

# JMIR Formative Research

Electronic, mobile, digital health approaches in cardiology and for cardiovascular health. Official partner journal of the European Congress on eCardiology and eHealth  
Volume 5 (2021), Issue 6 ISSN: 2561-326X Editor in Chief: Nico Bruining, PhD

## Contents

### Original Papers

|   |    |
|---|----|
| Adequate Management of Phosphorus in Patients Undergoing Hemodialysis Using a Dietary Smartphone App: Prospective Pilot Study ( <a href="#">e17858</a> )<br>Cosette Fakh El Khoury, Rik Crutzen, Jos Schols, Ruud Halfens, Mirey Karavetian. ....   | 2  |
| Using a Mobile App–Based Video Recommender System of Patient Narratives to Prepare Women for Breast Cancer Surgery: Development and Usability Study Informed by Qualitative Data ( <a href="#">e22970</a> )<br>Ilja Ormel, Charles Onu, Mona Magalhaes, Terence Tang, John Hughes, Susan Law. ....  | 13 |
| Multicultural Adaptation of Mighty Girls for Widespread Dissemination: Pilot Study, App Development and Usability Testing, and Gauging Parent Support With Focus Groups ( <a href="#">e24937</a> )<br>Anne Norris, Roxana Thalasinis, Michael Hecht. ....   | 26 |
| Testing the Feasibility of Sensor-Based Home Health Monitoring (TEC4Home) to Support the Convalescence of Patients With Heart Failure: Pre–Post Study ( <a href="#">e24509</a> )<br>Kendall Ho, Helen Novak Lauscher, Jennifer Cordeiro, Nathaniel Hawkins, Frank Scheuermeyer, Craig Mitton, Hubert Wong, Colleen McGavin, Dianne Ross, Glory Apantaku, Mohammad Karim, Amrit Bhullar, Riyad Abu-Laban, Suzanne Nixon, Tyler Smith. .... | 41 |
| Expanding the Reach of Research: Quantitative Evaluation of a Web-Based Approach for Remote Recruitment of People Who Hear Voices ( <a href="#">e23118</a> )<br>Benjamin Buck, Ayesha Chander, Rachel Brian, Weichen Wang, Andrew Campbell, Dror Ben-Zeev. ....   | 52 |
| Health Perceptions and Adopted Lifestyle Behaviors During the COVID-19 Pandemic: Cross-National Survey ( <a href="#">e23630</a> )<br>Nandi Manjunath, Vijaya Majumdar, Antonietta Rozzi, Wang Huiru, Avinash Mishra, Keishin Kimura, Raghuram Nagarathna, Hongasandra Nagendra. ....  | 65 |

### Short Paper

|   |    |
|---|----|
| Acceptability of Research and Health Care Visits During the COVID-19 Pandemic: Cross-sectional Survey Study ( <a href="#">e27185</a> )<br>Kathryn Ross, Young-Rock Hong, Rebecca Krukowski, Darci Miller, Dominick Lemas, Michelle Cardel. .... | 77 |
|---|----|

Original Paper

# Adequate Management of Phosphorus in Patients Undergoing Hemodialysis Using a Dietary Smartphone App: Prospective Pilot Study

Cosette Fakih El Khoury<sup>1</sup>, BSc, MSc, PhD; Rik Crutzen<sup>2</sup>, PhD; Jos MGA Schols<sup>1</sup>, PhD; Ruud JG Halfens<sup>3</sup>, PhD; Mirey Karavetian<sup>4</sup>, PhD

<sup>1</sup>Department of Health Services Research, Care and Public Health Research Institute, Faculty of Health, Medicine and Life Sciences, Maastricht University, Maastricht, Netherlands

<sup>2</sup>Department of Health Promotion, Care and Public Health Research Institute, Faculty of Health, Medicine and Life Sciences, Maastricht University, Maastricht, Netherlands

<sup>3</sup>Care and Public Health Research Institute, Department of Health Services Research, Maastricht University, Maastricht, Netherlands

<sup>4</sup>Department of Health Sciences, Zayed University, Dubai, United Arab Emirates

**Corresponding Author:**

Mirey Karavetian, PhD  
Department of Health Sciences  
Zayed University  
Academic city PO Box 19282  
Dubai  
United Arab Emirates  
Phone: 971 562446865  
Email: [kmirey@gmail.com](mailto:kmirey@gmail.com)

## Abstract

**Background:** The renal diet is complex and requires alterations of the diet and careful monitoring of various nutrients. Elevated serum phosphorus is common among patients undergoing hemodialysis, and it is associated with many complications. Smartphone technology could be used to support both dietitians and patients by providing a source of accessible and reliable information.

**Objective:** The aim of this pilot is to assess the potential efficacy of an intervention using the educational and self-monitoring mobile app KELA.AE on the phosphorous management in hemodialysis patients. Results will be used to improve both the app and a planned, rigorous large-scale trial intended to assess app efficacy.

**Methods:** This is a prospective pilot study performed at the hemodialysis unit of Al Qassimi Hospital (Emirate of Sharjah, United Arab Emirates). All patients were assessed for eligibility and, based on inclusion criteria, considered for enrollment. Participants met with a dietitian once a week and used the mobile app regularly for 2 weeks. Outcomes (knowledge, self-reported nonadherence, dietary intake, anthropometry, and biochemical data) were measured. This pilot is reported as per guidelines for nonrandomized pilot and feasibility studies and in line with the CONSORT (Consolidated Standards of Reporting Trials) 2010 checklist for reporting pilot or feasibility trials.

**Results:** Of 26 subjects, 23 successfully completed the pilot. Patient dietary knowledge about phosphorous management improved from 51.4% (SD 13.9) to 68.1% (SD 13.3) after intervention with a large effect size ( $d=1.22$ , 95% CI 0.59 to 1.85). Dietary protein intake increased from a mean of 0.9 g/kg (SD 0.3) per day to a mean of 1.3 g/kg (SD 0.5) per day with a large effect size ( $d=1.07$ , 95% CI 0.45 to 1.69). Phosphorus to protein ratio dropped from a mean of 18.4 mg/g protein to 13.5 mg/g protein with a large effect size ( $d=0.83$ , 95% CI 0.22 to 1.43). There was no evidence of change in phosphorous intake, self-reported nonadherence, and serum phosphorus.

**Conclusions:** The findings of this prospective pilot reveal the potential efficacy of a smartphone app as a supportive nutrition education tool for phosphorus management in patients undergoing hemodialysis. This pilot study showed that the KELA.AE app has the potential to improve knowledge and dietary choices. A rigorous randomized controlled trial should be performed to evaluate the efficacy, assessing app use of a long-term intervention.

(JMIR Form Res 2021;5(6):e17858) doi:[10.2196/17858](https://doi.org/10.2196/17858)

**KEYWORDS**

renal diet; mhealth; dietary app

**Introduction**

Dietary management plays an essential role in slowing down disease progression and improving the quality of life of people with chronic kidney disease (CKD) [1,2]. However, the renal diet is complex and requires targeted attention of the intake of various nutrients [3], and patients often express frustration and confusion about this [4]. Dietary adjustments are made continuously in response to alterations in blood parameters, and patients must be constantly monitored and followed up accordingly [5].

Elevation in blood phosphorus is specifically common among this patient group, and it is associated with many comorbidities such as cardiovascular disease, metabolic bone mineral disease, and mortality [5]. Even a mild hyperphosphatemia (greater than 5.0 mg/dL) is independently associated with an increase in mortality among hemodialysis patients [6]. Therefore, management of hyperphosphatemia is essential during hemodialysis; however, this seems to be particularly challenging. Patients are recommended to consume 1.2 g/kg body weight of protein to achieve protein needs during hemodialysis [3]. Moreover, phosphorus is typically found in protein-rich foods; thus, restricting dietary phosphorus to the recommended 800 to 1000 mg/d while maintaining adequate protein intake is the cornerstone of this diet [3]. Such recommendations are not easily compatible [7] and lead to conflicting and ambiguous information that requires simplification and clarification from the dietitian's side [8].

Adherence to the renal diet is, therefore, an essential component for the management of hemodialysis patients [9]. Patient knowledge can play a role in compliance with the diet [10]. Therefore, nutrition education and counseling might have a positive effect on blood phosphorous [11]. However, eating habits are complicated and not merely influenced by knowledge, but also by a patient's readiness to change and their health beliefs [12]. The association between knowledge and adherence is not always clear, and an increase in knowledge does not necessarily lead to improved adherence [13]. Nutrition education can, nevertheless, improve nutrition knowledge, which, in turn, can support increased dietary adherence [14,15]. This knowledge is especially valuable when patients are willing to change their dietary behaviors [13].

From the patient's perspective, receiving easy to understand individualized nutrition education at the early stages is desired [4]. Educational materials should be theory-based and adapted to the patient [2] to be effective. A thorough education has been listed among the facilitators for improvements of serum phosphorus. Such interventions consist of multiple long encounters with patients and thus may not always be feasible [16]. Time limitation during encounters with dietitians and physicians often act as a barrier to effective nutrition education [17].

A recent study qualitatively explored the experience of renal dietitians. Dietitians expressed frustration, limited resources,

and emotional and professional challenges in providing dietary education to CKD patients [8]. Hemodialysis patients show similar frustration and a need for continuous access to reliable nutrition information. Therefore, alternative approaches should be explored that may support both dietitians and patients in overcoming these difficulties. Smartphone technology can provide persons with chronic diseases with accessible and reliable information [18]. Additionally, in-app educational materials allow patients access to nutrition education in different modalities [19]. Accordingly, dietary apps may be effective at improving nutritional outcomes in chronic diseases [20].

Freely accessed educational websites are available to CKD patients, but they target persons with high computer literacy [21]. Commercially, some renal nutrition apps are also available, but they are mostly available in the English language only and may include a subscription fee [22,23]. Research in this area is still scarce as only a few publications have addressed the effectiveness of mHealth in the context of CKD [23]. Additionally, only a few registered clinical trials are active in the area of mHealth in CKD [24].

The IDEAS (integrate, design, assess, and share) framework for the development of effective digital interventions defines the process of assessing the efficacy of a developed product as starting with a pilot study aiming at estimating potential efficacy. Information gathered from the pilot study would then be used to improve the product itself and the study design of a rigorous randomized controlled trial (RCT) [25].

This is a pilot study that aims to explore the potential efficacy of an intervention using a smartphone app in the phosphorus management of patients undergoing hemodialysis. The results of this pilot study will be used to improve the app itself along with the study design of a rigorous RCT. The app used is research-based and includes self-monitoring features, educational features, and CKD-friendly recipes in English and Arabic. The description of the person-centered and theory-based app development is detailed in a separate publication [19].

**Methods****Study Design**

This is a prospective pilot study conducted using a theory-based educational dietary app Kidney Education Lifestyle Application (KELA.AE). This pilot followed the guidelines for reporting nonrandomized pilot and feasibility studies [26]. This study is also reported in line with the CONSORT (Consolidated Standards of Reporting Trials) 2010 checklist of information to include when reporting a pilot or feasibility trial excluding items pertinent to randomization (Multimedia Appendix 3) [26,27]. Outcome measures include knowledge, self-reported nonadherence, dietary intake, anthropometry, and biochemical data.

## Participants, Eligibility, and Recruitment

A list of all patients undergoing hemodialysis was obtained from the hemodialysis unit of Al Qassimi Hospital (Emirate of Sharjah, United Arab Emirates), and all subjects were approached during their scheduled dialysis session to identify those who met the inclusion criteria. The study was explained to eligible participants, and signed consent forms were collected from those who agreed to participate. A total of 26 participants were recruited. Patients undergoing hemodialysis for at least 3 months; free of life-threatening conditions; able to read, write, listen, and communicate in Arabic; owning an Android smartphone; and not having been hospitalized in the past 6 months were eligible to participate in the study. Recruitment and data collection began in February 2019 and ended in April 2019. Post hoc calculations of sample size in pilot studies, assuming detection of unanticipated problems with a probability of at least 15% ( $\pi=0.15$ ) and a 95% confidence level, resulted in a required sample of 19 subjects [28].

## Ethical Approvals

The study received Institutional Review Board approval (ZU17\_066\_F) from Zayed University, Dubai.

## Procedure

Participants were provided with a username to initiate the sign-in procedure. Upon registration, participants were provided with a brief orientation to the app features, and free access to KELA.AE was provided for 2 weeks. During this period, participants met face-to-face with a research dietitian once a week. The dietitian provided participants with reinforcements of the critical messages relayed by the educational materials and answered questions about the app use and content. The dietitians also collected data from patients before and after app use. Baseline and postintervention outcomes were assessed before app registration (T0) and after the completion of 2 weeks of app use (T1). The trial was stopped when all participants completed 2 weeks of app use. Participants could keep using the app if they wished; however, all data collection was completed 2 weeks after app use.

