association.

Differences in PTA may have affected the results. Although normal hearing sensitivity from 0.5 to 4.0 kHz was required for inclusion, the difference in hearing thresholds (ie, the difference in PTA between the BottomCATs and HIV-positive groups) might have affected the CAT results. Although it is unlikely that an averaged difference for both ears of 1.2 dB in PTA affected the results, it is possible that peripheral hearing sensitivity also factored into the trajectory of cognitive variables over time. This could, however, also be related to damage not reflected in hearing thresholds, such as damage to the synapses between hair cells and the cochlear nerve or further along the auditory pathway. Studies have suggested that peripheral hearing sensitivity is not a comprehensive picture of auditory function [79-81].

Conclusions

The overall results from this study suggest that CATs may be useful to track cognitive function over time in people with HIV. This could provide an easy-to-use, quick method of surveillance for this important public health problem. Subjects that performed in the bottom 20% of a battery of three CATs had a significantly different trajectory of cognitive variables over time, suggestive of cognitive dysfunction. The cognitive dysfunction seen was consistent with a failure to improve or decrease in executive functioning and speed of processing in those with poor central auditory function over time. This study supports the ideal that CATs should be studied further to track cognitive dysfunction in those with HIV-related cognitive deficits.

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Authors' Contributions

CN performed the statistical analysis and data interpretation, and was primarily responsible for writing the manuscript. AF was primarily responsible for training and study management; she assisted with study design, data analysis, and data interpretation. JL and TS assisted with data analysis and data interpretation. AM was primarily responsible for study management in Tanzania, enrolling patients, and data review. JG assisted with statistical analysis. OC assisted with study design, test development, and data analysis. EM assisted with study management, data analysis, and interpretation. NM assisted with study design and was primarily responsible for study oversight in Tanzania. MB assisted with cognitive data interpretation. NK assisted with study design, data analysis, and data interpretation. JB was the principal investigator, and was involved in study design, training, data analysis, and data interpretation. All authors assisted with revising the final work and approved the final version to be published. All authors agree to be accountable for all aspects of the work and ensuring that questions about the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Conflicts of Interest

None declared.

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Abbreviations

CAT: central auditory test
CNS: central nervous system
ExGaussian: exponentially modified Gaussian distribution
GAP: gap detection threshold
HINT: Hearing In Noise Test
MoCA: Montreal Cognitive Assessment
PTA: pure tone average
SNR: signal-to-noise ratio
TDT: Triple Digit Test
TOVA: Tests of Variables of Attention
WHATS: wireless automated hearing system

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Original Paper

COVID-19–Induced Fear in Infoveillance Studies: Pilot Meta-analysis Study of Preliminary Results

Styliani Geronikolou[1], BSc, MSc, PhD; George Chrousos[1], MD, PhD

University Research Institute of Maternal and Child Health and Precision Medicine, National and Kapodistrian University of Athens, Athens, Greece

Corresponding Author:
Styliani Geronikolou, BSc, MSc, PhD
University Research Institute of Maternal and Child Health and Precision Medicine
National and Kapodistrian University of Athens
Levadias 1
Athens
Greece
Phone: 30 2132013362
Email: sgeronik@gmail.com

Abstract

Background: The World Health Organization named the phenomenon of misinformation spread through social media as an "*infodemic*" and recognized the need to curb it. Misinformation infodemics undermine not only population safety but also compliance to the suggestions and prophylactic measures recommended during pandemics.

Objective: The aim of this pilot study is to review the impact of social media on general population fear in "*infoveillance*" studies during the COVID-19 pandemic.

Methods: The PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) protocol was followed, and 6 out of 20 studies were retrieved, meta-analyzed, and had their findings presented in the form of a forest plot.

Results: The summary random and significant event rate was 0.298 (95% CI 0.213-0.400), suggesting that social media–circulated misinformation related to COVID-19 triggered public fear and other psychological manifestations. These findings merit special attention by public health authorities.

Conclusions: Infodemiology and infoveillance are valid tools in the hands of epidemiologists to help prevent dissemination of false information, which has potentially damaging effects.

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KEYWORDS

COVID-19; social media; misinformation; infodemics; infodemiology; infoveillance; fear; meta-analysis

Introduction

The COVID-19 pandemic has raised health care, hospitalization, and research demands in an exponential manner. Apart from the burden of the confirmed cases and the high mortality rates, this pandemic has strained the public health systems of several countries. The World Health Organization (WHO) characterized this outbreak as a Public Health Emergency of International Concern [1,2]. In addition, the WHO identified potentially damaging misinformation spread through social media, or "*infodemics*," and recognized the need to curb it [3]. Indeed, citizens from all over the world were exposed to a plethora of information and misinformation, especially through social media, while public health authorities wrestled to broadcast evidence-based important information. *Infodemics* undermine compliance to health authority suggestions and prophylactic measures, and hence, compromises population safety. Moreover, misinformation challenges self-respect, personal rights, and survival instincts, causing fear, anxiety, panic, depression, and unpredictable behaviors such as violence and suicidal thoughts in the general population.

A recent systematic review recognized an increasing trend in studying social media misinformation during and after epidemics [4]. Previous reviews have illustrated the psychological and physical distress in health care professionals due to COVID-19 [5] and previous infectious epidemics [6,7]; however, the general population's fear and behavioral expressions are yet to be established. Massive fear may trigger unpredictable social processes and may result in posttraumatic stress disorder (PTSD) [8]. The attempt to collect and interpret data from social media

may reveal the dominant stressors in the epidemic, as well as information on personal and business communications. "*Infodemiology*" is a rapidly growing research field that collects internet data for epidemiologic and other public health needs [9,10]. The aim of this pilot study is to review the impact of social media on the negative sentiments of the general population in published "*infoveillance*" studies.

Methods

Databases such as MEDLINE and PUBMED (The National Library of Medicine) were searched using the keywords "infodemics COVID-19" or "fear due to COVID-19 social media misinformation" or "infodemiology and COVID-19" or "COVID-19 and social media impact on mental health." The literature search was conducted in mid-May 2020. The articles meeting the eligibility criteria were evaluated by the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines [11] (Multimedia Appendix 1).

The inclusion criteria were English language studies related to social media, fear, and infoveillance data retrieved from social media. Reviews, meta-analyses, and opinion articles were excluded from this analysis. Two of the authors (SG and GC) searched and screened articles, and agreed on their quality; the articles were scored using the Newcastle-Ottawa Scale for risk of bias evaluation (Multimedia Appendix 2). The Cohen kappa for interrater agreement was 90% (0.66) for the abstract selection but 96% for the full inclusion of the study. Any disagreement was addressed by mutual consensus.

The population targeted was social media users expressing fear (posts; P) because they had been exposed to misinformation during the first phase of the COVID-19 pandemic (E) in comparison to the total posts of the specific social media during the same period (C). The outcome (O; "events" or fear posts) were presented in effect sizes and calculated as event rates (p = events / total reference population; the proportion of patients and events in a group in which the "event" is observed). We further calculated:

Event Rate p = event / total **(1)**

logit (LogitEventRate = Log(p / (1 – p)) **(2)**

where LogitEventSE = Sqr(1 / (p * Total) + 1 / ((1 – p) * Total)) **(3)**

or EventRate = (e ^ LogitEventRate) / (e ^ LogitEventRate + 1) **(4)**

The probability of fear (f): f = ExpLogit / (1 + ExpLogit) **(5)**

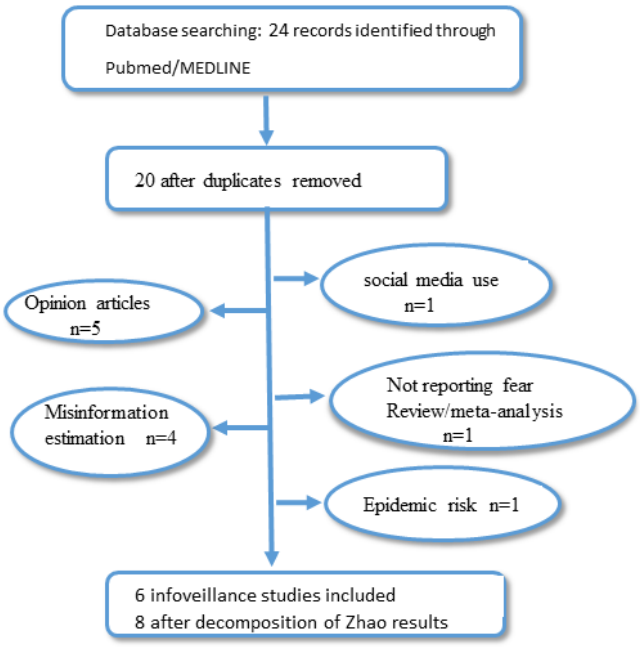
In this analysis, we applied and presented the random effects model, which assumes that the data being analyzed are drawn from a hierarchy of different populations [12]. We calculated the heterogeneity with I^2 [13,14] and τ^2 [15,16]. All calculations were performed in R software (R Foundation for Statistical Computing). The results are presented with their 95% CIs, and in the summary results, 95% prediction intervals were also estimated with Higgins et al's [17] formula. Lwin et al [18] did not report absolute patient numbers but daily proportions. Thus, we estimated these numbers by calculating the mean from the first figure of the relevant publication.

Results

Of the 20 studies retrieved originally [1,3,5,18-34], only 6 met the inclusion criteria [18,20-24].

One referred to the epidemic risks [34], 5 expressed opinions on infodemics [1,3,27,32,34], 1 counted social media use [25], 1 was a meta-analysis on depression and anxiety [5], and 4 estimated misinformation [19,26,29,31,33], and these were excluded from this study (Figure 1). As the Zhao et al [24] publication included three phases, we considered each phase as a separate study; thus, we summarized the results of 8 studies. We also included the Ahmad and Murad [20] and Gebbia et al [23] studies, even though they were actually surveys, because they were performed with data from Facebook and WhatsApp, respectively, and reported results on fear.

Figure 1. Flow chart.



The studies included herein had processed over three million social media events (Facebook, YouTube, Twitter, WhatsApp, and similar versions in China) from over 170 countries, with messages expressed in seven languages (Table 1). In sum, out of 20,330,510 posts referring to COVID-19, 8,741,601 were retrieved that expressed fear. These studies were meta-analyzed using event rates, and their random effect is presented in Figure 2 and Table 2. The calculated LogitEventRate random effect was 0.746 (95% CI –1.176 to –0.315), while the summary odds was calculated as 0.475 (95% CI 0.3086 to 0.7295; 95% prediction intervals 0.1018 to 2.2119; Tables 2 and 3). The probability was 0.322. When we excluded the Gebbia et al [23] study, the random effect LogitEventRate was –0.907 (95% CI –1.387 to –0.428; 95% prediction intervals –2.6052 to 0.7903; SE 0.245; variance 0.06; probability 0.288; Tables 2 and 3). The Ahmad and Murad [20] study reported observations on Facebook (82.6%) and other social media sources; the observations were reported unstratified, and the results were presented as Facebook results.

Table 1. Studies characteristics.