## KELA.AE App

The app consists of an Arabic, theory-based, and culture-specific Android app (KELA.AE). A formative study of the app has been published elsewhere [19]. The app was designed to provide dietary education and traditional renal diet-friendly recipes to hemodialysis patients. The transtheoretical model [29] and constructs from the reasoned action approach [30] were incorporated in the development of the educational materials. Three different stages of change have been included along with the concepts of self-efficacy, norms, and attitudes. Behavior change techniques used included self-monitoring of behavior, problem solving and coping planning, goal setting, social comparison of behavior, and verbal persuasion to boost self-efficacy. The stages and constructs were incorporated based on previously published, validated stage-based materials [31], qualitative data, and brainstorming sessions performed during app development by the research team [19]. Different educational modalities were used to deliver the behavior change techniques: notifications, podcasts, and videos. Each modality

is matched to a behavior stage and a construct from the reasoned action approach; an example would be a notification that is delivered to the user stating “Many dialysis patients have benefited from the advantages of exercising and were able to improve their quality of life. You can do it too!” (this is provided to a patient categorized in the action stage and linked to capacity/self-efficacy). Additional examples of educational materials are reported in a separate publication [19]. Self-monitoring features to track food intake and blood tests are also available.

The app was developed as a collaboration between the research team and the design team of an app development company. The technical development of the app software was outsourced by the research team to the development company. Educational materials were prepared by the research team in collaboration with the departments of Arabic and communications of Zayed University. The app is hosted on the servers of the development company.

## Self-Reported Nonadherence

The Dialysis Diet and Fluid nonadherence Questionnaire was used to assess self-reported dietary nonadherence [32] (Multimedia Appendix 1). The questionnaire includes 2 simple questions on the frequency and degree of nonadherence. The same questions are asked for overall dietary nonadherence and again for dietary phosphorus nonadherence (total of 4 questions). It requires the patient to report nonadherence as the number of nonadherent days in the last 14 days. The degree of nonadherence is reported on a Likert scale (0 to 4, where 0 means compliant and 4 means severe nonadherence). The questions were translated to Arabic but given their straightforward simplicity further validation was deemed unnecessary. Construct validity of the original tool was reported using a Kendall tau correlation for frequency and degrees of nonadherence ( $\tau=0.495$ ;  $P<.001$ ) [32]. Adherence via the app was not collected due to the lack of in-app analytics in the current version of the app.

## Knowledge

The Knowledge Questionnaire consists of 18 questions assessing knowledge about the renal diet (Multimedia Appendix 2). A total of 18 points can be achieved if all answers are correct; scores were then converted into a percentage. This tool was used in Arabic before [33] based on an adaptation of the original questionnaire [34] and now includes Arabic foods. A score of 60% in overall knowledge (all 18 questions) was considered as sufficient knowledge as recommended by the questionnaire [33]. Questions were clustered by topic, and a subanalysis was performed to understand knowledge in specific areas pertinent to phosphorous management (phosphorus content in food, consequences of hyperphosphatemia, and use of phosphate binders).

## Dietary Intake

Dietary intake was assessed by 2 trained research dietitians using face-to-face 24-hour recalls [35]. Participants were asked if the day before was deemed representative of the previous week, and if not, they were asked to report a typical day for better representation of the past week's intake. The 24-hour

recalls were analyzed using the FoodData Central of US Department of Agriculture databases [36]. Phosphorus needs were considered as 1000 mg/d for participants with serum phosphorus below 5.5 mg/dL and 12 mg/g of protein intake for participants with serum phosphorus below 5.5 mg/dL [37].

### Biochemical Parameters

Blood parameters were retrieved from patient medical records as part of the routine protocols of the hemodialysis unit (measurements are taken post hemodialysis session). Target values for serum phosphorus in hemodialysis were considered between 3.5 and 5.5 mg/dL based on the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF KDOQI) recommendations [3].

### Anthropometric Measurements

Body weight and height were retrieved from patient medical records, as measured postdialysis routinely. BMI was calculated accordingly using measured body weight and height. Comparative standards for body weight were used as suggested by the Nutrition Care Manual [37] based on the NKF KDOQI guidelines [3]. Accordingly, standard body weight from the National Health and Nutrition Examination Study was used for the calculation of nutrient needs. Adjusted edema-free body weight was used for the calculation of nutrient needs for participants with <95% or >115% of standard body weight [37] as recommended by the guidelines.

### Statistical Analysis

SPSS (version 21, IBM Corp) was used to perform all statistical analyses. Categorical variables were described using frequencies and percentages, while means and standard deviations were used to represent continuous variables. A Shapiro-Wilk normality test was performed to ensure that data are normally distributed. Paired *t* tests were used to compare the mean scores before and after the intervention. Two-tailed *P* values are reported. Effect sizes were calculated as Cohen *d* (with 95% CI) using mean difference and pooled standard deviations. The effect size was considered small at 0.2, medium at 0.5, and large at 0.8 and above [38].

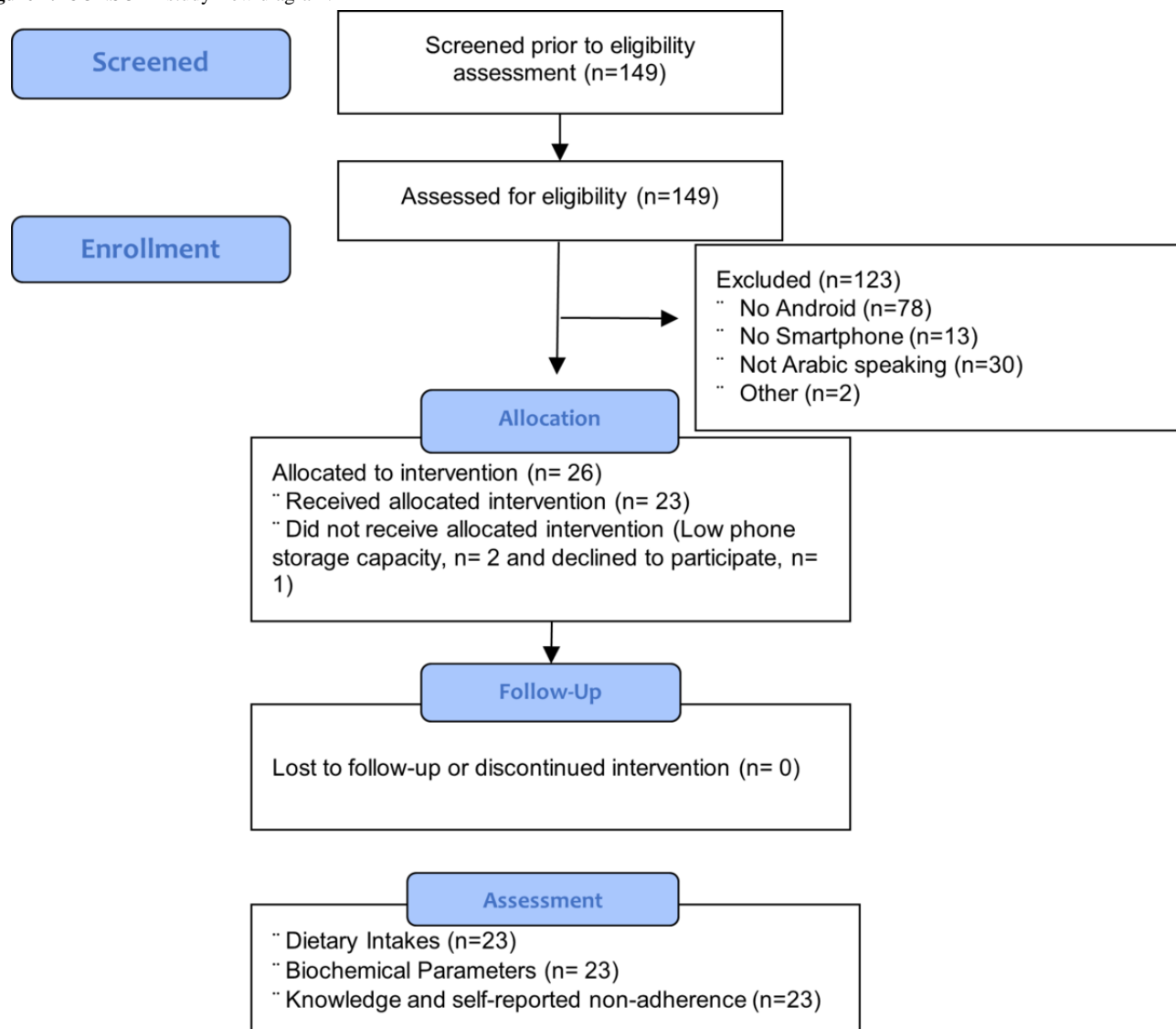
### Results

A total of 23 participants completed the app pilot testing. Two subjects were excluded due to issues related to low smartphone storage capacity, and one subject was not interested in downloading the app. The mean age of the participants was 48.5 (SD 13.7) years, mean BMI was 31.9 (SD 7.9) kg/m<sup>2</sup>, and mean time on dialysis was over 1 year, with 29.7 (SD 37.3) months of dialysis. More men were enrolled in the study (14/23, 61%), and most participants suffered from hypertension (16/23, 70%) or diabetes (11/23, 48%). Demographics measured at baseline are shown in Table 1. Figure 1 depicts the CONSORT flow diagram.

**Table 1.** Demographics and baseline characteristics of the study population (n=23).

| Characteristic                      | Value       |
|-------------------------------------|-------------|
| Age (years), mean (SD)              | 48.5 (13.7) |
| BMI (kg/m <sup>2</sup> ), mean (SD) | 31.9 (7.9)  |
| Months on dialysis, mean (SD)       | 29.7 (37.3) |
| <b>Gender, n (%)</b>                |             |
| Male                                | 14 (61)     |
| Female                              | 9 (39)      |
| Smoker, n (%)                       | 6 (26)      |
| <b>Comorbidities, n (%)</b>         |             |
| Hypertension                        | 16 (70)     |
| Diabetes                            | 11 (48)     |
| Dyslipidemia                        | 2 (9)       |
| Cancer                              | 1 (4)       |
| Liver disease                       | 1 (4)       |



**Figure 1.** CONSORT study flow diagram.

### Knowledge and Nonadherence

Overall, the mean self-reported nonadherence days dropped from 3.2 (SD 4.5) over the past 14 days to 2.0 (SD 3.0) days after exposure to in-app education with a small effect size ( $d=0.33$ , 95% CI  $-0.25$  to  $0.91$ ). The severity of nonadherence was mostly mild and moderate preintervention and postintervention.

The mean perceived days of nonadherence to the phosphorus content of the diet increased from 1.1 (SD 3.2) days to 1.9 (SD 3.0) days with a small effect size ( $d=0.25$ , 95% CI  $0.33$  to  $0.83$ ). The severity of nonadherence changed from 19 participants

reporting no deviation from the diet to only 10 reporting no deviation.

Knowledge was below the 60% cutoff point of adequate knowledge at baseline and improved to reach a mean of 68.1% (13.3) after intervention, with a large effect size ( $d=1.22$ , 95% CI  $0.59$  to  $1.85$ ). Specific knowledge pertinent to consequences of hyperphosphatemia and phosphate binders also improved (large effect sizes  $d=1.15$ , 95% CI  $0.53$  to  $1.77$ , and  $d=1.00$ , 95% CI  $0.39$  to  $1.61$ , respectively). Knowledge about the phosphorus content of food improved, with a medium effect size ( $d=0.54$ , 95% CI  $-0.05$  to  $1.12$ ). Results pertinent to adherence and knowledge are detailed in [Table 2](#).