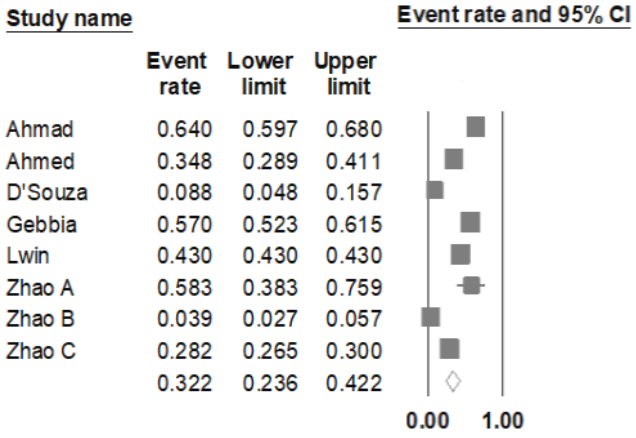
Study	Age (years)	Gender (male/female), n	Total messages screened, n	Messages expressing fear, n	Social media
Ahmad and Murad (2020) [20]	18-35: 65.1%; >51: 6%	222/336	516	330	Facebook[a]
Ahmed et al (2020) [21]	__[b]	—	233	81	Twitter
D'Souza et al (2020) [22]	—	—	113	10	YouTube
Gebbia et al (2020) [23]	Range 34-90	190/252	446	254	WhatsApp
Lwin et al (2020) [18]	—	—	20,325,929	8,740,150	Twitter
Zhao et al (2020) [24], part A	Range 18-41	—	24	14	Sina microblog
Zhao et al (2020) [24], part B	Range 18-41	—	639	25	Sina microblog
Zhao et al (2020) [24], part C	Range 18-41	—	2610	737	Sina microblog
Total	N/A[c]	N/A	20,330,510	8,741,601	N/A

[a]82.6% of the observed messages came from Facebook.

[b]Data was not available.

[c]N/A: not applicable.

Figure 2. Forest plot of fear random event rates 95% CI due to Covid-19 surge retrieved by infodemics.



Sexual dimorphism was reported in 2 studies [20,23] in which women circulated more fear- inducing misleading posts. The methodology of the remaining studies did not include any relevant calculations, so the gender prevalence could not be taken into account.

The social media type probabilities are listed in Table 4. Of those, the Twitter-induced fear probability, as well as the overall probability, might be considered most credible (including many countries, ethnicities, and languages).

Table 2. Meta-analysis results.

Study	Event rate (95% CI)	Logit (95% CI)	SE	Variance	Weight random	Residual random (event rate)
Ahmad and Murad (2020) [20]	0.64 (0.597 to 0.680)	0.57 (0.394 to 0.753)	0.0917	0.008	13.53	2.38
Ahmed et al (2020) [21]	0.348 (0.289 to 0.411)	–0.63 (–0.899 to –0.36)	0.1376	0.019	13.14	0.21
D'Souza et al (2020) [22]	0.088 (0.048 to 0.157)	–2.33 (–2.981 to –1.683)	0.3312	0.110	10.53	–2.48
Gebbia et al (2020) [23]	0.57 (0.523 to 0.615)	0.28 (0.092 to 0.467)	0.0956	0.009	13.5	1.85
Lwin et al (2020) [18]	0.43 (0.43 to 0.43)	–0.28 (–0.283 to –0.28)	0.0004	0.000	13.86	0.85
Zhao et al (2020) [24], part A	0.583 (0.383 to 0.759)	0.34 (–0.475 to 1.15)	0.4140	0.171	9.28	1.58
Zhao et al (2020) [24], part B	0.039 (0.027 to 0.057)	–3.20 (–3.6 to –2.8)	0.2040	0.042	12.37	–4.2
Zhao et al (2020) [24], et al	0.282 (0.265 to 0.300)	–0.93 (–1.018 to –0.85)	0.0435	0.002	13.78	0.34
Random effect	0.322 (0.236 to 0.422)	–0.75 (–1.176 to –0.315)	0.219	0.048	N/A[a]	N/A
Random effect without Gebbia et al [23] study	0.288 (0.200 to 0.395)	–0.907 (–1.39 to –0.428)	0.245	0.06	N/A	N/A

[a]N/A: not applicable.

Table 3. Prediction intervals and probability of fear random effect in all studies and when Gebbia study is not considered.

Studies	Random effect logit (95% prediction intervals)	Probability
All studies	–0.7455 (–2.2849 to 0.7939)	0.322
Gebbia et al [23] study excluded	0.9075 (–2.6052 to 0.7903)	0.288

Table 4. Probability of fear effect for each social media.

Social media type	Studies, n	Total reference population, n	Country	Logit event rate	Exp	Probability
Twitter	2	20,326,162	>170 countries	0.428	0.651811	0.288
WhatsApp	1	446	Italy	0.28	1.32313	0.57
Facebook	1	516	Iraqi Kurdistan	0.573346	1.774194	0.64
YouTube	1	113	US	–2.33214	0.097087	0.088
Sina microblog	3	3273	China	–1.283	0.277204	0.217

Discussion

Epidemics have caused burden on humankind since antiquity; past communities experienced shock that has been reflected in art, literature, massive population transitions, political turmoil, and changes in governance. Myths and legends evolved while people tried to deal with the unknown, the unpredictable, and the unexpected. Interpretations included, among others, divine interventions or punishment, conspiracy theories, religious fanaticism, racism, and scapegoating. Sparsity of data, especially in the beginning of an epidemic, facilitates misinformation spreading, and once this is initiated, "it is difficult to argue with reason" [35]. Interestingly, a recent psychology study established that "illusory pattern perceptions is a central cognitive function accounting for conspiracy theories and irrational beliefs" [36].

At the start of the current pandemic, the new coronavirus produced a broad clinical entity with an unpredictable natural history and uncertain treatment. The uncertainty caused feelings of fear, anxiety, and even depression, developing under an unexpected surge of serious morbidity and mortality [5,25,37,38].

These days, social media are a sine qua non for personal communications, business advertising, and updates [39]. During the pandemic, social media were used to empower the population and support public health measures. Yet, public health officials and academic researchers were alarmed by the size and spread of community confusion, frequently in response to "fake news" [21,25,27,40-42]. Thus, many nations were exposed to numerous misinformative communications regarding the origin of the epidemic (conspiracy theories, 5G antennas, etc), its transmission route (Asian neighbors, zoonotic or airborne transmission), the appropriate prophylactic measures (the herd immunity or isolation dilemma, vitamin and supplement effectiveness, etc), the treatment effectiveness (ibuprofen, hydroxychloroquine, etc), drug synergy (use of angiotensin-converting enzyme inhibitors, sartans), the vaccines expected (ineffective or even lethal), and the socioeconomic consequences (famine, unemployment). The scale of misinformation varied depending on the various political, religious, and cultural particularities of nations; however, the aforementioned issues were predominant in most countries. These characteristics influenced the between all and within Twitter studies' variance in our study.

Fear is an emotion that is caused by personal and societal threats and uncertainty (like the COVID-19 surge), while anger may originate from uncertainties caused by other persons [43]. Other negative emotions such as anxiety and depression are intertwined, individuality dependent, and have been evaluated in a previous meta-analysis [5]. Fear motivates unpredicted behaviors and merits attention in public health planning. Moreover, it was previously shown that indirect exposure to mass trauma through the media can accelerate the clinical manifestations of PTSD [8]. For all the previously mentioned reasons, we concentrated on fear in this meta-analysis.

Our study shows that the general population's fear was significantly dominant for one-third of the population due to COVID-19–related misinformation (Tables 2 and 3, and Figure 2). The effect was random (considering heterogeneity between and within studies) and of robust magnitude. Even when we excluded one study, the magnitude of the effect persisted, revealing that a considerable part of the population was negatively influenced by misinformation. More importantly, it was established recently that "tweet quality (misinformation vs. correct information) did not differ based on the number of likes or retweets, indicating that misinformation is as likely to spread and engage users as is the truth" [28]. Thus, the 5G conspiracy was spread through Twitter [21]. Zhao et al [24] reported that negative emotions decreased over time not only by habituation but also by the progress of scientific research, physical distancing, and the effectiveness of health care. The same was implied by Li et al [26], who studied 115,299 posts in 39 days but did not give numbers and was, thus, excluded from our analysis [26].

The importance and risk of communicating emotions through social media have been verified experimentally [44,45] and based on real data [27] and the history of other recent epidemics [2,46-48]. Comparing the summarized random size effect of fear p_f with p_i (insomnia relevant), p_a (anxiety relevant), and p_d (depression relevant) as reported by Pappa et al [5], we see that (p_f=p_i>p_d=p_a). The dominant effect of fear was similar to that causing insomnia but greater than that related to anxiety or depression. This is underlined by fear's nature; it is a primal emotion linked to survival, which may lead to complex feelings and moods such as anxiety and depressive manifestations or even clinical anxiety and depression.

The sexual dimorphism reported in two studies is indicative but cannot be assumed representative, as these specific studies were specific to ethnicity and had a small sample size. This observation may be explained from the fact that women tend to worry and distress by potential threats [49-51] and misleading information on potential risks in social media.

Our pilot study shows that the probability of social media users to develop fear due to misinformation is 32.2% (Table 3). The probability of fear varies upon the media used and the ethnicity and culture. Not including the WhatsApp cohort (Gebbia et al [23] study) that was targeted to a COVID-19 high risk group (patients with cancer), the fear effect probability decreased to 28.8% (Table 3). This phenomenon is reasonable considering that patient groups are physically more vulnerable to the virus and, perhaps, mentally more sensitive to any information, particularly misinformation. The observed decrease, however, is quite small at 3.4%.

The prediction intervals calculated indicated that effects of future studies might fall on the same side of the null and perhaps on both sides if the Gebbia et al [23] study is excluded. The prediction intervals "naturally account for heterogeneity" according to Higgins et al [17]; however, these intervals were criticized for their validity in small meta-analyses (including those with <20 studies) [52,53]. The heterogeneity in this meta-analysis was vast and persisted even when we excluded confounding studies, extreme-sized studies, or groups of studies (Table 5). It may be attributed to the small size of the summarized studies or to multicultural profiling. Yet, this meta-analysis is of value because its preliminary results and "difficulties" may guide future analyses on more studies to investigate group differences in social media type or culture homogeneous populations.

This study has to be viewed under its limitations: its pilot character; the time and period of conductance; the prematurity of the findings; the diversity of social media type surveyed; the multiethnicity, multicultural, and multi-language extracted data; and the unavailability of culture, age, gender, and education data in the retrieved studies.

Future cohort studies should better include more details on demographic, culture, and language data for more precise epidemiologic analyses, extracting targeted public health directions.

In conclusion, fear probability due to circulating misleading information was 32.2% for the general population, while when patient groups were excluded, fear probability diminished by 3.4%. Ethnicity and the social media type seem to be the main moderators of fear. Infodemiology and infoveillance may provide insight in epidemiologic research and contribute to the efficacy of public health measures. More importantly, our study suggests that public health officials must meet the challenge of curbing misinformation on the disease and its effects so as to protect their own credibility and effectiveness.

Table 5. Intrinsic heterogeneity in each included study or social media type population.

Study	Social media type	I^2	τ^2
Ahmad and Murad (2020) [20]	Facebook	0.00	0.00
Ahmed et al (2020) [21]	Twitter	0.00	0.00
Lwin et al (2020) [18]	Twitter	0.00	0.00
Ahmed et al [21] and Lwin et al [18]	Twitter	84.35	0.051
D'Souza et al (2020) [22]	YouTube	0.00	0.00
Gebbia et al (2020) [23]	WhatsApp	0.00	0.00
Zhao et al (2020) [24], part A	Sina microblog	0.00	0.00
Zhao et al (2020) [24], Part B	Sina microblog	0.00	0.00
Zhao et al (2020) [24], Part C	Sina microblog	0.00	0.00
Zhao et al [24], parts A, B, and C	Sina microblog	98.45	2.228
All studies	Combined social media	98.828	0.348
Gebbia et al [23] study excluded	WhatsApp excluded	98.934	0.376

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Conflicts of Interest

None declared.

Multimedia Appendix 1
The PRISMA Protocol.
[PDF File (Adobe PDF File), 148 KB - formative_v5i2e21156_app1.pdf]

Multimedia Appendix 2
Newcastle-Ottawa Scale for risk of bias.
[PDF File (Adobe PDF File), 66 KB - formative_v5i2e21156_app2.pdf]

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Abbreviations

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PTSD: posttraumatic stress disorder
WHO: World Health Organization

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Original Paper

Use of Teleconsultations in a Regional Stereotactic Radiosurgery Service: Pilot Study

Micheal O'Cathail[1,2], MBBS; Luis Aznar-Garcia[1], PhD, MD; Ananth Sivanandan[1], MBBS; Claire Diver[3], PhD; Poulam Patel[1,2], PhD; Pui-Shan Tang[4], BSc; Judith Christian[1], MD

[1]Department of Oncology & Radiotherapy, Nottingham University Hospital NHS Trust, Nottingham, United Kingdom

[2]School of Medicine, University of Nottingham, Nottingham, United Kingdom

[3]School of Medicine & Health Sciences, University of Nottingham, Nottingham, United Kingdom

[4]East Midlands Academic Health Science Network, Nottingham, United Kingdom

Corresponding Author:
Micheal O'Cathail, MBBS
Department of Oncology & Radiotherapy
Nottingham University Hospital NHS Trust
Hucknall Road
Nottingham, NG5 1PB
United Kingdom
Phone: 44 07460617317
Email: mocathail@gmail.com

Abstract

Background: The National Health Service Long Term Plan details plans to make digital interactions available to all patients in 5 years. Teleconsultations can improve access to specialist services; however, there is a lack of evidence for the use of teleconsultations in an oncology setting in the United Kingdom.

Objective: We aim to describe a service evaluation of teleconsultations for patients attending a regional brain metastases clinic. These patients have unique travel restrictions that prevent them from driving.

Methods: From April to October 2018, all patients attending the brain metastases clinic were offered the choice of teleconsultation in place of a face-to-face appointment. Feedback was assessed using a satisfaction questionnaire, and data of all clinic attendances were collected.

Results: A total of 69 individual patients had 119 appointments over the duration of the pilot, of which 36 (30.2%) were new patient appointments and 73 (61.3%) were follow-ups. Of the 69 patients, 24 (35%) took part in teleconsultations (41/119, 34.5%). User satisfaction was high, and no patients who took part in a teleconsultation reverted to face-to-face appointments. These patients avoided 2521 miles (61.6 miles per appointment) of hospital-associated travel and travel costs of £441.48 (US $599.83) to £10.78 (US $14.65) per appointment.

Conclusions: Teleconsultations appear to be acceptable in this cohort of patients with brain metastases attending a regional stereotactic radiosurgery service with the potential for significant savings in travel and expenses.

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KEYWORDS

telemedicine; teleconsultations; brain metastases; stereotactic radiosurgery; mobile phone

Introduction

Overview

As part of its “Five Year Forward View” in 2014 [1], National Health Service (NHS) England recognized the changing needs of patients and the need to capitalize on the opportunities that new technologies present. This view was reinforced in the recently announced “Long Term Plan” that aims to give all patients the choice of technology-enabled consultations, including the use of video consultations within the next 5 years [2].

The UK’s National Information Board and the Royal College of Physicians suggest that traditional models of outpatient care are outdated in the 21st century. Therefore, the NHS needs to

embrace technology and offer patients alternate ways of interacting with the NHS [3,4].

Health care is becoming increasingly specialized, with small hospitals now unable to provide a full range of health care service. Specialized services are therefore provided by larger institutions thus creating a *hub and spoke* model of health care [5]. In some services, such as specialized surgery and cancer care, this has been shown to improve the quality of care for patients [1]. However, this model may be quite burdensome on patients as it requires travel [6]. Telemedicine can reduce travel and improve access to such specialist services by bringing care to patients [7].

Telemedicine, as defined by Sood et al [8], is "The use of communications networks for delivery of health care services and medical education from one geographical location to another, primarily to address challenges like uneven distribution and shortage of infrastructural and human resources." The NHS uses *technology-enabled care* to describe digital patient interactions and *teleconsultations* for video consultations [9].

What Are Brain Metastases?

Brain metastases are secondary brain tumors that spread to the brain from other parts of the body. These patients may benefit from treatment with stereotactic radiosurgery (SRS), which is a specialized form of radiotherapy that can improve survival when compared with whole brain radiotherapy [10]. At present, this is only offered in a few regional centers in the United Kingdom [11]. The East Midlands brain metastases service was established in 2018 to improve patient access to this treatment in the region. Before its establishment, it was demonstrated that referrals for SRS were inconsistent, which meant that there was inequitable access to specialist care [12]. Patients with brain metastases face unique difficulties in attending hospital appointments owing to the fact that their diagnosis precludes them from driving [13]. They rely on family, public transport, or hospital transport to reach the hospital. The regional nature of our service makes this even more difficult. Therefore, a teleconsultation service was proposed with the aim of improving access to specialist care and reducing patient travel burden.

Current Evidence and International Experience

There is sparse evidence in the United Kingdom for the use of teleconsultations in a UK cancer care setting [14] and none specifically in radiotherapy care. A scoping review of the current evidence in the United Kingdom concluded that teleconsultations are safe and generally well received by patients across a broad variety of clinical settings but that they should be offered as a choice rather than a replacement of face-to-face appointments [15]. They and other authors concluded that the introduction of teleconsultation should be reviewed after a set period with service evaluations and feedback from stakeholders [14,15].

Teleconsultations in oncology have long been used in health services in Australia and Canada where burdensome traveling for patients and physicians and accessibility are issues [16,17]. In Australia, the distances that patients and staff have to travel to have a face-to-face appointment were so large that they would have to fly to make it practical. By implementing a teleconsultation service, they have demonstrated that safe oncological care can be provided while delivering a high-quality patient experience, with high rates of satisfaction. In addition, a teleconsultation service can realize significant cost savings for health care providers and patients alike [17-19]. Although this is not a likely scenario in the United Kingdom, some patients have to travel up to 5 hours to see the specialist SRS team.

Study Aim

The aim of this pilot study is to evaluate patient acceptability and satisfaction with the use of teleconsultations in the assessment and management of patients with brain metastases undergoing SRS and to describe the proportion of clinical activity. We aim to establish whether there are objective demographic differences among those who choose teleconsultations.

Methods

Study Participants

From April to October 2018, patients attending the regional brain metastases service in our center were offered the choice of having a face-to-face appointment or having a teleconsultation. To be able to take part in a teleconsultation, the patient had to have access to a device capable of supporting video calling (smartphone, tablet, laptop, or desktop computer with webcam) and an email address. A proprietary teleconsultation solution accredited for use in the NHS was used (Medio.link Involve Visual Collaboration Limited).

Clinical Setting

The East Midlands brain metastases service was established to assess and manage patients undergoing SRS. Cases were discussed at the regional brain metastases multidisciplinary team meeting, the rationale for which has been previously described [12], to determine technical suitability for SRS. Technically suitable patients were reviewed in the brain metastases clinic to ensure clinical suitability for treatment with SRS. All patients were offered the choice of attending either in person or by a teleconsultation link. Irrespective of their choice, they were seen during the same Wednesday afternoon clinic session. A separate clinic code was set up for each modality to record the attendances to each. Participants were free to switch appointment modalities for future appointments. Two physicians were involved in conducting both the teleconsultations and face-to-face clinic assessments, whereas a third was involved in face-to-face clinic assessments only. All 3 physicians covered the same patient group and thus access to the following treatment: patients were reviewed at 1 month and 3 months after SRS and then every 3 months for the first year following treatment.

Following the consultation, patients were asked to fill a feedback questionnaire that was administered through a web-based electronic survey service.

Feedback Questionnaire

A questionnaire, which was derived from previous studies, was designed. It assessed the use of teleconsultations in an outpatient oncology setting. This included questions on (1) basic

demographics (age and gender), (2) distance to the regional center, expected transport mode (if they had attended in person), and appointment type and duration, (3) type of internet connection and device used, (4) patient reported costs of their chosen appointment modality, (5) ranked patient reported benefit of teleconsultations (only if they indicated a preference for these), and (6) 9 statements regarding satisfaction (questions 9-16 and question 18) with different aspects of their consultation were included. Statements were recorded on a 5-point Likert scale with *1* indicating strong disagreement, *3* indicating no opinion, and *5* indicating strong agreement. Question 21 was left as free text to allow patients to suggest future improvements to the service. The satisfaction questions are taken from the previous studies, which has been mentioned earlier, exploring teleconsultations in oncology patients [16,17]. The final question (question 21) asked participants to complete an open-ended feedback question.

The questionnaire was sent to those patients who gave verbal consent at the time of the teleconsultation or confirmation by email afterward and none declined. A reminder was sent (via the e-survey website) a week later if the questionnaire was not completed. Although they may have had more than one appointment during the pilot, participants were asked to complete the questionnaire only once.

A similar feedback questionnaire was administered to patients who attended a face-to-face appointment for comparison. This was given by the clinic support worker when participants arrived for their appointment. Consent was assumed if the questionnaire was returned. A box for survey returns was placed on the reception desk. No reminder was provided to the patients who had face-to-face appointments. The questions are shown in Multimedia Appendix 1.

Patient and Public Involvement

Before implementing our teleconsultation service, participation in a preclinical pilot was sought from patient volunteers in a local cancer recovery group. In total, 4 participants took part in a test teleconsultation to provide feedback on the video platform's joining instructions and the quality of the video and audio streams. They were also provided with the proposed questionnaire to the pilot to assess local validity. Minor changes were made to the joining instructions; however, no amendments to the questionnaire were necessary. Following this, we established a teleconsultation service as an option to those attending the brain metastases clinic in April 2018. Here, we describe the results from our 6-month pilot.

Clinic Attendee Metrics

Anonymized demographic data were collected from all clinic attendances during the pilot duration. This included age, gender, distance, and travel time from the hospital based on the home postcode (fastest route planned by Google Maps), number of attendances, and appointment type (new consultation or follow-up). Appointment costs were estimated based on the distance of the return journey, an average fuel price of £1.28 (US $1.74) per liter (UK average during the pilot) [20] on the assumption that all attendees came by private car with a fuel economy of 51.7 mpg (average new car fuel efficiency in 2017) [21] and car parking costs of £4 (US $5.45) per attendance (based on the cost of trust parking for 1 hour).

Rationale for Study Design

The NHS, in its *technology-enabled care* guidance, recognizes that randomized controlled trials, though valuable, may prove too costly to be practical for evaluating changes in service provision. Therefore, a more pragmatic method of assessment is a service development review in which the technology can be assessed in practice, supported by patient feedback with the aim of assessing acceptability and satisfaction among users of the service [9]. The Healthcare Quality Improvement Partnership states that a service change is introduced based on evidence that exists in other health and social care settings that have evaluated the service change that these new service developments should be evaluated locally [22]. Moreover, Finch et al [23] found that the evaluation of telemedical services requires more flexible approaches to evidence production than those permitted within the rigid construct of controlled study designs, which may not be reproducible in the real world.