**Table 2.** Baseline and postintervention self-reported dietary nonadherence and dietary knowledge (n=23).

| Questionnaire   | Baseline    | Postintervention | Cohen <i>d</i> (95% CI) | <i>P</i> value |
|---|-------------|------------------|-------------------------|----------------|
| <b>DDFQ<sup>a</sup>, overall</b>  |             |                  |                         |                |
| Nonadherence (days), mean (SD)  | 3.2 (4.5)   | 2.0 (3.0)        | 0.33 (–0.25 to 0.91)    | .32            |
| <b>Nonadherence (degree), n (%)</b>                                       |             |                  |                         |                |
| No deviation (0)  | 11 (48)     | 11 (11)          | — <sup>b</sup>          | —              |
| Mild (1)  | 5 (22)      | 4 (4)            | —                       | —              |
| Moderate (2)  | 4 (17)      | 7 (7)            | —                       | —              |
| Severe (3)  | 2 (9)       | 1 (1)            | —                       | —              |
| Very severe (4)   | 1 (4)       | 0 (0)            | —                       | —              |
| <b>DDFQ, phosphorus</b>   |             |                  |                         |                |
| Nonadherence (days), mean (SD)  | 1.1 (3.2)   | 1.9 (3.0)        | 0.25 (0.33 to 0.83)     | .45            |
| <b>Nonadherence (degree), n (%)</b>                                       |             |                  |                         |                |
| No deviation (0)  | 19 (83)     | 10 (44)          | —                       | —              |
| Mild (1)  | 1 (4)       | 5 (22)           | —                       | —              |
| Moderate (2)  | 2 (9)       | 7 (30)           | —                       | —              |
| Severe (3)  | 0 (0)       | 1 (4)            | —                       | —              |
| Very severe (4)   | 1 (4)       | 0 (0)            | —                       | —              |
| <b>KnQ<sup>c</sup>, mean (SD)</b>   |             |                  |                         |                |
| % Overall knowledge (>18 questions)                                       | 51.4 (13.9) | 68.1 (13.3)      | 1.22 (0.59 to 1.85)     | <.001          |
| Knowledge of phosphorus content of food (>7 questions)                    | 47.8 (21.4) | 57.1 (12.2)      | 0.54 (–0.05 to 1.12)    | .06            |
| Knowledge of consequences of high levels of phosphorus (>4 questionnaire) | 43.5 (18.8) | 66.3 (20.8)      | 1.15 (0.53 to 1.77)     | <.001          |
| Knowledge of phosphate binders (>4 questions)                             | 48.9 (29.6) | 76.1 (24.4)      | 1.00 (0.39 to 1.61)     | <.001          |

<sup>a</sup>DDFQ: Dialysis Diet and Fluid Questionnaire.<sup>b</sup>Not applicable.<sup>c</sup>KnQ: Knowledge Questionnaire.

### Serum Phosphorus and Dietary Intake

Dietary protein intake increased from a mean intake of 0.9 (SD 0.3) g/kg per day to a mean intake of 1.3 (SD 0.5) g/kg per day with a large effect size ( $d=1.07$ , 95% CI 0.45 to 1.69). Phosphorus intake as compared to phosphorus needs did not change. However, the phosphorus to protein ratio dropped from a mean of 18.4 mg/g of protein to 13.5 mg/g of protein with a large effect size ( $d=0.83$ , 95% CI 0.22 to 1.43). This result is

desirable given that it is closer to the recommended 12 mg/g of protein.

No changes were identified in serum phosphorus; however, the number of participants with serum phosphorus above 6 mg/dL increased to become 10 subjects as compared to 6 at baseline. This may be in line with the increase in protein intake and a slight increase in total phosphorus intake. Table 3 illustrates data on serum phosphorus and dietary intake.

**Table 3.** Baseline and postintervention dietary intake and serum phosphorus level (n=23).

| Parameter                                      | Baseline       | Postintervention | Cohen <i>d</i> (95% CI) | <i>P</i> value |
|--|----------------|------------------|-------------------------|----------------|
| <b>Phosphorus intake, mean (SD)</b>            |                |                  |                         |                |
| Dietary phosphorus (mg/d)                      | 1152.5 (489.8) | 1343.1 (83.0)    | 0.42 (–0.15 to 1.01)    | .88            |
| % compliance to phosphorus needs               | 108.3 (44.5)   | 109.4 (45.5)     | 0.02 (–0.55 to 0.60)    | .72            |
| Dietary protein (g/d)                          | 71.1 (26.4)    | 103.8 (37.8)     | 1.00 (0.38 to 1.61)     | <.001          |
| Dietary protein (g/kg/d)                       | 0.9 (0.3)      | 1.3 (0.5)        | 1.07 (0.45 to 1.69)     | <.001          |
| Phosphorus to protein ratio (mg/g)             | 18.4 (7.9)     | 13.5 (2.9)       | 0.83 (0.22 to 1.43)     | .01            |
| Serum phosphorus (mg/dL), mean (SD)            | 5.3 (1.5)      | 5.5 (2.0)        | 0.15 (–0.43 to 0.73)    | .60            |
| <b>Nonadherence to serum phosphorus, n (%)</b> |                |                  |                         |                |
| < 5 mg/dL                                      | 11 (48)        | 11 (48)          | — <sup>a</sup>          | —              |
| 5–6 mg/dL                                      | 6 (26)         | 2 (9)            | —                       | —              |
| > 6 mg/dL                                      | 6 (26)         | 10 (43)          | —                       | —              |

<sup>a</sup>Not applicable.

## Discussion

### Principal Findings

The main findings of this prospective pilot study show that in-app nutrition education, as a supportive tool to dietitians, can improve knowledge of the renal diet among patients undergoing hemodialysis. Thus, the in-app educational features (notifications, podcasts, videos, and recipes) of the KELA.AE app might have potential as a useful source of nutrition education for patients undergoing hemodialysis. The use of smartphones as supportive tools to deliver education may help overcome the time limitation barrier that is reported during face-to-face encounters with dietitians and physicians [17]. Accordingly, app availability may be beneficial to both patients and health care practitioners as supportive tools for regular care.

However, self-reported adherence to the renal diet was not changed after the use of the KELA.AE smartphone app. Self-reported dietary questionnaires may be a source of bias related to social desirability. Nevertheless, adherence to phosphorus intake (24-hour recalls) and serum phosphorus did not improve either. Knowledge scores were not satisfactory at baseline (below the 60% cutoff used) and increased significantly to reach a mean score of 68.1%. It seems that the association between knowledge and dietary nonadherence in dialysis patients is not always clear [39]. In the results of this prospective pilot, nonadherence to the phosphorus content of the diet increased after the intervention. The increase in knowledge may explain this. Patients might have become more aware of the phosphorus content of food and therefore, their self-perception of nonadherence changed accordingly. A study performed in patients with heart failure reported that despite knowledge on the sodium restriction diet being high, only 40% of participants were adherent to the restrictions based on urine sodium excretion. However, perception of the benefits of the diet was correlated with dietary adherence [40]. Nevertheless, other studies have found that intense nutrition education [41,42] and dietary knowledge [15] improve adherence. Accordingly, longer exposure to continuous education both by dietitians and in-app

education material may be needed to understand if increased knowledge may improve adherence and possibly serum phosphorus.

An increase in dietary protein was nevertheless observed as an outcome of the intervention. Protein intake in hemodialysis is essential for the prevention of malnutrition. There is also an association between reduced protein intake and increased mortality [43]. The participants in this pilot study started with low protein intake as compared to the needs of  $\geq 1.2$  g/kg/d recommended by NKF KDOQI guidelines [3] and achieved an average intake in line with recommendations postintervention. The contradiction between the protein and phosphorous recommendations of the dialysis diet may lead to protein restriction as a result of decreased phosphorous intake. Baseline and postintervention phosphorus intake were within phosphorus recommendations. Therefore, the increase in protein intake did not negatively impact phosphorus intake. Additionally, the phosphorus to protein ratio postintervention was closer to the recommended ratio of 10 to 12 mg/g of protein [3], meaning that patients increased their protein intake while choosing foods that were lower in phosphorus. These dietary changes may be a result of increased patient knowledge. However, the duration of the intervention may have been too short to detect changes in serum phosphorus, which is a limitation of the pilot. This will be better explored in the future trial.

Adherence to phosphate binders is also an essential component in the phosphorous management of dialysis patients. In this pilot, knowledge pertinent to phosphate binders improved postintervention; however, adherence to binders was not measured directly. Additionally, types of binders and their prescriptions were not investigated and benchmarked with recommendations.

### Limitations

Another limitation of the pilot study is the lack of app use data, which was not retrievable due to the lack of in-app analytics. The first and last access for each user are the only data available, and all users had accessed the app at least once during each week. The next version of the app will include in-app analytics



to allow the future trial to track if app use influences improvement in outcomes.

Additionally, user acceptability should also be further assessed. A questionnaire was used during this pilot study to explore acceptability; however, all participants provided answers indicating that they strongly agree with all the questions. The team considered the data collected unsuitable for the assessment of acceptability. Acceptability will be assessed in the future trial using the validated Arabic version of the Mobile Application Rating Scale [44]. Qualitative data will also be added to the assessment during the future trial.

Valid interpretation, translation, and generalizability of mHealth interventions also depend on the assessment of treatment fidelity [45]. The future trial will also assess treatment fidelity in-depth to ensure integrity, reliability, and validity of this mHealth intervention before the interpretation and generalizability of the results. During this pilot, we were unable to ensure compliance with all the goals of treatment fidelity proposed by the Treatment Fidelity Workgroup of the National Institutes of Health Behavior Change Consortium [46]. Among the goals that we were able to meet during the pilot are the standardization of treatment and prevention of contamination, participants' ability to use the app, and provider training. The steps included automated notifications delivered equally to all participants, an orientation session for participants, pilot testing of educational materials, and the training provided to the dietitians meeting patients weekly. However, due to the lack of in-app analytics, we were unable to track the enactment of the self-monitoring tools adequately.

The intervention included encounters with dietitians that may have influenced the outcomes. This methodology was opted as this is how the app use is envisioned in the practice setting. The app would be a tool that dietitians use to support patient education and self-monitoring. The reinforcement of the

dietitians, however, may have influenced the results. Accordingly, the future trial will include a control group whereby dietitians see patients with the same frequency but without app use.

This pilot aimed to assess and refine the methodology and procedures of a future trial aiming to detect the efficacy of app use in the adequate management of phosphorous in patients undergoing hemodialysis. Similar to the few available studies evaluating dietary apps for CKD on a smartphone [23], our results show potential benefits on dietary intake. However, this study is unique for evaluating the potential of apps as educational tools to support dietitians. Additionally, it is the first intervention reporting the role of dietary apps for CKD in Arabic. Based on the findings, the planned trial should be designed to compare regular dietary interventions with dietary interventions supported by the app to avoid the possible confounding effects of the dietitian. During this study, participants often consulted with the research team throughout the regular weekly visits; thus, it would be important to explore further if the app enhances the phosphorous management or if it is instead the frequent dietary follow-up that leads to improvements. In conclusion, the future trial should also evaluate the use of phosphate binders, app use data, acceptability, and fidelity, and it should be designed in a way to detect if the app provides any advantages in the clinical outcomes of phosphorous management as compared to intensive dietary follow up by a dietitian.

## Conclusions

The findings of this pilot study indicate that there is potential in the use of a smartphone app as a supportive nutrition education tool. A rigorous RCT should be performed to evaluate the efficacy, in which app use and long-term impact should be assessed.

---

## Acknowledgments

We acknowledge the staff and students from Zayed University who volunteered by contributing to the app development at many steps. This study was funded by research grant R18060 provided by Zayed University.

---

## Conflicts of Interest

None declared.

---

### Multimedia Appendix 1

Dialysis Diet and Fluid non-adherence Questionnaire.

[DOCX File, 41 KB - [formative\\_v5i6e17858\\_app1.docx](#)]

---

### Multimedia Appendix 2

Knowledge Questionnaire.

[PDF File (Adobe PDF File), 118 KB - [formative\\_v5i6e17858\\_app2.pdf](#)]

---

### Multimedia Appendix 3

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial.

[DOC File, 228 KB - [formative\\_v5i6e17858\\_app3.doc](#)]

---

## References

1. Palmer SC, Maggo JK, Campbell KL, Craig JC, Johnson DW, Sutanto B, et al. Dietary interventions for adults with chronic kidney disease. *Cochrane Database Syst Rev* 2017 Apr 23;4:CD011998 [[FREE Full text](#)] [doi: [10.1002/14651858.CD011998.pub2](https://doi.org/10.1002/14651858.CD011998.pub2)] [Medline: [28434208](#)]
2. Beto JA, Ramirez WE, Bansal VK. Medical nutrition therapy in adults with chronic kidney disease: integrating evidence and consensus into practice for the generalist registered dietitian nutritionist. *J Acad Nutr Diet* 2014 Jul;114(7):1077-1087. [doi: [10.1016/j.jand.2013.12.009](https://doi.org/10.1016/j.jand.2013.12.009)] [Medline: [24582998](#)]
3. Kopple JD. National Kidney Foundation K/DOQI clinical practice guidelines for nutrition in chronic renal failure. *Am J Kidney Dis* 2001 Jan;37(1 Suppl 2):S66-S70. [doi: [10.1053/ajkd.2001.20748](https://doi.org/10.1053/ajkd.2001.20748)] [Medline: [11158865](#)]
4. Hollingdale R, Sutton D, Hart K. Facilitating dietary change in renal disease: investigating patients' perspectives. *J Ren Care* 2008 Sep;34(3):136-142. [doi: [10.1111/j.1755-6686.2008.00034.x](https://doi.org/10.1111/j.1755-6686.2008.00034.x)] [Medline: [18786080](#)]
5. Abe M, Okada K, Soma M. Mineral metabolic abnormalities and mortality in dialysis patients. *Nutrients* 2013 Mar 22;5(3):1002-1023 [[FREE Full text](#)] [doi: [10.3390/nu5031002](https://doi.org/10.3390/nu5031002)] [Medline: [23525083](#)]
6. Rodriguez-Benot A, Martin-Malo A, Alvarez-Lara MA, Rodriguez M, Aljama P. Mild hyperphosphatemia and mortality in hemodialysis patients. *Am J Kidney Dis* 2005 Jul;46(1):68-77. [doi: [10.1053/j.ajkd.2005.04.006](https://doi.org/10.1053/j.ajkd.2005.04.006)] [Medline: [15983959](#)]
7. Shaman AM, Kowalski SR. Hyperphosphatemia management in patients with chronic kidney disease. *Saudi Pharm J* 2016 Jul;24(4):494-505 [[FREE Full text](#)] [doi: [10.1016/j.jsps.2015.01.009](https://doi.org/10.1016/j.jsps.2015.01.009)] [Medline: [27330380](#)]
8. Lambert K, Mansfield K, Mullan J. Qualitative exploration of the experiences of renal dietitians and how they help patients with end stage kidney disease to understand the renal diet. *Nutr Diet* 2019 Apr;76(2):126-134. [doi: [10.1111/1747-0080.12443](https://doi.org/10.1111/1747-0080.12443)] [Medline: [29968271](#)]
9. Clark-Cutaia MN, Ren D, Hoffman LA, Burke LE, Sevvick MA. Adherence to hemodialysis dietary sodium recommendations: influence of patient characteristics, self-efficacy, and perceived barriers. *J Ren Nutr* 2014 Mar;24(2):92-99 [[FREE Full text](#)] [doi: [10.1053/j.jrn.2013.11.007](https://doi.org/10.1053/j.jrn.2013.11.007)] [Medline: [24462498](#)]
10. van Doorn-van Atten MN, de Groot LCPGM, de Vries JHM, Haveman-Nies A. Determinants of behaviour change in a multi-component telemonitoring intervention for community-dwelling older adults. *Nutrients* 2018 Aug 10;10(8):1 [[FREE Full text](#)] [doi: [10.3390/nu10081062](https://doi.org/10.3390/nu10081062)] [Medline: [30103399](#)]
11. Caldeira D, Amaral T, David C, Sampaio C. Educational strategies to reduce serum phosphorus in hyperphosphatemic patients with chronic kidney disease: systematic review with meta-analysis. *J Ren Nutr* 2011 Jul;21(4):285-294. [doi: [10.1053/j.jrn.2010.11.006](https://doi.org/10.1053/j.jrn.2010.11.006)] [Medline: [21429764](#)]
12. Elliott JO, Ortman C, Almaani S, Lee YH, Jordan K. Understanding the associations between modifying factors, individual health beliefs, and hemodialysis patients' adherence to a low-phosphorus diet. *J Ren Nutr* 2015 Mar;25(2):111-120. [doi: [10.1053/j.jrn.2014.08.006](https://doi.org/10.1053/j.jrn.2014.08.006)] [Medline: [25282006](#)]
13. Durose CL, Holdsworth M, Watson V, Przygodzka F. Knowledge of dietary restrictions and the medical consequences of noncompliance by patients on hemodialysis are not predictive of dietary compliance. *J Am Diet Assoc* 2004 Jan;104(1):35-41. [doi: [10.1016/j.jada.2003.10.016](https://doi.org/10.1016/j.jada.2003.10.016)] [Medline: [14702581](#)]
14. Philippou E, Middleton N, Pistos C, Andreou E, Petrou M. The impact of nutrition education on nutrition knowledge and adherence to the Mediterranean Diet in adolescent competitive swimmers. *J Sci Med Sport* 2017 Apr;20(4):328-332. [doi: [10.1016/j.jsams.2016.08.023](https://doi.org/10.1016/j.jsams.2016.08.023)] [Medline: [27692575](#)]
15. Bonaccio M, Di Castelnuovo CA, Costanzo S, De Lucia F, Olivieri M, Donati MB, et al. Nutrition knowledge is associated with higher adherence to Mediterranean diet and lower prevalence of obesity: results from the Moli-sani study. *Appetite* 2013 Sep;68:139-146. [doi: [10.1016/j.appet.2013.04.026](https://doi.org/10.1016/j.appet.2013.04.026)] [Medline: [23665233](#)]
16. Karavetian M, de Vries N, Rizk R, Elzein H. Dietary educational interventions for management of hyperphosphatemia in hemodialysis patients: a systematic review and meta-analysis. *Nutr Rev* 2014 Jul;72(7):471-482. [doi: [10.1111/nure.12115](https://doi.org/10.1111/nure.12115)] [Medline: [24920494](#)]
17. Anderson CAM, Nguyen HA. Nutrition education in the care of patients with chronic kidney disease and end-stage renal disease. *Semin Dial* 2018 Mar;31(2):115-121. [doi: [10.1111/sdi.12681](https://doi.org/10.1111/sdi.12681)] [Medline: [29455475](#)]
18. Gabrielli S, Dianti M, Maimone R, Betta M, Filippi L, Ghezzi M, et al. Design of a mobile app for nutrition education (TreC-LifeStyle) and formative evaluation with families of overweight children. *JMIR Mhealth Uhealth* 2017 Apr 13;5(4):e48 [[FREE Full text](#)] [doi: [10.2196/mhealth.7080](https://doi.org/10.2196/mhealth.7080)] [Medline: [28408361](#)]
19. Fakih El Khoury C, Karavetian M, Halfens RJG, Crutzen R, El Chaar D, Schols JMGA. Dietary application for the management of patients with hemodialysis: a formative development study. *Healthc Inform Res* 2019 Oct;25(4):262-273 [[FREE Full text](#)] [doi: [10.4258/hir.2019.25.4.262](https://doi.org/10.4258/hir.2019.25.4.262)] [Medline: [31777669](#)]
20. Fakih El Khoury C, Karavetian M, Halfens RJG, Crutzen R, Khoja L, Schols JMGA. The effects of dietary mobile apps on nutritional outcomes in adults with chronic diseases: a systematic review and meta-analysis. *J Acad Nutr Diet* 2019 Apr;119(4):626-651. [doi: [10.1016/j.jand.2018.11.010](https://doi.org/10.1016/j.jand.2018.11.010)] [Medline: [30686742](#)]
21. Diamantidis CJ, Zuckerman M, Fink W, Hu P, Yang S, Fink JC. Usability of a CKD educational website targeted to patients and their family members. *Clin J Am Soc Nephrol* 2012 Oct;7(10):1553-1560 [[FREE Full text](#)] [doi: [10.2215/CJN.03690412](https://doi.org/10.2215/CJN.03690412)] [Medline: [22798537](#)]

22. Siddique AB, Krebs M, Alvarez S, Greenspan I, Patel A, Kinsolving J, et al. Mobile apps for the care management of chronic kidney and end-stage renal diseases: systematic search in app stores and evaluation. *JMIR Mhealth Uhealth* 2019 Sep 04;7(9):e12604 [FREE Full text] [doi: [10.2196/12604](https://doi.org/10.2196/12604)] [Medline: [31486408](https://pubmed.ncbi.nlm.nih.gov/31486408/)]
23. Kosa SD, Monize J, D'Souza M, Joshi A, Philip K, Reza S, et al. Nutritional mobile applications for CKD patients: systematic review. *Kidney Int Rep* 2019 Mar;4(3):399-407 [FREE Full text] [doi: [10.1016/j.ekir.2018.11.016](https://doi.org/10.1016/j.ekir.2018.11.016)] [Medline: [30899867](https://pubmed.ncbi.nlm.nih.gov/30899867/)]
24. Search results for chronic + kidney + disease AND mHealth. *ClinicalTrials.gov*. 2020. URL: <https://www.clinicaltrials.gov/ct2/results?cond=Chronic+Kidney+Diseases&term=mHealth&cntry=&state=&city=&dist=> [accessed 2020-11-03]
25. Mummah SA, Robinson TN, King AC, Gardner CD, Sutton S. IDEAS (Integrate, Design, Assess, and Share): a framework and toolkit of strategies for the development of more effective digital interventions to change health behavior. *J Med Internet Res* 2016 Dec 16;18(12):e317 [FREE Full text] [doi: [10.2196/jmir.5927](https://doi.org/10.2196/jmir.5927)] [Medline: [27986647](https://pubmed.ncbi.nlm.nih.gov/27986647/)]
26. Lancaster GA, Thabane L. Guidelines for reporting non-randomised pilot and feasibility studies. *Pilot Feasibility Stud* 2019;5:114 [FREE Full text] [doi: [10.1186/s40814-019-0499-1](https://doi.org/10.1186/s40814-019-0499-1)] [Medline: [31608150](https://pubmed.ncbi.nlm.nih.gov/31608150/)]
27. Schulz KF, Altman DG, Moher D. CONSORT 2010 statement: updated guidelines for reporting parallel group randomized trials. *Ann Intern Med* 2010 Jun 1;152(11):726-732. [doi: [10.7326/0003-4819-152-11-201006010-00232](https://doi.org/10.7326/0003-4819-152-11-201006010-00232)] [Medline: [20335313](https://pubmed.ncbi.nlm.nih.gov/20335313/)]
28. Viechtbauer W, Smits L, Kotz D, Budé L, Spigt M, Serroyen J, et al. A simple formula for the calculation of sample size in pilot studies. *J Clin Epidemiol* 2015 Nov;68(11):1375-1379. [doi: [10.1016/j.jclinepi.2015.04.014](https://doi.org/10.1016/j.jclinepi.2015.04.014)] [Medline: [26146089](https://pubmed.ncbi.nlm.nih.gov/26146089/)]
29. Prochaska JO, Velicer WF. The transtheoretical model of health behavior change. *Am J Health Promot* 1997;12(1):38-48. [doi: [10.4278/0890-1171-12.1.38](https://doi.org/10.4278/0890-1171-12.1.38)] [Medline: [10170434](https://pubmed.ncbi.nlm.nih.gov/10170434/)]
30. Fishbein M. A reasoned action approach to health promotion. *Med Decis Making* 2008;28(6):834-844 [FREE Full text] [doi: [10.1177/0272989X08326092](https://doi.org/10.1177/0272989X08326092)] [Medline: [19015289](https://pubmed.ncbi.nlm.nih.gov/19015289/)]
31. Karavetian M, de Vries N, Elzein H, Rizk R, Bechwaty F. Effect of behavioral stage-based nutrition education on management of osteodystrophy among hemodialysis patients, Lebanon. *Patient Educ Couns* 2015 Sep;98(9):1116-1122. [doi: [10.1016/j.pec.2015.05.005](https://doi.org/10.1016/j.pec.2015.05.005)] [Medline: [26070468](https://pubmed.ncbi.nlm.nih.gov/26070468/)]
32. Vlamincx H, Maes B, Jacobs A, Reyntjens S, Evers G. The dialysis diet and fluid non-adherence questionnaire: validity testing of a self-report instrument for clinical practice. *J Clin Nurs* 2001 Sep;10(5):707-715. [doi: [10.1046/j.1365-2702.2001.00537.x](https://doi.org/10.1046/j.1365-2702.2001.00537.x)] [Medline: [11822521](https://pubmed.ncbi.nlm.nih.gov/11822521/)]
33. Karavetian M, Abboud S, Elzein H, Haydar S, de Vries N. Nutritional education for management of osteodystrophy (NEMO) trial: design and patient characteristics, Lebanon. *Nutr Res Pract* 2014 Feb;8(1):103-111 [FREE Full text] [doi: [10.4162/nrp.2014.8.1.103](https://doi.org/10.4162/nrp.2014.8.1.103)] [Medline: [24611112](https://pubmed.ncbi.nlm.nih.gov/24611112/)]
34. Ford JC, Pope JF, Hunt AE, Gerald B. The effect of diet education on the laboratory values and knowledge of hemodialysis patients with hyperphosphatemia. *J Ren Nutr* 2004 Jan;14(1):36-44. [doi: [10.1053/j.jrn.2003.09.008](https://doi.org/10.1053/j.jrn.2003.09.008)] [Medline: [14740329](https://pubmed.ncbi.nlm.nih.gov/14740329/)]
35. Van Horn L, Beto J. *Research: Successful Approaches in Nutrition and Dietetics*, 4th Edition. Cleveland: Academy of Nutrition and Dietetics; 2019.
36. FoodData Central. US Dept of Agriculture. 2019. URL: <https://fdc.nal.usda.gov/> [accessed 2019-04-01]
37. *Nutrition Care Manual*. Cleveland: Academy of Nutrition and Dietetics; 2019.
38. Cohen J. A power primer. *Psychol Bull* 1992 Jul;112(1):155-159. [Medline: [19565683](https://pubmed.ncbi.nlm.nih.gov/19565683/)]
39. Miyata KN, Shen JJ, Nishio Y, Haneda M, Dadzie KA, Sheth NR, et al. Patient knowledge and adherence to maintenance hemodialysis: an International comparison study. *Clin Exp Nephrol* 2018 Aug;22(4):947-956 [FREE Full text] [doi: [10.1007/s10157-017-1512-8](https://doi.org/10.1007/s10157-017-1512-8)] [Medline: [29185127](https://pubmed.ncbi.nlm.nih.gov/29185127/)]
40. Lennie TA, Worrall-Carter L, Hammash M, Odom-Forren J, Roser LP, Smith CS, et al. Relationship of heart failure patients' knowledge, perceived barriers, and attitudes regarding low-sodium diet recommendations to adherence. *Prog Cardiovasc Nurs* 2008;23(1):6-11. [doi: [10.1111/j.1751-7117.2008.04628.x](https://doi.org/10.1111/j.1751-7117.2008.04628.x)] [Medline: [18326994](https://pubmed.ncbi.nlm.nih.gov/18326994/)]
41. Paes-Barreto JG, Silva MIB, Qureshi AR, Bregman R, Cervante VF, Carrero JJ, et al. Can renal nutrition education improve adherence to a low-protein diet in patients with stages 3 to 5 chronic kidney disease? *J Ren Nutr* 2013 May;23(3):164-171. [doi: [10.1053/j.jrn.2012.10.004](https://doi.org/10.1053/j.jrn.2012.10.004)] [Medline: [23194841](https://pubmed.ncbi.nlm.nih.gov/23194841/)]
42. Deif H, Elsayi K, Selim M, NasrAllah M. Effect of an educational program on adherence to therapeutic regimen among chronic kidney disease stage 5 (CKD5) patients under maintenance hemodialysis. *J Educ Pract* 2015;6(5):21-33 [FREE Full text]
43. Fouque D, Horne R, Cozzolino M, Kalantar-Zadeh K. Balancing nutrition and serum phosphorus in maintenance dialysis. *Am J Kidney Dis* 2014 Jul;64(1):143-150. [doi: [10.1053/j.ajkd.2014.01.429](https://doi.org/10.1053/j.ajkd.2014.01.429)] [Medline: [24819675](https://pubmed.ncbi.nlm.nih.gov/24819675/)]
44. Bardus M, Awada N, Ghandour LA, Fares E, Gherbal T, Al-Zanati T, et al. The Arabic version of the Mobile App Rating Scale: development and validation study. *JMIR Mhealth Uhealth* 2020 Mar 03;8(3):e16956 [FREE Full text] [doi: [10.2196/16956](https://doi.org/10.2196/16956)] [Medline: [32130183](https://pubmed.ncbi.nlm.nih.gov/32130183/)]
45. Shaw RJ, Steinberg DM, Zullig LL, Bosworth HB, Johnson CM, Davis LL. mHealth interventions for weight loss: a guide for achieving treatment fidelity. *J Am Med Inform Assoc* 2014;21(6):959-963. [doi: [10.1136/amiainl-2013-002610](https://doi.org/10.1136/amiainl-2013-002610)] [Medline: [24853065](https://pubmed.ncbi.nlm.nih.gov/24853065/)]