Data Handling and Analysis

Data were input and stored in an Excel (Microsoft Corporation) file, and descriptive data were generated for each variable. Statistical analyses were performed using GraphPad Prism 7 (GraphPad Software, Inc.). An independent *t* test was used for normally distributed continuous variables. Mann-Whitney *U* test was used for continuous variables that were not normally distributed. Chi-square test was used to determine whether there was an association between categorical variables.

Ethical Statement

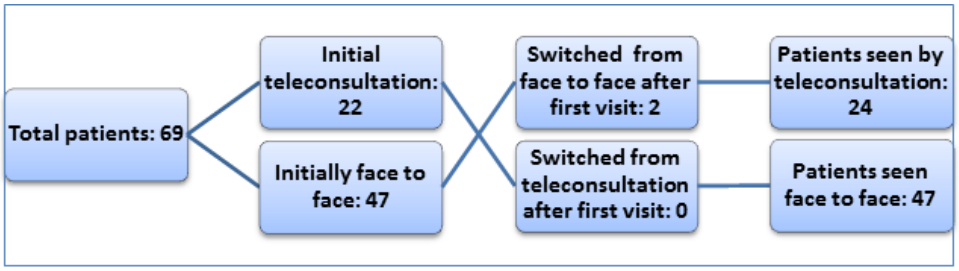
The scope of this service evaluation was approved by and carried out under the scrutiny of the Audit Office of Nottingham University Hospital NHS Trust. According to the Health Research Authority's decision tool, this project did not require NHS Research Ethics Committee approval.

Results

Study Groups

In total, 69 individual patients had 119 appointments over the duration of the pilot. Of these, 30.2% (36/119) were new patient appointments and 61.3% (73/119) were follow-ups. In all, 65.5% (78/119) of the appointments were face-to-face and 34.5% (41/119) were teleconsultations. Clinic medium participation is illustrated in Figure 1. Two participants switched after their first face-to-face appointment (both new appointments) to teleconsultations for follow-up.

Figure 1. Patient choice of consultation.



Clinic Attendee Metrics

There were several differences between the 2 study groups. Participants in the teleconsultation group was more likely to live further from the hospital and were younger, with a median age of 59 years compared with 65 years in the face-to-face group. The proportion of new consultations was slightly higher in the face-to-face group (26/47, 55%) than in the teleconsultation group (10/22, 45%). There were 78 attendances in the face-to-face group with 40% (19/47) of patients having at least 2 appointments. In the teleconsultation group, there were 41 attendances, with 54% (13/41) of the patients having at least 2 appointments. These are outlined in Table 1.

Table 1. Classification of the study participants (N=69) based on their appointment choice and clinic attendance metrics.

Characteristic and Metric	Face to face	Teleconsultation	*P* value
Total patients who chose each consultation type[a] (N=71), n (%)	47 (66)	24 (34)	N/A[b]
Sex, n (%)			
Male	17 (36)	11 (46)	.43[c]
Female	30 (64)	13 (54)	.43[c]
Median age (years; range)	65 (23-84)	59 (32-88)	<.001[d]
Clinic attendance metrics			
Patient choice for initial consultation (N=69), n (%)	47 (100)	22 (100)	
New consultation	26 (55)	10 (45)	.44[c]
Follow-up consultation	21 (45)	12 (55)	.44[c]
Return journey metrics (per appointment)			
Median distance, miles (range)	33 (5.2-82)	61.6 (8-130.6)	<.001[e]
Median estimated travel time[f], minutes (range)	78 (21-144)	109[g] (30-198)	<.001[e]
Median estimated travel costs[h], [range]	£7.63 (US $10.39) [£4.57-£13.02 (US $6.22-US $17.73)]	£10.78[g] (US $14.68) [£4.88-£18.37 (US $6.65-US $25.01)]	<.001[e]
Total appointments (N=119), n (%)	78 (65.5)	41 (34.5)	
Total distance traveled[f], miles	2382	2521[g]	N/A[b]
Total estimated travel time[f], hours	86.7	69.9[g]	N/A[b]
Travel costs	£574.04 (US $781.73)	£441.48[g] (US $601.20)	N/A[b]
Carbon footprint (CO_2e)[i], tonne	0.46	0.49[g]	N/A[b]

[a]Two patients switched from face-to-face to teleconsultation after first visit.

[b]Statistical test not applicable.

[c]Chi-square test.

[d]Independent *t* test (2-tailed).

[e]Mann-Whitney test.

[f]Estimated by Google Maps based on the return journey to the hospital from their home address.

[g]Indicative cost, time, and travel miles avoided by the teleconsultation group.

[h]Based on the average fuel price of £1.28 (US $1.74) per liter during the pilot, 51.7 mpg fuel efficiency, and hospital parking charge of £4 (US $5.45).

[i]Calculated assuming the same fuel efficiency and total mileage of all trips.

Questionnaire Feedback

Teleconsultation Group

Of the 24 attendees who participated in teleconsultations, 20 (83%) returned the questionnaire. One respondent gave answers only up to question 8; therefore, there were 19 complete surveys. Laptops or PCs (8/20,40%) and smartphones (8/20, 40%) were the most commonly used devices for participants, with tablets (4/20, 20%) also being used. Home broadband was used in the majority of cases with only 1 participant using mobile broadband. Furthermore, 3 respondents reported difficulty in seeing or hearing during the consultation. One patient reported that they felt physical examination was important (question 15), whereas 74% (14/19) disagreed with the statement and a further 21% (4/19) had no opinion. There was no self-reported cost associated with teleconsultations. Self-reported consultation time, taking the set up into account, was less than 30 minutes in 90% of cases and less than an hour in all cases. When asked if they would rather come in person in the future (question 19), only 1 person stated a preference to come in face-to-face next time. Participant satisfaction responses are shown in Figure 2. The travel method and total appointment duration time (including associated travel) of respondents are available in Table 2.

Figure 2. Satisfaction responses in teleconsultation and face-to-face appointment groups.

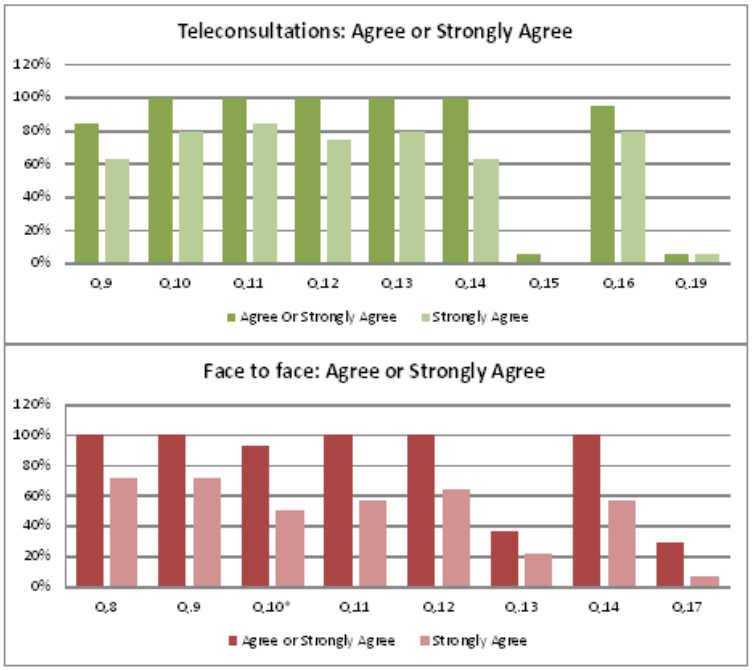


Table 2. Results of feedback questionnaires.

Question subject	Teleconsultation appointments (n=20)	Face-to-face appointments (n=14)
Sex, n (%)		
Male	10 (50)	7 (50)
Female	10 (50)	7 (50)
Travel method (if had to attend), n (%)		
Family or friends	15 (75)	12 (86)
Other (hospital or public transport)	5 (25)	2 (14)
Total appointment duration (including travel or set up time), n (%)		
<30 minutes	18 (90)	0 (0)
30 minutes to 1 hour	2 (10)	2 (14)
1-2 hours	0 (0)	4 (29)
2-3 hours	0 (0)	5 (36)
3-4 hours	0 (0)	1 (7)
>4 hours	0 (0)	2 (14)

If participants stated a preference for teleconsultations, they were asked to rank potential reasons (time saving, cost saving, travel saving, minimization of disruption to family life, and prefer teleconsultations over face to face) for this in order of importance (1 being the highest importance and 5 being the least important). Of the 18 who provided answers, the reasons marked *1* or *2* most commonly were time saving (n=12), minimization of disruption to family life (n=11), and travel saving (n=9) as the most important. Cost saving (n=3) and the preference for teleconsultations (n=1) were the least important to patients.

Question 21, concerning issues to improve, was used by participants to share their thoughts regarding teleconsultations. Several respondents shared that there is stress and cost attached to hospital appointments and that the teleconsultations had improved this—a retired couple traveling from 50 miles away said:

> *Wonderful to be able to speak to specialists in the privacy of our own home. This relieves the stress attached to travelling to and attending clinic. Thank you for offering this service. It would have cost us £50-£60 to attend.*

Another commented:

> *No, the video link has been instrumental in reducing stress levels for face to face clinical appointments. It would have cost £25-30 to attend in person on the stressful nature of face to face clinics and felt teleconsultations had reduced stress, as well as saving money.*

One participant, aged 88 years and the main carer for his wife, said, "I felt that this was an excellent way to have an appointment and enabled me to continue caring for my wife as well as receive expert care." Another added that it was "much more convenient." Another commented on the suitability of different clinical scenarios that: "It was fine for a routine follow up."

Any comments that suggested areas for improvement were regarding difficulties receiving the email appointment link or problems with internet speed:

> *The only problems encountered were due to my signal issues. However I have had difficulties receiving the 'joining' instructions email.*
>
> *The email with regard to the clinic could only be accessed on my laptop. It never was received on my iPhone or iPad. Apple seemed to have blocked it.*

In these cases, the email appointment with the joining link was marked as spam by the recipient's email carrier. Once the email was retrieved from the spam folder and marked as *safe* by the participant, no further issues were encountered.

Face-to-Face Group

Of the 47 participants that attended, 14 (30%) questionnaires were returned. Most (12/14, 86%) patients got to the hospital with the help of family or friends, with 14% (2/14) depending on hospital transport. Self-reported consultation time, taking into account the travel time, was understandably longer with only 14% (2/14) respondents reporting that their appointment from leaving home to returning would take less than 1 hour. In total, 57% (8/14) respondents expected it would take more than 2 hours with two of those expecting to spend more than 4 hours away from home.

As with the teleconsultation survey, user satisfaction was high with all patients reporting satisfaction with their appointment. As with teleconsultations, the proportion of patients who felt physical examination was important was low (5/14, 36%), with most declaring *no opinion* (8/14, 57%). In addition, 4 patients expressed an interest in having a video consultation, with 57% (8/14) preferring to come face to face. All these patients cited a preference for, or a belief that face-to-face appointments were better than teleconsultations.