46. Bellg AJ, Borrelli B, Resnick B, Hecht J, Minicucci DS, Ory M, et al. Enhancing treatment fidelity in health behavior change studies: best practices and recommendations from the NIH Behavior Change Consortium. *Health Psychol* 2004 Sep;23(5):443-451. [doi: [10.1037/0278-6133.23.5.443](https://doi.org/10.1037/0278-6133.23.5.443)] [Medline: [15367063](https://pubmed.ncbi.nlm.nih.gov/15367063/)]

## Abbreviations

**CKD:** chronic kidney disease

**CONSORT:** Consolidated Standards of Reporting Trials

**IDEAS:** integrate, design, assess, and share framework

**KELA.AE:** Kidney Education Lifestyle Application

**NKF KDOQI:** National Kidney Foundation Kidney Disease Outcomes Quality Initiative

**RCT:** randomized controlled trial

*Edited by G Eysenbach; submitted 17.01.20; peer-reviewed by M Bardus, YC Kato-Lin, AA Dumas, L Donkin; comments to author 23.09.20; revised version received 18.11.20; accepted 04.04.21; published 01.06.21.*

*Please cite as:*

*Fakih El Khoury C, Crutzen R, Schols JMGA, Halfens RJG, Karavetian M*

*Adequate Management of Phosphorus in Patients Undergoing Hemodialysis Using a Dietary Smartphone App: Prospective Pilot Study*

*JMIR Form Res* 2021;5(6):e17858

URL: <https://formative.jmir.org/2021/6/e17858>

doi: [10.2196/17858](https://doi.org/10.2196/17858)

PMID: [34061034](https://pubmed.ncbi.nlm.nih.gov/34061034/)

©Cosette Fakih El Khoury, Rik Crutzen, Jos MGA Schols, Ruud JG Halfens, Mirey Karavetian. Originally published in JMIR Formative Research (<https://formative.jmir.org>), 01.06.2021. This is an open-access article distributed under the terms of the Creative Commons Attribution License (<https://creativecommons.org/licenses/by/4.0/>), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Formative Research, is properly cited. The complete bibliographic information, a link to the original publication on <https://formative.jmir.org>, as well as this copyright and license information must be included.

Original Paper

# Using a Mobile App–Based Video Recommender System of Patient Narratives to Prepare Women for Breast Cancer Surgery: Development and Usability Study Informed by Qualitative Data

Ilja Ormel<sup>1,2</sup>, MPH; Charles C Onu<sup>1,3</sup>, BSc, MSc; Mona Magalhaes<sup>1</sup>, MA; Terence Tang<sup>4</sup>, MD; John B Hughes<sup>5</sup>, CM, MD; Susan Law<sup>1,2,4,6</sup>, PhD

<sup>1</sup>St Mary's Research Centre, Montreal, QC, Canada

<sup>2</sup>Department of Family Medicine, McGill University, Montréal, QC, Canada

<sup>3</sup>School of Computer Science, McGill University, Montréal, QC, Canada

<sup>4</sup>Trillium Health Partners, Mississauga, ON, Canada

<sup>5</sup>McGill University, Montréal, QC, Canada

<sup>6</sup>Institute for Health Policy, Management and Evaluation, University of Toronto, Toronto, ON, Canada

**Corresponding Author:**

Ilja Ormel, MPH

Department of Family Medicine

McGill University

5858 Côte-des-Neiges Rd

Montréal, QC, H2T 1W1

Canada

Phone: 1 (514) 345 3511 ext 5060

Email: [ilja.ormel@mail.mcgill.ca](mailto:ilja.ormel@mail.mcgill.ca)

## Abstract

**Background:** Women diagnosed with breast cancer are often bombarded with information. Such information overload can lead to misunderstandings and hamper women's capacity for making informed decisions about their care. For women with breast cancer, this uncertainty is particularly severe in the period before surgery. Personalized narratives about others' experiences can help patients better understand the disease course, the quality and type of care to be expected, the clinical decision-making processes, and the strategies for coping. Existing resources and eHealth apps rarely include experiential information, and no tools exist that tailor information for individual preferences and needs—offering the right information at the right time and in the right format. Combining high-quality experiential evidence with novel technical approaches may contribute to patient-centered solutions in this area.

**Objective:** This study aims to design and seek preliminary feedback on a mobile app that will improve information access about surgery for patients with breast cancer, by drawing on a qualitative collection of personal narratives from a diverse sample of Canadian women and using video and audio recordings or audio recordings from the Canadian Health Experiences Research Network.

**Methods:** In a previous study, we conducted in-depth interviews with 35 Canadian women and used video and audio recordings or audio recordings to collect stories about the lived experiences of breast cancer. The participants highlighted the need for more specific information between diagnosis and surgery that was relevant to their personal situations and preferences. They also wanted to learn from other women's experiences. We worked with patients, clinicians, and informatics experts to develop a mobile app that provides access to tailored experiential information relevant to women's personal situations and preferences. We completed focus groups and qualitative interviews, conducted a further analysis of the original qualitative data, designed novel software using artificial intelligence, and sought preliminary feedback from users on a new app via focus groups and a survey.

**Results:** The secondary analysis of the breast cancer narratives revealed key themes and their interconnections relevant to the experience of surgery, including preparation, treatment decisions, aftercare, reconstruction, prostheses, lumpectomy and mastectomy, and complications. These themes informed the development of the structure and content of the app. We developed a recommender system within the app by using content matching (user and speaker profiles and user interests and video content) and collaborative filtering to identify clips marked as relevant by the user and by similar users. A 2-minute animated introductory video for users was developed. Pilot testing revealed generally positive responses regarding the content and value of this type of e-tool.



**Conclusions:** Developing reliable, evidence-based tools and apps that are based on diverse collections of people's experiences of illness offers a novel approach to help manage the plethora of information that women face after a diagnosis of breast cancer.

(JMIR Form Res 2021;5(6):e22970) doi:[10.2196/22970](https://doi.org/10.2196/22970)

## KEYWORDS

qualitative research; illness narratives; experiential information; breast cancer; surgery; tailored information; recommender system; patient information and communication; mobile app; mobile phone

## Introduction

### Background

The last few decades have been marked by the rapid expansion of web-based health information [1], and breast cancer has been noted as the most searched for health topic on the web [2]. This has not only helped to promote the availability of relevant breast cancer information but also exacerbated challenges related to information overload [3]. Therefore, women with breast cancer are particularly vulnerable to experience information overload, which is associated with a negative impact on patients' treatment or behavioral decisions [3-6] and associated with anxiety and distress [6]. In biomedical research, the information bottleneck has shifted from data collection to data management and analysis [7], and it appears that there is a parallel shift regarding information for patients. Tailoring information to individual needs can better support patients in their search and retrieval efforts for securing *appropriate* information [8]. This will not only reduce information overload but also ensure that patients do not miss important treatment information, which is another factor that negatively impacts the health and well-being of women with breast cancer [9,10].

Mobile apps offer innovative solutions for improving health care for various health conditions [11]. Several of these apps include the provision of tailored information [12-15]. This innovation has evolved rapidly in the last decade, and it is estimated that by 2018, nearly 2 billion smartphone and tablet users accessed health care-related apps [16].

### Experiential Information in Apps

A recent systematic review of empirical studies on mobile apps (n=29) for breast cancer care [17] and another review on the evidence for mobile app use (n=9) during the treatment of breast cancer [11] identified only one study that included access to experiential information in the form of a personal story forum containing five recorded stories [18]. This is despite evidence that patients turn to the internet and other sources to purposefully search for experiential information [19]. However, the quality and access to this type of information is highly variable, and there is a need to provide rigorously developed, reliable, and tailored information regarding the experiences of others with similar conditions. Experiences of other patients are an important part of the evidence base that is available to patients; experiential evidence increases awareness of various treatment options, normalizes aspects of illness and treatment, and supports and informs decision making. Dismissing personal stories as *anecdotes* is a serious misunderstanding [20]. To date, research findings underscore the value and impact of patients' exposure to experiential information, which includes providing comfort

and ensuring a more realistic outlook about the future [21]. Similarly, Ziebland and Wyke [19] reported that experiential information can support people in making better health care choices, raising awareness of certain health issues, improving health literacy, comparing each other's situation, and accessing more appropriate services. From our study on women's experiences of breast cancer, we found that experiential information can complement women's information needs about subjects that are not always communicated through factual and biomedical types of information [22]. It is argued that the inclusion of experiential health information will remain a key feature of eHealth strategies because of the appeal and memorability of stories and the need to make contact with peers [19]. However, there are concerns regarding people's reliance on the internet for experiential information and the quality and reliability of this information [19]. A review of existing apps demonstrated that such resources are scarce. Few of them are evidence-based and many are misleading [23], as apps are often introduced into clinical care before benefits and risks for patients and health care professionals are evaluated [11]. Both the systematic reviews mentioned earlier found that rigorous trials in this area are lacking.

Women not only need to receive the right information at the right time and in the right format but also need to receive information from trustworthy sources, such as health care professionals, patient support organizations, and other patients, especially when information is offered on the web or through a mobile app. The challenge lies in developing evidence-based information tools that respond to women's personal information needs. Such tools are relatively rare to date, and to our knowledge, no tools exist that provide information that is *tailored* to individual preferences and needs. Greater insights regarding women's needs at particular times in their cancer journeys and regarding the technical requirements for such a tool would contribute to novel solutions. To our knowledge, there are no tools yet that help patients understand how to prepare for breast cancer surgery based on lived experiences and, in particular, that draw from experiential evidence gathered through rigorous qualitative methods. This paper reports on the development of a new tailored information app called Health Experiences and Real Stories (HERS) that allows women with newly diagnosed breast cancer to retrieve information (in English or French) from an existing database of women's experiences with breast cancer. One of the key findings from previous studies was that women missed important information during the diagnostic phase, especially while preparing for surgery. However, women also reported that they struggled to handle information at the start of their breast cancer journey [22]. Women with suspicious lumps or other symptoms of potential breast cancer may often be seen and treated by a

surgeon before they come under the care of a specialized breast cancer team (providing multidisciplinary care and support throughout the *journey* [8]). This diagnostic stage is typically described as one of the most bewildering periods [8,24] when women are usually coming to terms with this new disease and may be seeking information about breast cancer, treatments, and options [25].

## Objective

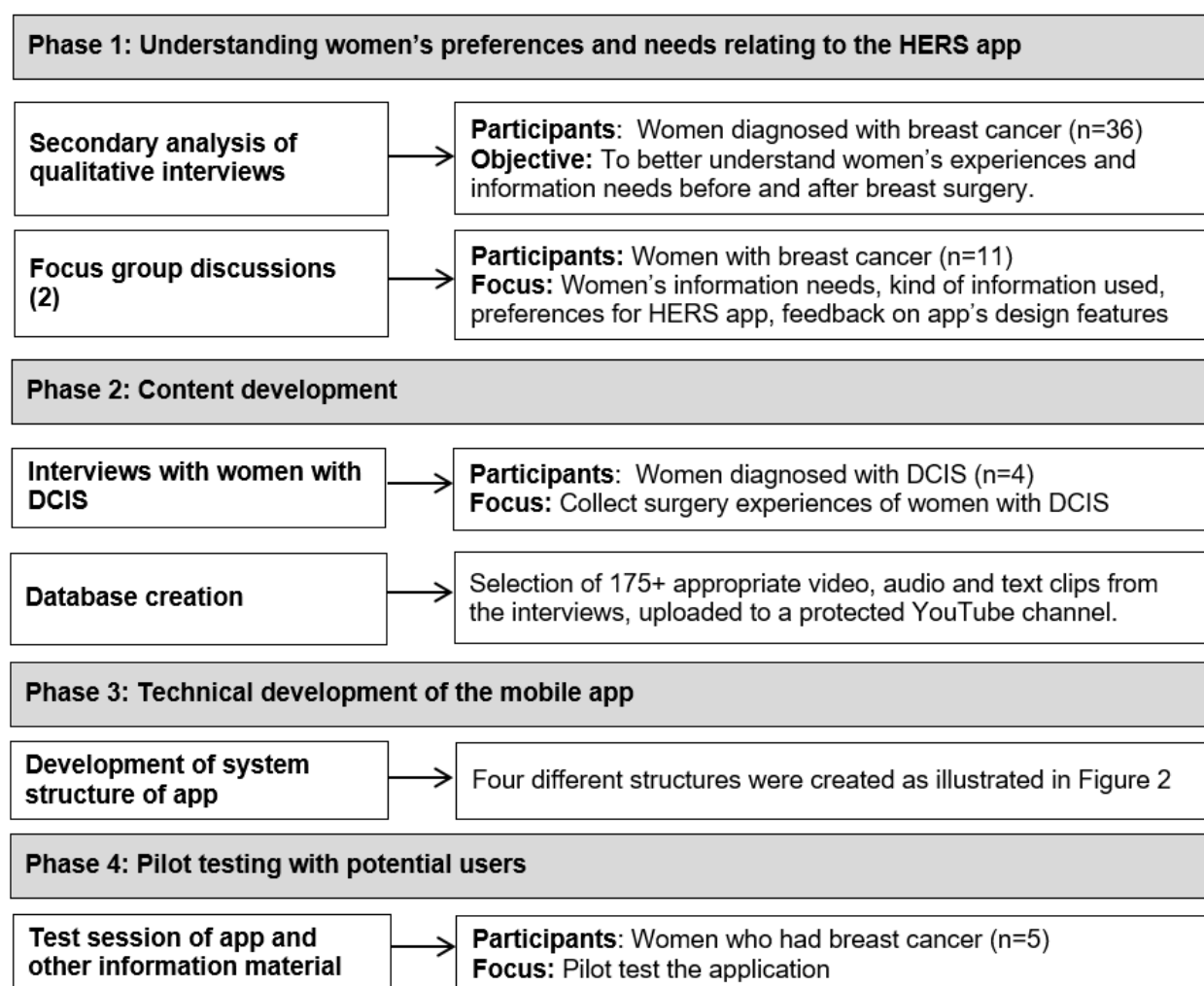
This study aims to contribute to the development of tools that provide patients with tailored experiential information based on rigorous qualitative research. In the following sections, we describe the work undertaken in four phases to conceptualize, develop, and obtain preliminary feedback from users for the HERS app.

## Methods

### Overview

Our multidisciplinary research team (clinicians, computer engineers, and researchers) worked in close collaboration with an expert advisory panel (patients, representatives of breast cancer organizations, and clinicians) to develop and test the HERS app over the study period from July 2016 to June 2018. The four phases of work consisted of understanding women's preferences and needs related to the app (phase 1), content development (phase 2), technical development (phase 3), and pilot testing (phase 4), as presented in Figure 1. The research ethics committee of Saint Mary's Hospital Center (SMHC) in Montreal, Quebec, Canada, approved the study in June 2016 (reference number 11-22 B, amendment 3). Participants for the interviews and focus groups were recruited through breast cancer patient and community organizations and support groups, personal networks, our expert advisory committee, and social media. Informed consent was obtained from all participants.

**Figure 1.** Process of the Health Experiences and Real Stories app development. DCIS: ductal carcinoma in situ; HERS: Health Experiences and Real Stories.



## Phase 1: Understanding Women's Preferences and Needs Relating to the HERS App

A secondary analysis of the transcripts from 35 interviews previously conducted with women with breast cancer was undertaken to identify women's information needs before and after surgery. This analysis informed the questions developed for the focus group discussions in this study. Details regarding the methods for the original qualitative research have been published elsewhere [22].

Two focus groups involving women with experiences of breast cancer were convened in July 2016 (n=6) and September 2016 (n=5) to (1) consider information needs (helpful information, information needs, and lack of information) related to surgery, (2) review sample videos to understand the value of experiential information, and (3) better understand their preferences regarding design features of a tailored information app. In focus group 2 (different participants), we presented a summary of the results of focus group 1 and discussed the findings further. The women were aged between 43 and 65 years. The participants had been diagnosed with breast cancer and had undergone various surgeries (lumpectomy, single or double mastectomy, and reconstruction). Both focus groups were facilitated by the principal investigator, senior qualitative researcher, and computer scientists.

## Phase 2: Content Development

The content for this app was drawn primarily from the data collected in previous qualitative research completed by our team regarding the experiences of 35 Canadian women with breast cancer (Canadian Women's Experiences with Breast Cancer study). These results are presented on the web (Canadian Health Experiences Research Network, 2021 [26]) where we created topic summaries, including illustrative video and audio clips, from our analysis of issues important to the women that we interviewed. Given that we had previously excluded women diagnosed with the earliest form of breast cancer—ductal carcinoma in situ (DCIS), [22]—because of the particular definition of breast cancer adopted for the original collection and the fact that this group also underwent breast surgery (patients with DCIS would therefore be inclusive of potential users of the app), we conducted four additional interviews with women diagnosed with DCIS between October 2016 and September 2017 using the same methods for collecting narrative interviews as per the original study. Women were asked to share their experiences with breast cancer beginning with an open narrative question (“Can you tell me about your experiences with breast cancer from the beginning up until now?”) followed by a semistructured set of questions. Participants in the narrative interviews had already consented to the future use of their interview materials (transcript, audio, and video recordings), which included apps such as web-based resources and for research and teaching; all participants were provided with a transcript of their interview for review.

Qualitative analysis of the four DCIS interviews was conducted, along with a secondary analysis of the original 35 interviews (36 interviews were conducted but one participant withdrew from the study) of women with breast cancer, focusing on women's experiences of breast surgery. Using the framework

method [27], we selected text from the 39 interviews that were specifically related to breast surgery, such as experiences with surgical procedures, but also topics such as body image, talking to children, sexuality, and information needs. Two senior qualitative researchers analyzed the data, using the analytic software NVivo 10 (QSR International), and then developed a list of relevant topics relating to content (in collaboration with the principal investigator and computer engineers) for the HERS app based on the themes and categories that emerged from the coding framework.

## Phase 3: Technical Development of the Mobile App

Working closely with an expert advisory panel and women diagnosed with breast cancer, we built the HERS app based on the needs and preferences of women with breast cancer for tailored information from phase 1 with content from phase 2. We developed the HERS app as a mobile app for Android smartphones or tablets in the Java programming language. The content (video clips) is housed on a YouTube platform on the web. To provide tailored information to users, we developed a recommendation engine as a web service (based on the representational state transfer protocol) powered by a Microsoft structured query language database that stores user information and metadata of available videos. The mobile app accesses the web service and retrieves appropriate content from YouTube to display to users (Multimedia Appendix 1).

After completion of the prototype app, we made further improvements and iterations based on the feedback from a test session (testing the app, focus group, and surveys), as described in phase 4.

## Phase 4: Obtaining Preliminary Feedback From Potential Users

The test session took place in June 2018 with 5 women (aged 51–66 years with a minimum of high school education), who had been diagnosed with breast cancer between 2005 and 2016. Two of the women had a recurrence of cancer since their diagnosis and 2 women previously participated in the focus group of phase 1. The goals of the session were as follows:

- To consider women's responses to existing web-based resources for breast surgery that contain more factual information and to the pilot version of the HERS app presenting experiential information
- To gather perspectives on the HERS mobile app regarding what was useful and to gather any recommendations for improvement

The women first explored the information resources offered by the app. These included resources offered by reliable breast cancer organizations such as the Canadian Breast Cancer Foundation, Canadian Breast Cancer Network, and Canadian Cancer Society. These resources mostly offer what we have termed more biomedical or *facts and figures*—type information related to breast cancer (eg, illness stages and surgery procedures) and may occasionally include some experiences of women as testimonials. After reading these resources (20 min), the participants completed a questionnaire (15 min). We considered adopting the questions from the eHealth Impact Questionnaire evaluation tool [28] for this study; however, to

align the tool with the content and process used in this study, we substantially adapted the questions but retained the 5-point Likert scale. This process was then repeated for the information on the experiential information in the HERS app. The focus group ended with a discussion of the value of biomedical-oriented information resources and experiential app resources.

## Results

In this section, we present a summary of the results for each phase of the project. See [Multimedia Appendix 4](#) for a Powerpoint presentation of the research study.

**Textbox 1.** Women's experiences with information related to breast cancer surgery.

### Information received

- Women's contrasting experiences with regard to the information that they received was striking; some felt that they had received excellent information and others felt they were hardly informed.
- For the majority, it seemed as though there was both too much and too little information.

### Information needs

- Women described that they were unaware of their information needs ("I think I didn't know what I needed to know") after finding the lump and while preparing for surgery.
- Women were understanding of the limited availability of health care professionals.
- Women described a need for experiential information on issues, such as impact on life, intimacy issues, and how to tell children.
- Women found that biomedical information about breast cancer was covered the best (in comparison with experiential or pragmatic information).
- The flow of information typically improved once patients saw their oncologist.

### Lack of information

- Information in relation to care practices and surgery: wound care, preparation for surgery, how it will look, pain, and check-up frequency
- Experiential information: return to work, telling children, and effects on relationships. Women felt that this kind of information should be considered essential for patients.
- Women experienced a lack of information about and support for decisions related to surgery and reconstruction. They did not receive sufficient information about the importance of exercise after surgery.
- Women described feeling misinformed.