A total of 10 patients self-reported costs of attendance, which ranged from £5 (US $6.78) to £40 (US $54.27); 80% (8/10) reported costs of at least £10 (US $13.57), whereas 30% (3/10) reported costs of at least £20 (US $27.14). Only 20% (2/10) patients felt that there was no financial cost to attend, one of whom attended hospital transport, whereas the other came with a friend. When asked about improvements that could be made, only 1 person responded stating that "car parking and directions to the department" could be improved.

Discussion

Principal Findings

The use of teleconsultations in the United Kingdom has a relatively long history, with studies dating back to the mid-1990s [24]. Technological advances mean that many of the early studies in the United Kingdom relied on expensive audio-visual systems, which made them impractical for outpatient care, especially in a cost-conscious public health service [25]. The Office of National Statistics figures reported that internet access (90% of households) and smartphone usage (78% of adults) is now extremely high throughout the population and rising steadily every year [26]. This means that video calling technology is now accessible to millions of potential patients. Nuffield trust found that public willingness to use video consultations for a variety of medical conditions was as high as 63%, which varied little with age [27]. With their Long Term Plan, the NHS has now put digital interactions to the forefront of its plans. A stated goal is to transform the way outpatients work to avoid up to 30 million face-to-face appointments by using digital interactions [2]. A recent scoping review of the current and historical context of teleconsultations concluded that teleconsultations are safe in a broad range of clinical contexts and are generally well received by patients; however, acceptability cannot be presumed and that local evaluation following implementation should be performed to ensure acceptability and safety [15].

This pilot is the first UK-based evidence in a radiotherapy setting and the first described internationally among patients with brain metastases. The limitations that these patients face with respect to travel and the regional nature of our brain metastases service meant that the natural advantages of teleconsultations could be experienced by those who find it

most difficult to attend. At present, in the United Kingdom, a criticism of commercial, General Practice based video services available is that they cater to the healthiest patients. Our service was set up specifically considering the limitations of some of the least able in mind.

Over a third of all patients in our pilot took part in a teleconsultation; this is noteworthy as most teleconsultation services typically report uptake rates of less than 20%. In fact, rates have been as low as 2% among a diabetic cohort, with the highest rate (20%) reported among postoperative patients with hepatobiliary cancer [14]. The relatively high uptake among patients with cancer in our study and among patients with hepatobiliary cancer compared with published rates in other specialties is perhaps unsurprising as oncology patients spend a significant proportion of their time either in hospital or attending hospital appointments, and patients with brain metastases spend more time in the hospital than patients with metastases elsewhere [28]. The conventional doctrine of teleconsultations is that they are best placed to provide routine clinical care and that more complex situations should be dealt with face to face [14]. However, the high use of such services by patients with cancer alludes to a willingness to challenge such preconceptions. Patients with cancer may receive bad news at any consultation; this did not deter patients from using the teleconsultation service. Further qualitative exploration of patients' experiences of this medium is underway to explore this in greater depth.

How far the patient lived from the treatment center was a significant factor in their decision to participate in teleconsultations. This is supported by the reasons chosen by patients with time saving and less disruption to family life being most important to them. The patient feedback alludes to the stress associated with traveling to the hospital. This is consistent with the findings of a recent report that found that 20% of older patients find simply traveling to hospital stressful [29].

There is a potential for bias in allowing patients to choose their own appointment type (ie, patients will choose it because they think it will be better for them). The rationale behind this is well rooted in the literature with consistent findings from patients that the choice should remain with the patient and that teleconsultations should be offered as an alternative rather than a replacement for face-to-face appointments [14,15,30].

This service evaluation suggests that teleconsultations were acceptable among this group of patients. Satisfaction with the brain metastases service was universally high and this did not differ in the teleconsultation group. Patients felt that nothing was missed (question 12) as their consultant was able to provide satisfactory care (question 13) and that privacy and confidentiality (question 14) were maintained. Interestingly, patients in both groups felt that physical examination was not important for their consultation, which is in contrast to other studies where a lack of physical examination was cited as a concern among patients [17]. Humer et al [31] pointed out that the patient perceived the importance of physical examination may be overstated. An interesting perspective on physical examination is that it has become a ritual done to satisfy the basic needs of patients to feel cared for and for physicians to feel like their work is meaningful [32].

Patients largely self-selected themselves for their preferred service; any patient who took part in a teleconsultation did not switch back to face to face afterward, and among the face-to-face attendees, only 2 of the 47 patients subsequently took part in a teleconsultation. This also demonstrates one of the difficulties in using randomized controlled trial methodology for teleconsultations. The NHS rightly suggests that patients should be able to choose how they see their doctor and that teleconsultations should be an alternative rather than a replacement of traditional appointments [9]. This is supported by a recent report from the Royal College of Physicians, which suggests a mix of appointment types as the ideal model of care [4].

Cost analysis aims to attribute cost to the travel and parking associated with the appointments and is likely to be an underestimate because it does not take into account the cost of the family member's time, including the potential for loss of earnings associated with hospital appointments. Our assumptions are the *best case* scenario. The real estimated cost of attending an outpatient appointment, reported at an NHS conference, was £17.36 (US $23.64) per hour of travel for a face-to-face appointment, £2 (US $2.72) for a telephone interaction, and £1 for a digital interaction [33]. Therefore, the real cost of the face-to-face appointments was £1505.11 (US $2048.67), and the real cost of the teleconsultations was £41 (US $55.80), with a net saving of £1172.46 (US $1596.62) or £28.60 (US $38.95) per appointment.

The environmental impact of patient travel may seem trivial, but the NHS has a carbon footprint of 22.8 million tons of CO_2 per year or 6% of the total carbon footprint of the United Kingdom, of which nearly 10% is attributed to travel [34].

Limitations

A limitation of our work is that we did not include health care provider–associated costs. As this was a pilot study with relatively small numbers of patients, it was not thought to be meaningful data. A larger study would provide better data for this.

We have not collected socioeconomic data on this cohort; therefore, we are unable to draw any conclusions in relation to patient education status, income, and professional status. We have not looked at feedback from health care professionals owing to the small number of clinicians involved. The population involved has disease-specific transport limitations, and although these may apply to other ailments, the results of this pilot may not be generalizable to other services.

Conclusions

This pilot has demonstrated that teleconsultations in this selected oncology population with travel limitations are popular and acceptable. These benefits may be seen among other patients with cancer, and we plan further pilots in other aspects of cancer care. Further qualitative exploration of participants' experiences is underway to explore some of the issues raised in this paper in greater depth. The expansion and development of this

teleconsultation service is underway, which will allow for further evaluation studies to assess the wider implications of more integrated teleconsultation use in the NHS.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Feedback questionnaires.
[DOCX File , 15 KB - formative_v5i2e15598_app1.docx]

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Abbreviations

NHS: National Health Service
SRS: stereotactic radiosurgery

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Original Paper

A Couples-Based Intervention (Ghya Bharari Ekatra) for the Primary Prevention of Intimate Partner Violence in India: Pilot Feasibility and Acceptability Study

Ameeta Shivdas Kalokhe[1,2], MSc, MD; Sandhya Iyer[3], MA; Keshav Gadhe[3], MSW; Tuman Katendra[3], MSc; Ambika Kolhe[3], MSW; Girish Rahane[3], MA; Rob Stephenson[4], MSc, PhD; Seema Sahay[3], MSc, PhD

[1]Division of Infectious Diseases, Department of Medicine, Emory University School of Medicine, Atlanta, GA, United States

[2]Department of Global Health, Emory Rollins School of Public Health, Atlanta, GA, United States

[3]Department of Social and Behavioral Research, National AIDS Research Institute, Pune, India

[4]Department of Systems, Population and Leadership, University of Michigan School of Nursing, Ann Arbor, MI, United States

Corresponding Author:
Ameeta Shivdas Kalokhe, MSc, MD
Division of Infectious Diseases
Department of Medicine
Emory University School of Medicine
5003 CNR Building
1518 Clifton Road
Atlanta, GA, 30322
United States
Phone: 1 404 712 1924
Email: akalokh@emory.edu

Abstract

Background: The high global prevalence of intimate partner violence (IPV) and its association with poor physical and mental health underscore the need for effective primary prevention. We previously developed Ghya Bharari Ekatra (GBE), a couples-based primary prevention intervention for IPV among newly married couples residing in slum communities in Pune, India.

Objective: Through this pilot study, we aimed to explore the acceptance, safety, feasibility, and preliminary efficacy of GBE.

Methods: Between January and May 2018, we enrolled and assigned 20 couples to receive GBE plus information on IPV support services and 20 control couples to receive information on IPV support services alone. The GBE intervention was delivered over 6 weekly sessions to groups of 3 to 5 couples by lay peer educators in the communities in which the participants resided. Intervention components addressed relationship quality, resilience, communication and conflict negotiation, self-esteem, sexual communication and sexual health knowledge, and norms around IPV. Outcome evaluation included exit interviews with participants and peers to examine acceptance and feasibility challenges and baseline and 3-month follow-up interviews to examine change in IPV reporting and mental health (by women) and alcohol misuse (by men). The process evaluation examined dose delivered, dose received, fidelity, recruitment, participation rate, and context.

Results: Half (40/83) of the eligible couples approached agreed to participate in the GBE intervention. Retention rates were high (17/20, 85% across all 6 sessions), feedback from exit interviews suggested the content and delivery methods were very well received, and the community was highly supportive of the intervention. The principal feasibility challenge involved recruiting men with the lowest income who were dependent on daily wages. No safety concerns were reported by female participants over the course of the intervention or at the 3-month follow-up. There were no reported physical or sexual IPV events in either group, but there were fewer incidents of psychological abuse in GBE participants (3/17, 18%) versus control participants (4/16, 25%) at 3-month follow-up. There was also significant improvement in the overall mental health of female intervention participants and declines in the control participants (change in mean General Health Questionnaire-12 score: –0.13 in intervention vs 0.13 in controls; P=.10).

Conclusions: GBE has high acceptance, feasibility, and preliminary efficacy in preventing IPV and improving mental health among women. Next steps include refining the intervention content based on pilot findings and examining intervention efficacy through a large-scale randomized trial with longer follow-up.

Trial Registration: ClinicalTrials.gov NCT03332134; https://clinicaltrials.gov/ct2/show/NCT03332134. Clinical Trials Registry of India CTRI/2018/01/011596; http://ctri.nic.in/Clinicaltrials/pmaindet2.php?trialid=21443

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KEYWORDS

intimate partner violence; prevention; pilot study; gender-based violence; domestic violence; violence; India; intervention; prevalence; mental health; acceptance; safety; feasibility; efficacy

Introduction

Intimate partner violence (IPV), defined by the World Health Organization (WHO) as "any behavior within an intimate relationship that causes physical, psychological, or sexual harm to those in the relationship," is experienced by one-third of women globally [1,2]. IPV has consistently been associated with poor mental health, poor sexual and reproductive health, and injury [2]. The United Nations has identified the elimination of IPV against women as a public health priority, and the WHO has called for research to build the evidence base "to address the current lack of information on effectiveness programs for primary prevention" [3,4]. To date, however, there exist few evidence-based primary IPV prevention interventions globally. Further, existing interventions have been largely developed in high-income settings and engage women alone [5-7], men alone [8-11], men and women in independent parallel groups [12-14], men and women together in large groups [15], or communities at large (ie, through mobilization campaigns) [16,17].

In recognition of the gap, we previously developed Ghya Bharari Ekatra (GBE, Marathi for "Take a Flight Together") [18], the first published couples-based intervention for primary IPV prevention in a resource-limited setting. GBE was designed in Pune, India, to prevent IPV among newly married couples of low socioeconomic status, given the high IPV prevalence in this group and limited availability of support services to them [19]. GBE is culturally sensitive and delivered in the first year of marriage, as opposed to Western countries, where primary IPV prevention traditionally occurs in school years [20,21]. This intervention timing is due to social taboos restricting in-school discussion of intimacy and sexual health in India, the frequent absence of premarital courtship, and the delayed age of individuals' first sexual relationship, enabling primary prevention to occur later, as well as the recognition that the husband-wife dyad is highly impressionable to behavior modification in early marriage [22]. GBE was delivered by a team of lay peer educators to groups of 3 to 5 couples in 6 weekly 2-hour sessions in the communities in which the couples resided. It makes use of engaging culturally tailored delivery methods (games, role-plays, films, and reflective discussion) to challenge norms and build knowledge and skills in addressing 6 key IPV determinants: limited relationship quality time, poor self-esteem, resilience, communication and conflict management, sexual communication and sexual health knowledge, and conservative IPV norms and definitions.

The development of GBE has been previously described [18]. Briefly, GBE is grounded in the couples interdependence theory [23], which posits that both intrapersonal and interpersonal dyadic processes serve as determinants of a couple's behavior change, underscoring the need for IPV prevention to engage the couple as a unit. It was developed using a mixed-methods approach to intervention mapping [24], in which intervention components were designed to target determinants of IPV experience and perpetration identified through surveys with newly married women and men, respectively [25,26]. Intervention content and delivery were informed by qualitative research with Indian gender-based violence experts and the lay community [18]. We herein describe the findings of the initial pilot study, which aimed to explore GBE's acceptance, feasibility, safety, and preliminary efficacy in preventing IPV.

Methods

Study Design

This pilot study used a prospective nonrandom design in which groups of 3 to 5 married couples were assigned to receive the intervention or the control condition. Couples assigned to the intervention arm received the 6-session GBE group intervention over a 6-week period plus the ethical standard of care, a list of IPV and mental health support services provided to the female dyadic member. Couples assigned to the control condition received the ethical standard of care alone. Ghya Bharari Ekatra (Marathi for "Take a Flight Together") is composed of 6 weekly 2-hour sessions, 5 of which are facilitated by a pair of male-female lay community peer educators, with the sixth (focused on sexual communication and sexual and reproductive health) being co-led by medical officers and delivered in gender-concordant groups. Study outcomes assessed included intervention acceptance, feasibility, safety, and preliminary efficacy in preventing IPV, enhancing mental health among women, and reducing alcohol use among men at 3 months.

Ethics Statement

The study was approved by the National AIDS Research Institute Ethics Committee (Pune, India) and the Emory University Institutional Review Board (Atlanta, Georgia). Written informed consent was obtained from all participants prior to their participation in the study. The trial was registered at ClinicalTrials.gov (registration number NCT03332134) and the Clinical Trials Registry of India (registration number CTRI/2018/01/011596).

Study Setting and Context

The study was conducted in slum communities in Pune, the second largest metropolis in the western state of Maharashtra, India. According to the most recent census, 22.28% (690,545/3,100,000) of Pune's populations resides in slums

[27,28]. IPV and mental health disorders occur with greater frequency in slums and low-income settings, with national estimates demonstrating IPV prevalence to be 2.5 times higher and morbidity due to mental illness to be 1.3 times higher in the lowest versus highest wealth quintile [19].

Study Population: Eligibility Criteria and Recruitment

Participants were recruited between January and May of 2018. To be eligible to participate, both members of the couple needed to be 18 years or older; married for ≤1 year; in their first marriage; cohabiting in a slum, chawl, or slum redevelopment community; and fluent in Marathi or Hindi. As GBE was designed to be a primary IPV prevention intervention, couples in which the female member screened positive for physical or sexual IPV using an abridged version of the Indian Family Violence and Control Scale (IFVCS) [29] at baseline were excluded, as were those in the third trimester of pregnancy (since women in the region traditionally return to their natal home during the perinatal period). Both members of the couple had to meet eligibility criteria for the couple to participate.

The participant identification process began with mapping and identifying individual slum communities in Pune (incorporating a geographic buffer around identified communities to prevent contamination). Next, we used a multistaged community sensitization and recruitment process. First, study staff and community-based organizations (CBOs) with whom the Indian Council of Medical Research National AIDS Research Institute (ICMR-NARI) had partnered in prior research studies together contacted community key leaders to notify them of the intent and overall delivery of the intervention. Second, the CBOs and key community leaders then led community sensitization meetings within each slum community to bring community-level awareness of GBE's aim of fostering healthy relationships and help build intervention support and prevent potential community uprisings that could result from erroneous community speculation of GBE's intent to preach family planning, publicly disclose household abuse, or treat HIV. Third, CBOs and key leaders identified potential peer educators (to be intervention facilitators) and potentially eligible couple participants. Fourth, study staff then met with families of the couples at their homes to seek initial permission (as per cultural norms). Fifth, study staff met with the couples individually at a private venue of convenience to them (ie, homes, workplaces, community halls) to obtain written informed consent, confirm eligibility, and conduct baseline surveys with each member individually. Once 3 to 5 couples were identified from a particular slum community, the group was assembled and intervention delivery began. In parallel, couples recruited from a neighboring slum community were assigned to the control arm.

Intervention Preimplementation and Implementation Team

GBE delivery employed a preimplementation phase (led by teams of community leaders and CBOs) and implementation phase (led by peer educators and government medical officers). Community leaders (ie, local government and political figures) and CBOs facilitated community sensitization and entry and helped recruit potential participants and peer educators. Peer educators (one man and one woman per GBE intervention group), who facilitated delivery of the GBE sessions, were lay community people who were married and demonstrated strong oratory, group facilitation, and critical thinking skills and community involvement. They were recruited from various local agencies, including *anganwadis* (government childcare centers), *mitra mandals* (male youth social groups), and CBOs. Session 5, "Sexual Communication and the Sexual Relationship," was the only session delivered in gender-concordant groups and jointly facilitated by a gender-concordant peer educator and government medical officer. While it may seem counterintuitive that this session was delivered in gender-concordant groups rather than in couples, the strategy was highlighted as imperative by participants involved in the formative GBE design for enhancing acceptance and participant trust [18]. The medical officers were recruited from the government Reproductive Health and Family Planning centers.

Intervention Facilitation Training: Safeguarding Fidelity

Peer educators underwent a weeklong training by study staff on IPV and gender equality; GBE intent, content, and intervention facilitation methods; methods for establishing rapport; and the safety protocol. The second half of each training day was dedicated to peer educators to practice intervention delivery and receive real-time feedback from the study team. Additionally, during the 6-week intervention delivery period, peer educators received 1-hour weekly paired retraining meetings with a study staff member to practice delivery of the specific module and have module-specific questions answered. These meetings also enabled a space for peer educators to notify study staff of concerns about the safety of particular participants and discuss emotional trauma they themselves were experiencing as intervention facilitators (with study staff facilitating peer referral to support services as necessary). Prior to delivering session 5, "Sexual Communication and the Sexual Relationship," medical officers received a 2-hour training on the module intent, content, and delivery methods by the research team.

Intervention

The GBE intervention was delivered to groups of 3 to 5 newly married couples in weekly 2-hour sessions over a 6-week period. It was facilitated by a male-female pair of trained peer educators, conducted in Marathi, and held at a community-based venue (eg, school, community hall, *anganwadi*, CBO) in the slum communities in which the couples resided. The intervention was highly participatory, making use of reflections, discussions, role-plays, games, films, and competitions.

Session 1, "You, Me, and Us: Spending Meaningful Time Together," aimed to increase the quality time spent together in the relationship and employed a series of self-, couple, and group reflections on the benefits of a marital relationship, the current amount of time the couple spends together, barriers and facilitators to spending quality time with one another, and couple-based planning of strategies to increase quality relationship time.

Session 2, "I'm a Champion: I Can't Be Broken and I Don't Accept Defeat," aimed to increase self-esteem and resilience

and employed (1) facilitated group exercises in which participants brainstormed available community and human resources and methods to help address common adversities (eg, job loss, poor health, relationship difficulties) and (2) a guided interview between the two members of a couple in which each gets to know the other on a deeper level (ie, background, hobbies, sources of pride and worry, strengths, modifiable and less modifiable weaknesses), culminating with the recognition of the need to recognize each other as a unit and support the growth of one another.

Session 3, "Building Communication and Conflict Management Skills," aimed to improve communication and conflict management skills and employed 2 short films that describe the initial hopes, dreams, and expectations of a newly married bride and groom and the subsequent challenges they face and emotions they feel in adjusting to married life in the context of a larger joint, low-income family. This was followed by a powerful peer-led discussion that culminated with the participant group together brainstorming strategies for handling each of the presented situations.

Session 4, "Empowerment of the Couple: Planning Ahead," aimed to empower both members of the couple through improved goal setting and goal implementation skills and employed (1) couples-based reflections on their personal dreams followed by peer-assisted establishment of and planning for attainable goals and (2) role-plays demonstrating skills to effectively prepare for and participate in a job interview.

Session 5, "Sexual Communication and the Sexual Relationship," aimed to improve sexual communication and the sexual relationship and was the only module co-led by peer educators and government medical officers and delivered in gender-concordant groups. It employed (1) medical officer–delivered lectures on sexual and reproductive health, (2) a quiz with facilitated discussion that addressed and dispelled commonly held reproductive and sexual health myths, (3) a Snakes and Ladders game adapted to methods for fostering romance in the relationship, and (4) a lecture regarding the importance of and methods for sexual communication with a follow-up question-and-answer period (which made use of an anonymous question box).

Session 6, "A Lens Into Domestic Violence," aimed to expand participant definitions of behaviors constituting IPV and to challenge subjective norms of IPV occurrence. It employed (1) a facilitated discussion of the different forms and effects of IPV on all members of the family and (2) an exercise in which each participant ranked examples of violence by severity to initiate a discussion about the factors individuals use to define acts of violence, highlighting individual-level differences in conceptualization of violence, and to challenge participants to expand their definitions of IPV and commit to a life of nonviolence. The session ended with a closing video of scrolling photos of the participants engaged in the sessions, presentation to each couple of a framed photo of themselves, announcement of the winner of the competitions embedded in the intervention, and final words from the participants, in which they shared the changes they planned to implement as a result of participating in the intervention.

Control

Both the control and intervention groups received the ethical standard of care. An appropriate ethical standard of care was designed in consultation with the WHO Ethical and Safety Recommendations for Research on Domestic Violence Against Women [30], and it included the provision of a list of IPV and mental health support services concealed in a phone diary of other services. The IPV support services were included among other services so that if the diary were to be found by the woman's spouse (a potential IPV perpetrator), he would not be aware of the nature of information provided and her safety would not be jeopardized. The diaries were provided to all female participants at the time of consent regardless of whether they disclosed IPV.

Outcomes and Data Collection

The main outcomes assessed included intervention acceptability, feasibility, and safety, and secondary outcomes assessed included preliminary efficacy. Outcome evaluation used semistructured group interviews with the intervention participants after each session, semistructured interviews with GBE facilitators after each session, and baseline and 3-month follow-up surveys with individual participants (both control and intervention). The interviews and surveys were conducted by trained research staff. All tools were translated in Marathi prior to use.