### Helpful information

- Information from health care professionals: information session on breast cancer in hospital, visual explanations (eg, drawings showing the drains), link to a web-based decision-making tool, referrals to a sexologist and physiotherapist
- Personal resources women used to find information: websites, research articles, support groups, experiences of others, a specialized boutique that provides postmastectomy clothing, and being accompanied by a friend of a family member who can help remember the information shared during appointments with health care providers.
- Support groups: support groups were found to provide helpful resources. However, most women were only informed of the existence of a support group after surgery.

## Value of Experiential Information

In the focus groups, women were shown some relevant experiential videos that were published on our website (Canadian Health Experiences Research Network, 2021 [26]) to discuss the value of experiential information; women described experiencing a certain comfort from watching these videos (quote 1), an ability to learn from other experiences (quote 2), and how it may have influenced their decision making (quote 3):

## Phase 1: Understanding Women's Preferences and Needs Relating to the HERS App

### Information Needs Related to Surgery

A synthesis of the analysis of the information needs of women during the surgery phase (secondary analysis and focus groups) is shown in [Textbox 1](#).

*It's nice to see um I would have liked that, you know. To see some real-life women, you know, like really talking about it and saying something about it. It would have been comforting, you know, because sometimes you, you just don't know. And by the time you get into these support groups you've already gone through a lot of the uh stuff, the surgery.... [Quote 1]*  
*So a lot of my friends were telling me "Don't worry, radiation it's not bad you're going to be fine." But I would have liked to have maybe a buddy or a nurse*



*or somebody who I'm looking for people who have had the same thing that I have. Because I wanted to know what was your experience? Did you have the same symptoms that I had?* [Quote 2]

*But I think before I had my surgery when I was making decisions surgery or chemo and I saw, if I saw her video it might have really influenced that decision.* [Quote 3]

They further said that the videos might help women who are going through a similar experience so that they feel less alone. They also highlighted the fact that women in the videos described real issues (eg, sexuality or talking to children about their diagnosis) that were not always easily discussed.

The videos also raised concerns. One participant felt that video clips may also negatively influence decision making. Another concern was related to how users were to filter and validate this type of anecdotal information. Despite the two challenges raised within the group, participants agreed that there should be a place for these kinds of videos; the participants suggested that the project team should balance more provocative videos with other videos that present solutions or different experiences of similar situations.

### **Key Design Preferences**

Focus group participants were asked to describe their preferences for a mobile app and were also asked to give their opinion to certain proposed features for the app (such as the possibility to take notes); a summary of this discussion can be found in [Textbox 2](#).

**Textbox 2.** Key design features for the Health Experiences and Real Stories app as discussed in focus groups to inform the development of the app.

#### **General feedback**

- Availability of information that relates to user's own situation
- Offer a range of experiences and information
- Important to include different age groups, stages and severities of breast cancer, marital status, and whether they have children
- Include *how to* videos
- Information should help women to normalize their experiences and include the message that each experience is unique

#### **Videos**

- Personal features of speakers (eg, age, ethnic background, and educational level) not defining of the information
- Provide culturally sensitive information
- Don't overemphasize or profile certain personal attributes as videos with speakers with different characteristics may still be relevant for users with other characteristics
- Topics should be grouped according to stage and by topic including social impact
- Include information on choices for surgery and posttreatment experiences
- Include a wide variety of experiences

#### **Language use**

- Use language that can be understood

#### **Resources**

- Provide links to other resources
- Resources should be up to date and cover a wide range of information needs
- Ability to save the link.
- To increase awareness, multiple women suggested using social media outlets such as Facebook

#### **Note-taking**

- Could relieve some stress accompanied with getting information
- Helpful to prepare questions

## **Phase 2: Content Development**

More than 175 illustrative clips, with original video, audio, and text clips from the interviews with a length of about 1-2 minutes, were extracted from the recordings of the 39 interviews with women with breast cancer (n=35) and DCIS (n=4). They were

related to various topics of breast cancer surgery, including preparation for surgery, types of reconstruction, and body image. These serve as the content of the HERS app.



### Topic List: Core Content

The thematic analysis of the interview data defined the core content for the app to be organized within 11 major topics and 23 subtopics ([Multimedia Appendix 2](#)). The creation of this framework was an iterative process and was discussed with an interdisciplinary team and advisors. An additional search filter was added for the treatment phase (before surgery, surgery, after surgery, reconstruction, and impact on life). The themes and filter enable the recommender system to provide tailored information. All clips were tagged with keywords from the subthemes and treatment phase in a database server. Clips with medical information were reviewed by our health care professional advisors, such as surgeons, oncologists, and radiotherapists. Clips with potentially distressing information or unusual experiential information were reviewed by a psychologist, a representative of a breast cancer organization, or women diagnosed with breast cancer. After review, a small

number of clips were removed from the database to mitigate any potential misinterpretation and an explanatory text was added other clips. The clips were then prepared and uploaded for video storage on YouTube.

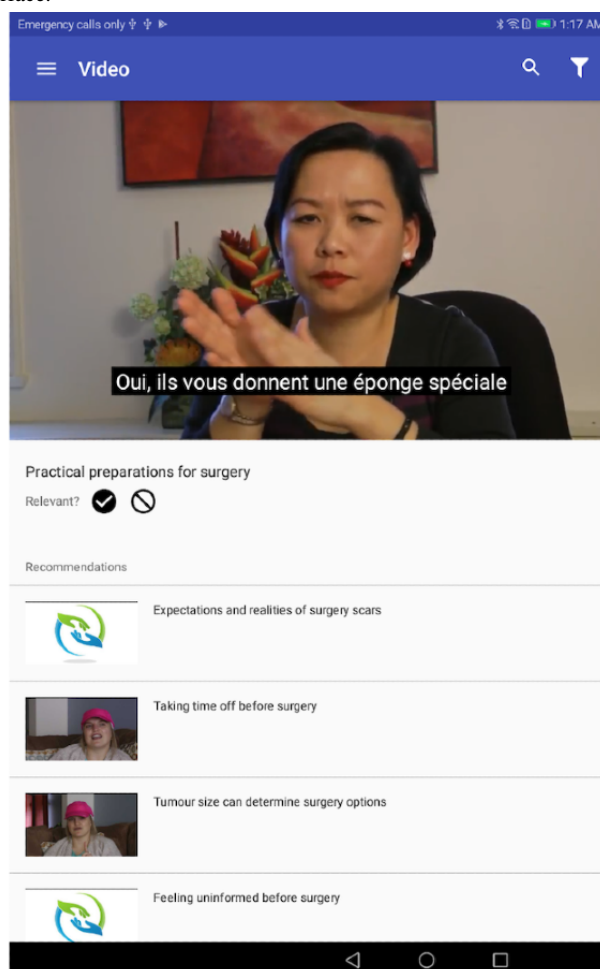
### Preparation of an Introductory Instructional Video

Members of the project team used the app *Powtoon* to develop a short plain language introduction video, which was included in the app for users to review as a guide to the HERS app.

### Phase 3: Technical Development of Mobile App, Recommender System, and Back End

The requirements and suggestions as described in the former two sections, together with the team's interpretation of the requirements of the app, supported the development of the HERS app (see [Figure 2](#) for a sample screenshot of the app interface).

**Figure 2.** Sample screenshot of app interface.



[Multimedia Appendix 3](#) details the functionality of the app. As previously described, the ability of the app to provide tailored information was a key design consideration. This was achieved through the development of a recommendation engine.

The recommendation engine performs content-based matching by recommending videos of speakers with similar characteristics as the user (based on user profiles such as age, marital status, and profession) on topics selected by the user and through

collaborative filtering (videos related to videos liked by the user and by *similar* users).

The following three key principles informed our approach to recommendations:

1. Make the most informed recommendations initially
2. Increasingly reduce designer bias and let users drive recommendations
3. Account for diversity in recommendations

As expected, in a user's very first session, little is known about what kinds of content the user is actually interested in. Nevertheless, we make informed *guesses* based on the user's demographic information as registered in the user's profile and match that against the speaker profile in the metadata of the videos. After at least one session, the app analyses the user's indication of topics of interest (either done explicitly in the preferences view or implicitly by marking one or more videos as *relevant*). In addition to making recommendations based on similarity matching between users and videos, the app also makes recommendations based on diversity. The idea is to help users discover interesting content even if their preference

settings and usage history do not indicate that the content is relevant to them. Heuristics are used to select videos on the diversity criteria, for example, videos that are most marked as relevant by the community.

#### Phase 4: Exploring Preliminary Feedback From Potential Users

##### Feedback

The pilot app, containing a total of 175 clips extracted from interviews with 39 women, was tested by potential users (see [Textbox 3](#) for more detailed feedback).

**Textbox 3.** Feedback on general aspects, videos, and resources of the Health Experiences and Real Stories app after testing the app.

##### General feedback

- The app could help process information received from doctor (not all information was retained from doctor's visits)
- The app could be so interesting that the user would stay too long—guide users to access videos step by step
- The app looked professional, was well organized, and was easy to navigate. Some technical problems with the app—in some instances, the app would freeze
- The tool could help women be better prepared for the next stage

##### Videos

- Liked speakers' personalities
- Presentation and tone were described as intelligent and nonpatronizing
- Appreciation of range of topics and realistic videos
- Liked the ability to choose own videos or skip videos
- Length was good (not too long)
- If videos felt short, participant liked that other videos were available or that they could replay videos
- Organization by topic was helpful
- One participant liked the *snippets* of information; it worked for her
- Information well balanced: not too happy nor too sad
- One participant described how she recognized the experiences of one speaker

##### Resources

- Resources were appreciated and perceived as trustworthy
- Good step-by-step process
- Professional outlook and quality of resources
- Information would have a relaxing and calming effect on women during diagnoses phase
- Add contact information and feature for asking questions
- Appreciation of combination of biomedical and experiential information

#### Survey Results

In total, 5 female participants were asked to complete the questionnaire twice: first after reading selected biomedical information resources that can be found on reliable websites and then after visiting the experiential section of the HERS

information app (see [Table 1](#) for the results). The results revealed that participants positively perceived the biomedical information, and the results were slightly better after viewing the app information, for example, they seemed to feel less overwhelmed with information. However, this is a very small sample, and further testing is required.

**Table 1.** Results from survey questions (N=5)<sup>a</sup>.

| Question   | After reading biomedical information <sup>b</sup> , median (range) | After reading app information <sup>c</sup> , median (range) |
|--|--|---|
| 1. I feel better informed after viewing the resources.   | 4 (3-5)  | 4 (4-5)   |
| 2. I had a lot of my questions answered by the resources or this app.  | 4 (3-5)  | 4 (4-4)   |
| 3. I better understand the information I need to prepare for the next steps in treatment or stages of the illness.           | 4 (3-4)  | 4 (4-4)   |
| 4. I was able to easily find the information I was looking for.  | 4 (3-5)  | 4 (4-5)   |
| 5. The resources made me feel less lonely or isolated.   | 4 (3-5)  | 4 (4-5)   |
| 6. If a friend or family member were in a similar position, would you recommend the resources or this app to her?            | 5 (3-5)  | 5 (4-5)   |
| 7. I have a better understanding of where to seek information about breast cancer and surgery.                               | 4 (4-5)  | 4 (3-5)   |
| 8. Looking at the resources or site raised more questions for me than it answered.   | 3 (2-4)  | 2 (2-3)   |
| 9. There was so much information here, I felt overwhelmed.   | 3 (1-4)  | 2 (1-4)   |
| 10. It was difficult for me to relate to the information or the stories in this resource.                                    | 1 (1-3)  | 2 (1-2)   |
| 11. The information on this app will not help me feel more confident discussing my questions and concerns with my doctor(s). | 1 (1-2)  | 1 (1-2)   |

<sup>a</sup>The questionnaire used a Likert scale of 1 to 5 for all questions except question 8 (1=strongly disagree; 2=disagree; 3=neither agree nor disagree; 4=agree; 5=strongly agree). For question 8, the responses represented the following: 1=definitely would not; 2=would not; 3=neither would nor would not; 4=would; and 5=definitely would.

<sup>b</sup>Total criteria satisfied (rated 4 or 5 for question 1 or 7 and rated 1 or 2 for question 8 or 11) was 9.

<sup>c</sup>Total criteria satisfied (rated 4 or 5 for question 1 or 7 and rated 1 or 2 for question 8 or 11) was 11.

## Discussion

### Principal Findings

This paper describes the development and piloting of a mobile app that provides tailored information for women, based on their preferences and needs, about others' experiences of breast surgery. This system draws upon an existing evidence-based data set of video narratives featuring Canadian women's experiences of breast surgery and uses advanced computing engineering and machine learning in the design of a recommendation algorithm to provide tailored information (similar to the popular Netflix platform). Our aim was to contribute to efforts that provide the right information at the right time and in the right format to help women manage information at a critical time in their care journey for breast cancer. In a preliminary pilot test, we found generally positive responses to questions regarding the content and value of this type of e-tool.