Acceptability of the intervention to the dyad was gauged through the postsession semistructured group interviews, wherein the group of participants were collectively asked by the research team about their satisfaction with session content and delivery. The group interview after the sixth (final) session additionally explored satisfaction with the number and duration of the intervention sessions and intervention facilitators, while the follow-up survey included items asking female participants about the perceived adequacy of the study safety procedures. Intervention feasibility was assessed during the postsession interviews with the intervention facilitators, during which they were asked about ease of and challenges with session delivery, their perceptions of participant understanding of the intervention, and logistical problems they encountered with the intervention setting, timing, trainings, and debriefings.

Safety of the intervention was gauged through the follow-up surveys with the women assessing incidents of IPV (using an abridged version of the IFVCS) [29] and an item examining whether the participant felt family or spousal conflict resulted from her participation in the intervention. Additionally, an optional women's day was held halfway through the intervention period, which female participants could attend to confidentially convey safety concerns to study team members. CBOs and peer educators additionally monitored how the intervention and study were being discussed in the community, a step in the safety protocol designed to defuse concerns early prior to escalation.

Preliminary efficacy was assessed through survey responses measuring changes in (1) past 1-month IPV experience among women (using an abridged version of the IFVCS), (2) mental health among women (using the General Health Questionnaire-12 [GHQ-12]), and (3) past 3-month alcohol

consumption among men (using the Alcohol Use Disorders Identification Test [AUDIT]) between baseline and 3-month follow-up.

The process evaluation was conducted by trained study staff members and examined key elements proposed by Saunders et al [31]: fidelity, dose delivered, dose received, participation rate, recruitment, and context. Dose delivered was assessed during each GBE session by the study team member and measured by the number of GBE sessions delivered, percentage of expected content delivered per session, extent to which GBE materials were used in the sessions, and time required to deliver each module. Fidelity was assessed by the extent to which the peer educator and implementation staff training was provided as planned, the extent to which peer educators could deliver each GBE activity during the training session, the extent to which GBE activities were implemented as intended during actual intervention delivery, and exploration of the difficulties that interventionists experienced in delivering GBE activities (through exit interviews at the end of session 6). Recognizing the sensitivity of topics covered, GBE sessions were not recorded to foster open participation. Instead, fidelity was assessed by study staff who were physically present during the sessions (at the back of the intervention venue to minimize disruption) and documented the extent to which each exercise was delivered as intended. Dose received was assessed by a study team member, measured as the level of overall participant engagement (participation) in each module exercise, and through exit interviews with the peer educators and participants at the end of session 6 to assess module-related satisfaction. Participation rate was captured through session attendance tracking and staff contact with participants who missed sessions to assess barriers to participation. Recruitment data were captured through number of participants approached, number who consented, number assessed for eligibility (and reasons for ineligibility where appropriate), and number who completed baseline assessment. Lastly, context was assessed through structured study team observation of the responsiveness of community leaders, community members during sensitization meetings, family members at the time of initial permission, and peer educator and implementation team reporting of the barriers and facilitators encountered in delivering GBE during exit interviews, conducted upon completion of session 6.

Data Analysis

Intervention acceptance was assessed by exploring trends across the postsession group interviews regarding participant satisfaction with module content and suggested changes. Similarly, feasibility was explored by examining trends across postsession facilitator interviews regarding ease of and difficulty with delivering sessions. Safety was assessed through descriptive analysis of the corresponding items in the follow-up survey. Past 1-month IPV was assessed through the reporting of any physical, sexual, or psychological violence or control using the IFVCS. Mental health was measured using the GHQ-12 total score and past 3-month alcohol consumption was assessed using the AUDIT total score. Intervention efficacy was assessed using the difference in change in each of the 3 parameters from baseline to 3 months between the intervention and control group. Bivariate analyses utilized unpaired *t* tests to test the differences between groups.

Results

Participants

Community gatekeepers identified 135 potentially eligible couples, of which 17 were not reachable, resulting in 118 couples being assessed for eligibility (Figure 1). Of the 118 couples, 28 did not meet eligibility criteria (because the woman was in the third trimester of pregnancy, the couple had been married more than 12 months, a member of the dyad was not fluent in Marathi, the couple was not cohabitating, or it was their second marriage), 43 declined to participate (citing insufficient time, lack of interest, or that their family refused their participation), and 7 were interested and eligible but there were insufficient couples to form an intervention group in the couple's community. Ultimately, 40 of 83 eligible couples (48%) were enrolled, with 20 assigned to the intervention groups and 20 to the control condition. A total of 5 intervention groups of 3 to 5 couples were formed.

Baseline participant characteristics are described in Table 1. Female participants were an average of 21.6 years (σ=2.8 years) of age, 30% (12/40) were employed, 70% (28/40) had a monthly income of less than Rs 10,000 (US $136.63), and 15% (6/40) were in the first or second trimester of pregnancy. There were statistically significant differences in educational attainment between female participants in the intervention versus control group, with 75% (15/20) of women in the intervention completing secondary or higher education versus 45% (11/20) of women in the control group (*P*=.05). Male participants were an average of 26.4 years (σ=3.1 years) of age, 98% (39/40) were employed, and 60% (24/40) had completed secondary or higher education. There were statistically significant differences in monthly income between male participants in the intervention versus control group, with 85% (17/20) of men in the intervention having a monthly income of more than Rs 10,000 (US $136.63) versus 35% (7/20) of men in the control group (*P*=.001). The majority of couples were Hindu (32/40, 80%), were of a reserved caste (22/40, 55%), lived in joint families (32/40, 80%), and had an average of 5.2 (σ=2.4) members per household. The average marital duration was 6.1 months (σ=3.9 months), with the majority of marriages arranged (29/40, 73%) and occurring within the family (26/40, 65%) and caste (36/40, 90%).

Figure 1. Recruitment and enrollment of participants into Ghya Bharari Ekatra intervention and control groups.

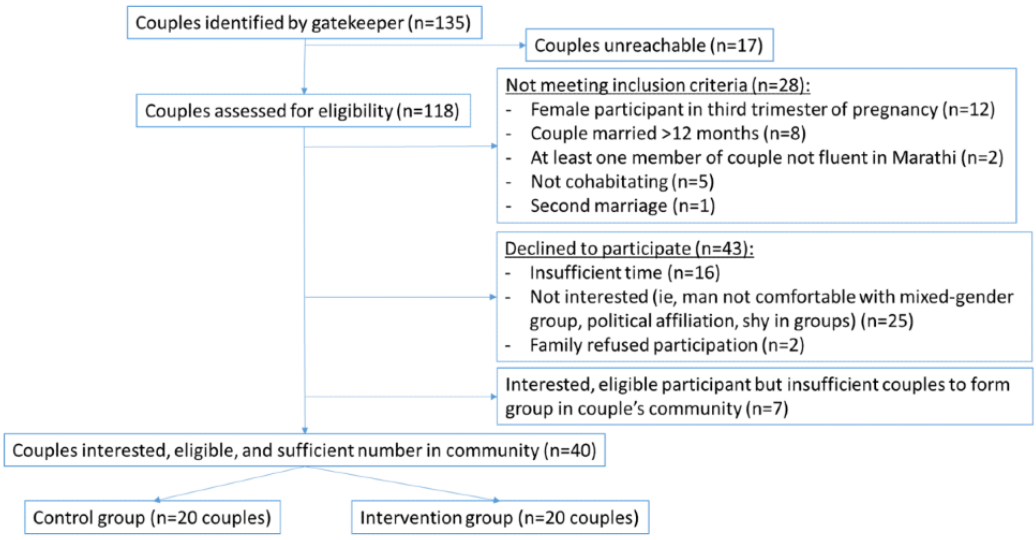

Table 1. Baseline participant characteristics.

Characteristic	Women (n=40)			Men (n=40)		
	Intervention (n=20)	Control (n=20)	*P* value	Intervention (n=20)	Control (n=20)	*P* value
Age (years), mean (σ)	21.0 (3.1)	22.2 (2.5)	.16	27.0 (3.3)	25.8 (2.8)	.22
Secondary education or higher, n (%)	15 (75)	11 (45)	.05	14 (70)	10 (50)	.20
Employed, n (%)	5 (25)	7 (35)	.49	20 (100)	19 (95)	__[a]
Women's income (none), n (%)	15 (75)	13 (65)	.49	N/A[b]	N/A	N/A
Men's income Rs >10,000[c], n (%)	N/A	N/A	N/A	17 (85)	7 (35)	.001
Religion (Hindu), n (%)	16 (80)	16 (80)	>.99	15 (75)	16 (80)	.14
Reserved caste, n (%)	10 (50)	12 (60)	.53	—	—	—
Family type (joint), n (%)	14 (70)	18 (90)	.11	—	—	—
Premarital family type (joint), n (%)	6 (30)	9 (45)	.33	—	—	—
Household members, mean (σ)	5.6 (3.0)	4.8 (1.6)	.34	—	—	—
Marital duration (months), mean (σ)	—	—	—	5.5 (3.6)	6.8 (4.2)	.28
Marriage type (arranged), n (%)	14 (70)	15 (75)	.72	—	—	—
Within-caste marriage, n (%)	18 (90)	18 (90)	>.99	—	—	—
Within-family marriage, n (%)	15 (75)	11 (55)	.18	—	—	—
Pregnant, n (%)	2 (10)	4 (20)	.38	—	—	—

[a]Not available.

[b]N/A: not applicable.

[c]Rs 10,000=US $136.63.

Acceptance

The intervention had high overall acceptance by the participants. At 3-month follow-up, 100% (17/17) of female intervention participants reported they would recommend participating in the intervention to their friends, reporting that the intervention presented them with new information; enabled the couple to build partnership and closeness, understand one another's goals, and resolve existing misunderstandings; and resulted in their valuing and dedicating more time to their relationship.

Group exit interviews after the individual GBE sessions suggested all 6 sessions were highly accepted, with participants specifically mentioning they enjoyed the participatory nature and integrated games and competitions. Session 3, "Building Communication and Conflict Management Skills," and Session 5, "Sexual Communication and the Sexual Relationship," were the most favored. Participants endorsed easily connecting with the session 3 video content, as the dialogs paralleled the frustrations participants faced in their own relationships and family circumstances. Many reported that the videos and subsequent group reflections enabled them to recognize their shared histories and broaden their understanding of their partner's perspective, thereby fostering cohesion within and among couples in the group. Session 5, "Sexual Communication and the Sexual Relationship," was highly accepted, as participants reported it filled a key gap in their knowledge and was delivered by trusted health professionals in Marathi. Session 2, "I'm a Champion: I Can't Be Broken and I Don't Accept Defeat," was the least favored, as the delivery of many activities required a higher level of literacy and critical thinking among participants and peer educators. Specific session-specific feedback is presented in Table 2.

Table 2. Suggested session modifications to enhance acceptance and feasibility of Ghya Bharari Ekatra intervention delivery.

Session	Suggested modifications
1	• The exercise 2 "Prioritizing Time in Relationship" reflections should include additional probes to foster depth of discussion.
2	• In the group reflection, peer educators should be reminded to use existing probes about barriers to and strategies for addressing completion of the home assignment, which would enable effective group reflection, even among couples unable to complete the assignment. • Exercise 1, "Increased Social Participation," should directly link participants to community-based organizations hosting social events in place of relying on peers to collect and convey the social event information. • The exercise 2 "Enhanced Social Support" group diagramming exercise should be replaced with role-plays and reflections to reduce reliance on literacy and peer critical thinking skills and foster participation. Additionally, scenarios of greater relevance to female group members should be included.
3	• To foster depth of discussion and reflection among participants, the film for exercise 2, "Vadal Manache: Film and Discussion," should incorporate a scene depicting the couple attempting to reconcile differences.
4	• Exercise 3 "Getting the Job I Want" mock interviews should be prerecorded to address differences in facilitator skill and comfort level with acting. • The resume-building exercise should be replaced with a presentation on the importance of job retention, budget management, and financial resources, as this knowledge is of greater relevance to the intervention population.
5	• Two items (No. 7 and No. 10) on the exercise 2 "Misconceptions Quiz" need clarification. • Incorporate additional information on HIV, oral sex, and sham infertility treatments.
6	• Exercise 1.2, "Expanding My Definition of Violence," needs additional probes and examples of violence by in-laws and violence related to dowry to foster depth of discussion during reflection. Also, pictures should be added to address literacy challenges with the exercise.

Safety

No adverse events or safety concerns were raised during the intervention period by participants to research staff. At 3-month follow-up, 100% (17/17) of women reported feeling safe during the 6-week intervention period and none (0/17) reported spousal or family conflicts arising from their participation in the intervention. Study safety procedures were overall well received, with 16 of 17 women reporting the resource diary (which included domestic violence resources) helpful and 15 of 17 women reporting that having the contact information of study staff to be able to contact them at any time was helpful. No women used the women's day optional session to disclose safety concerns. CBO and peer educator passive monitoring of how the intervention was being discussed in the community also did not identify community tension or safety concerns caused by holding GBE in the communities.

Feasibility

Feasibility concerns with the delivery of GBE were minor and included (1) challenges with recruitment of male peer facilitators, as many men, while interested in the position, were unwilling to leave their jobs given the temporary nature; (2) challenges with delivering group-based activities (ie, games, group discussions) in sessions where the group size declined from 5 couples to 3 couples due to attrition; (3) delays in initiating session 1 due to the first portion of the study visit being dedicated to obtaining informed consent; (4) occasional temporary difficulties with showing session 3 films due to power outages; and (5) heat exhaustion of facilitators and participants due to lack of fans and air conditioning in most community

venues in intense summer temperatures. Sessions 2 and 4 relied on guest key informants (ie, of community-based organizations) who were variably in attendance; while their in-person presence enhanced the quality of the information presented and the discussion, their absence did not significantly impact session delivery, as the material was instead gathered and presented by the peer educators.

Process Evaluation

GBE was piloted in 5 separate groups of 3 to 5 participants.

Dose Delivered

In 4 of 5 groups, all 6 sessions were delivered. One of the 5 groups did not receive session 3 due to participant absence. Expected session content was delivered for all 6 sessions, with the exception of the session 2 group reflection on the home assignment, which was not consistently feasible, as it was dependent on participants having completed the associated home assignment. All intended GBE materials were used across sessions. The average duration of sessions 1 to 6 were 130, 138, 128, 123, 134, and 125 minutes, respectively.

Fidelity

The 1-week peer educator and health educator training was provided as planned for all GBE sessions. Overall, peer educators and health educators delivered GBE activities without difficulty during the training. The exception was session 2's exercises 2 and 3 and the session end summaries, during which facilitators improvised rather than following the script during the training. During the weekly refresher training sessions that preceded each session delivery, the study team focused on retraining the peer educators on the activities they found most challenging. During the actual intervention delivery, all activities were delivered as intended with the exception of session 2's group reflection (as delivery required that participants had completed the home assignment, which often was not the case), exercise 1 (as it required peers having researched social activities in their communities, which often was not the case), and exercise 2 (as it required a higher level of critical thinking by the facilitator); session 4's exercise 3 ("The Bad Interview"), as peers had difficulty acting out the bad interview; and session 6's exercise 1.1, as peers improvised rather than reading directly from the script.

Dose Received

Overall participant engagement was high across all session activities. Exceptions were the activities in which the facilitators experienced challenges with delivery (session 1 exercise 2, "Prioritizing the Time Spent in the Relationship"; session 2 exercise 2.1, "Realizing I Have Social Support"; and session 6 exercise 1.2, "Expanding My Definition of Violence").

Participation Rate

A total of 85% (17/20) of couples attended at least 5 of the 6 intervention sessions; 100% (20/20) attended session 1, 80% (16/20) attended session 2, 85% (17/20) attended session 3, 70% (14/20) attended session 4, 85% (17/20) attended session 5, and 85% (17/20) attended session 6. A total of 16% (19/120) of the total sessions were missed due to participant work (7/19, 37%), personal illness (5/19, 26%), family illness (3/19, 16%), the participant being out of town (3/19, 16%), or the participants attending a place of worship (1/19, 5%).

Recruitment Data

A total of 118 couples were approached, of which 28 (23.7%) did not meet inclusion criteria, 43 (36.4%) declined to participate, and 7 (5.9%) were not included due to insufficient other eligible couples in their community to form an intervention group. The remaining 40 were assigned to the intervention (n=20) and control group (n=20), with all providing informed consent and completing the baseline assessment (Figure 1).

Context

During the preimplementation process, study staff approached key community leaders and law enforcement officials to garner support. Community leaders were highly supportive, helping identify venue space (eg, community childcare centers, community halls) and waiving venue fees, providing electricity, and helping the study team make contacts with peers and potential participants. Law enforcement officials were also highly supportive of the intervention, warned female staff members of security risks at night, and vowed to be alert and responsive if security concerns arose in the community during the intervention. Preimplementation community sensitization meetings had variable attendance (3 to 11 members). Often, only men and mothers-in-law attended, but the meetings enabled study staff to clarify the intent of the intervention, foster dialogue around gatekeeper concerns for the intervention, and conduct an initial eligibility assessment. Preimplementation home visits by study staff to inform the families (particularly the mothers-in-law as household gatekeepers) of the intervention, assess interest, and establish eligibility of the couple were critical to participant recruitment and retention. During the intervention delivery, as the venues were located within often crowded slum communities, ambient noise and maintenance of privacy was often a challenge and required study staff to guard the door and distract onlookers. Additional challenges included adequacy of cooling and emergency lighting.

Preliminary Efficacy

As the study was a pilot, the sample was small and the follow-up period was short. In this context, there were no reported physical or sexual IPV events in either group but fewer incidents of psychological abuse in GBE participants (3/17, 18%) versus control participants (4/16, 25%) at 3-month follow-up. There was significant improvement in overall mental health of female intervention participants and declines in mental health among the control participants (change in mean GHQ-12 score: –0.13 intervention, 0.13 controls; P=.10). Last, among male intervention participants, the mean change in past 3-month alcohol use as measured by the AUDIT was –0.35 in the intervention and –0.11 in the control group (P=.74)

Discussion

GBE is the first documented couples-based primary prevention intervention for IPV developed and piloted in resource-limited settings. The exhaustive pilot evaluation demonstrated high acceptance, feasibility, safety, and preliminary efficacy of GBE

in preventing IPV and improving mental health in the female partner. It also identified challenges with participant recruitment and delivery, which could be easily addressed to improve acceptance and fidelity.

The high acceptance, participation, retention rate, safety, and overall feasibility can be attributed to the extensive use of community-based participatory methods during GBE development [18]. Intervention content and delivery was relevant and engaging, as it was designed around stories shared by participants during the development phase and responsive to their request to make the intervention fun and interactive and to have games and competitions. The few changes to enhance acceptance and feasibility (Table 2) would address literacy challenges, further decrease reliance on variance in critical thinking ability by the lay peer educators, and increase depth of reflection and discussions. The high retention was likely also due to the intervention being delivered by lay peer educators recruited from the communities of the participants and acquainted with the participants, the participants knowing one another, the intervention taking place in the communities, and early engagement of key gatekeepers, including the community and families. Early community sensitization, parent engagement, police knowledge, and lack of discussion of relationship IPV also were key to ensuring safety. Noted challenges to feasibility were easily addressable. Difficulties with male peer educator recruitment resulted from the men prioritizing their long-term work over the short-term income generated from attending the 1-week training, 1-hour retrainings, and facilitation of 6 weekly sessions. This barrier would be overcome if the intervention were ultimately implemented and peer facilitators formally hired. To overcome difficulties with recruiting couples of the lowest socioeconomic status (ie, day laborers), compensation should be increased to be commensurate with compensation for lost daily wages. Given the difficulties that arose when group size declined to 3 couples, future delivery should ensure that a minimum of 5 to 6 couples are present per group at the start of the 6-week intervention. Lastly, challenges with electricity shortages and overheating during the summer months could be addressed by selecting venues with backup electric generators and ensuring that fans and video projectors with battery backup are provided.

Although the pilot study used a small sample with a short follow-up, GBE was associated with significantly less reporting of psychological IPV and enhanced mental health among female participants. The prevention of IPV can be attributed to GBE being designed to address the determinants of IPV perpetration and experience identified in these communities [25,26]. There were no reported events of physical or sexual IPV by couples in the experimental or control arm, possibly because these forms of violence are less prevalent in the initial year of marriage [19]. As psychological IPV is often a predecessor of physical and sexual IPV, detection of prevented psychological IPV in the group receiving GBE may be a signal of the longitudinal prevention of physical and sexual forms of abuse in this group as well. The improvement in mental health may have been secondary to the prevention of IPV and strengthening of the relationship quality, as well as other potential social and cognitive mediators modified by the intervention. The absence of a detectable change in alcohol use by the male participants could have been due to low rates of alcohol use during the first year of marriage, the study being inadequately powered to detect these differences between groups, and alcohol harm reduction not being a core focus of GBE.

The study had several strengths and limitations. Strengths included the rigor of the process evaluation, the use of a community-based participatory approach that was inclusive of community sensitization predelivery of the intervention, the engaging interactive nature of the intervention, and the community-based delivery by lay peer educators from within the same community. One limitation was the significantly lower enrollment of couples of the lowest socioeconomic status into the intervention versus the control group due to lack of randomization. This bias was likely toward the null, however, as we would expect those of the lowest income to benefit most. A second limitation was the short follow-up period due to the pilot nature of the study, leaving unknown the longitudinal impact of the intervention on participant safety, IPV, mental health, and alcohol use. Future evaluation studies should extend the follow-up period to a minimum of 1 to 2 years to examine sustainability of effect.

In conclusion, GBE has high acceptance, feasibility, and preliminary efficacy in preventing IPV and improving mental health among women. Next steps include refining the intervention content based on the pilot findings and examining intervention efficacy through a large-scale randomized trial with longer follow-up across other regions of India. Implementation data will be collected as part of the trial to inform future dissemination and scaling. If deemed effective, GBE could be scaled across similar settings in Southeast Asia to address the high burden of IPV and mental health disorders.

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Conflicts of Interest

None declared.

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Abbreviations

AUDIT: Alcohol Use Disorders Identification Test
CBO: community-based organization
GBE: Ghya Bharari Ekatra
GHQ-12: General Health Questionnaire-12
ICMR-NARI: Indian Council of Medical Research National AIDS Research Institute
IFVCS: Indian Family Violence and Control Scale
IPV: intimate partner violence

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130 Queens Quay East.
Toronto, ON, M5A 3Y5
Phone: (+1) 416-583-2040
Email: support@jmir.org