Our findings regarding women's information needs and their experiences related to missing relevant treatment information and information overload are consistent with the existing literature [29-31]. There is a need for the development and assessment of more interventions that help information seekers manage health information overload [3] and a need to develop information filters to help information seekers identify relevant web-based health information [5]. None of the identified articles in a recent systematic review on mobile apps for breast cancer care used a recommender system to generate tailored

information and only three mentioned a feature with regard to tailoring information [12,13]. Although the use of recommender systems is still sparse in the health sector, it has the potential to contribute to tailored health interventions [32], and mobile apps for breast cancer could contribute to reducing information overload by offering tailored information and machine learning. This study contributes to the scarce existing knowledge related to evidence-based eHealth apps that are designed to provide information and support for women with breast cancer in addition to the novel application of a recommender system to do so. Scientific literature presenting narrative-based apps designed on the basis of rigorous research is virtually nonexistent, as per our preliminary review of the literature.

### Considerations for Future Research

Research in the last decade has demonstrated the challenges of measuring the health effects associated with health information usage of information offered on the web or through web-based tools. These mechanisms are complex and interrelated with many factors. Tools, such as the one described in this paper, offer the potential to contribute to new knowledge and to a better understanding of information-seeking practices because of the ability to relate the user feedback on the videos (relevant or not) to the app usage as well as to the personal characteristics of the user, the speaker, and the content of the video. For example, the app makes it possible to better understand whether certain personal user characteristics, such as age, ethnic background, having children, marital status, and literacy level, influence one's preference for certain speakers with similar characteristics. In the future, it may also be possible to add other important

characteristics that influence information needs [29], such as preexisting knowledge of the illness and preference for more basic or advanced illness information. A recently developed narrative taxonomy defines three different kinds of narratives: process, experience, and outcome narratives [33]. The authors argue that, for each type of app (information tool, decision aid, and behavior change information), different narrative types should be used. For example, for an information tool, creators should include narratives about a process or experience but exclude narratives focused on the outcome. Future research should aim to better understand the impact of different types of narratives on the effectiveness and uptake of particular mobile apps for health. Finally, it is important to further test the impact of the app on the users, for example, through a randomized controlled trial.

Our research group is part of a global network of researchers who conduct similar research in their respective countries. This app offers the possibility of expansion by including clips from international collections of breast cancer narratives or by creating similar tools that use scientifically gathered, personal experiences of a variety of health conditions. An international working group is currently formed with member countries of an international network for patients' experiences [34] for the application of the HERS app elsewhere.

In addition, it is important that the app also offers information that the user does not yet know that she needs to know (eg, information on lymphedema exercises and the need to consider fertility treatment). Research on how women can best be introduced to these subjects through the app would be important. For instance, should the recommender system continuously offer clips on these specific subjects or should women be made aware of them through other pathways? It would also be important to consider how other unexpected events or complications during treatment (such as drain tube removal or unclear margins) should be introduced without engendering unnecessary fear or anxiety.

### Limitations

The limitations of this study are primarily related to the scale and the limited nature of the pilot study. We convened a small

sample of breast cancer survivors to conduct a preliminary *test* of the functionality and user experience of the app. Admittedly, our targeted app users are women who are yet to undergo surgery. In this study, we chose to involve women who had already undergone surgery to provide retrospective insights into how this app would have helped them during their journey. The participants first accessed biomedical information and then experiential information; the order of this information may have influenced their responses to the survey. This would need to be explored in future trials of this product. Although the results were not intended to provide any statistical significance, we were encouraged by the favorable trends in their responses. We will now seek additional opportunities to expand the evaluation of the app to involve more women with breast cancer who are yet to undergo surgery, develop an iOS version of the app for Apple mobile devices, invite other health experience research groups using similar methods to test the addition of an expanded data set (video narratives gathered in other jurisdictions and on different health conditions), optimize the saturation of information within topics identified for this app, and consider a cloud-based deployment to eliminate the need to be bound to a specific server. The aim of our next phase of development will be to formally evaluate the utilization and impact of this eHealth tool on women's shared decision making and the perceived needs for information and support around the time of surgery in their breast cancer journey.

### Conclusions

In this paper, we provide preliminary evidence for the feasibility and acceptability of an innovative eHealth app designed to tailor experiential information for women preparing for breast cancer surgery. The HERS app, based on a recommender system, is a unique attempt to ensure that women receive the right information at the right time in the right format; however, further testing is still required to measure the impact of the app.

We believe that these kinds of tools offer great potential to improve health information competence and reduce information overload, while ensuring that women receive timely, relevant information that meets their needs, and they complement more factual, biomedical information about their illness that they receive from their care team and other sources.

### Acknowledgments

This study, to develop a tailored information app, was supported by financial contributions from the Quebec Breast Cancer Foundation (SMHC #11-22B). The original breast cancer study was supported by St. Mary's Hospital Foundation (SMHC #11-22B Women's Wellness Initiative) and the McGill Rossy Cancer Network (SMHC #11-22C RCN). The sponsors had no role in the design and conduct of the research project. The authors would like to thank the original study participants for sharing their stories to help inform others about the diversity of lived experiences with breast cancer; the authors also thank their project advisory group that included patients, community organizations, collaborating breast cancer support organizations, clinicians, and other researchers. This study received support from St. Mary's Research Centre staff, Montreal. The authors thank Dr Sylvie Lambert and Dr Jeannie Haggerty who provided advice at the outset of this project regarding the study design and methods and Dr Adelaide Doussau for statistical analysis. They also thank Stephanie Babinski for overall editing support.

### Conflicts of Interest

None declared.

## Multimedia Appendix 1

System structure of breast cancer video service.

[\[DOCX File , 135 KB - formative\\_v5i6e22970\\_app1.docx \]](#)

## Multimedia Appendix 2

Framework for coding and Health Experiences and Real Stories app.

[\[DOCX File , 14 KB - formative\\_v5i6e22970\\_app2.docx \]](#)

## Multimedia Appendix 3

Description of app functions.

[\[DOCX File , 13 KB - formative\\_v5i6e22970\\_app3.docx \]](#)

## Multimedia Appendix 4

Bringing Netflix technology to video narratives of experiences of breast surgery: helping women navigate the information tsunami.

[\[PPTX File , 2263 KB - formative\\_v5i6e22970\\_app4.pptx \]](#)

## References

1. Jo HS, Park K, Jung SM. A scoping review of consumer needs for cancer information. *Patient Educ Couns* 2019 Jul;102(7):1237-1250. [doi: [10.1016/j.pec.2019.02.004](#)] [Medline: [30772114](#)]
2. McHugh SM, Corrigan M, Morney N, Sheikh A, Lehane E, Hill AD. A quantitative assessment of changing trends in internet usage for cancer information. *World J Surg* 2011 Feb;35(2):253-257. [doi: [10.1007/s00268-010-0830-8](#)] [Medline: [20972679](#)]
3. Khaleel I, Wimmer BC, Peterson GM, Zaidi ST, Roehrer E, Cummings E, et al. Health information overload among health consumers: a scoping review. *Patient Educ Couns* 2020 Jan;103(1):15-32. [doi: [10.1016/j.pec.2019.08.008](#)] [Medline: [31451363](#)]
4. Halkett GK, Kristjanson LJ, Lobb E, Little J, Shaw T, Taylor M, et al. Information needs and preferences of women as they proceed through radiotherapy for breast cancer. *Patient Educ Couns* 2012 Mar;86(3):396-404. [doi: [10.1016/j.pec.2011.05.010](#)] [Medline: [21664788](#)]
5. Swar B, Hameed T, Reyachav I. Information overload, psychological ill-being, and behavioral intention to continue online healthcare information search. *Comput Hum Behav* 2017 May;70:416-425. [doi: [10.1016/j.chb.2016.12.068](#)]
6. Chae J, Lee C, Jensen JD. Correlates of cancer information overload: focusing on individual ability and motivation. *Health Commun* 2016;31(5):626-634. [doi: [10.1080/10410236.2014.986026](#)] [Medline: [26512760](#)]
7. Tao C, Gong Y, Xu H, Zhao Z. Introduction: the International Conference on Intelligent Biology and Medicine (ICIBM) 2016: special focus on medical informatics and big data. *BMC Med Inform Decis Mak* 2017 Jul 05;17(Suppl 2):77 [FREE Full text] [doi: [10.1186/s12911-017-0462-0](#)] [Medline: [28699553](#)]
8. Trussler T. *Toward Kinder Care: Tracing Women's Experience of Breast Cancer from Risk Awareness through Detection, Diagnosis, Treatment and Survivorship*. Toronto: Canadian Breast Cancer Foundation; 2007:1-56.
9. Campbell-Enns HJ, Woodgate RL. The psychosocial experiences of women with breast cancer across the lifespan: a systematic review. *Psychooncology* 2017 Nov;26(11):1711-1721. [doi: [10.1002/pon.4281](#)] [Medline: [27648726](#)]
10. Gorman JR, Usita PM, Madlensky L, Pierce JP. Young breast cancer survivors: their perspectives on treatment decisions and fertility concerns. *Cancer Nurs* 2011;34(1):32-40 [FREE Full text] [doi: [10.1097/NCC.0b013e3181e4528d](#)] [Medline: [20697269](#)]
11. Cruz FO, Vilela RA, Ferreira EB, Melo NS, Reis PE. Evidence on the use of mobile apps during the treatment of breast cancer: systematic review. *JMIR Mhealth Uhealth* 2019 Aug 27;7(8):e13245 [FREE Full text] [doi: [10.2196/13245](#)] [Medline: [31456578](#)]
12. Foley NM, O'Connell EP, Lehane EA, Livingstone V, Maher B, Kaimkhani S, et al. PATI: Patient accessed tailored information: a pilot study to evaluate the effect on preoperative breast cancer patients of information delivered via a mobile application. *Breast* 2016 Dec;30:54-58. [doi: [10.1016/j.breast.2016.08.012](#)] [Medline: [27611236](#)]
13. Harder H, Holroyd P, Burkinshaw L, Watten P, Zammit C, Harris PR, et al. A user-centred approach to developing bWell, a mobile app for arm and shoulder exercises after breast cancer treatment. *J Cancer Surviv* 2017 Dec;11(6):732-742 [FREE Full text] [doi: [10.1007/s11764-017-0630-3](#)] [Medline: [28741202](#)]
14. Liua Y, Genga Z, Wua F, Yuana C. Developing "Information Assistant": a smartphone application to meet the personalized information needs of women with breast cancer. *MEDINFO 2017: Precision Healthcare Through Informatics*. 2017. URL: <https://ebooks.iospress.nl/pdf/doi/10.3233/978-1-61499-830-3-156> [accessed 2021-05-11]
15. Young-Afat DA, van Gils CH, Bruinvels DJ, van der Pol CC, Witkamp AJ, Sijtsema S, et al. Patients' and health care providers' opinions on a supportive health app during breast cancer treatment: a qualitative evaluation. *JMIR Cancer* 2016 Jun 07;2(1):e8 [FREE Full text] [doi: [10.2196/cancer.5334](#)] [Medline: [28410170](#)]



16. Device software functions including mobile medical applications. U.S. Food and Drug Administration. 2019. URL: <https://www.fda.gov/medical-devices/digital-health/device-software-functions-including-mobile-medical-applications> [accessed 2021-11-05]
17. Jongerius C, Russo S, Mazzocco K, Pravettoni G. Research-tested mobile apps for breast cancer care: systematic review. *JMIR Mhealth Uhealth* 2019 Feb 11;7(2):e10930 [FREE Full text] [doi: [10.2196/10930](https://doi.org/10.2196/10930)] [Medline: [30741644](https://pubmed.ncbi.nlm.nih.gov/30741644/)]
18. Zhu J, Ebert L, Xue Z, Shen Q, Chan SW. Development of a mobile application of Breast Cancer e-Support program for women with breast cancer undergoing chemotherapy. *Technol Health Care* 2017;25(2):377-382. [doi: [10.3233/THC-161292](https://doi.org/10.3233/THC-161292)] [Medline: [28085020](https://pubmed.ncbi.nlm.nih.gov/28085020/)]
19. Zieband S, Wyke S. Health and illness in a connected world: how might sharing experiences on the internet affect people's health? *Milbank Q* 2012 Jun;90(2):219-249 [FREE Full text] [doi: [10.1111/j.1468-0009.2012.00662.x](https://doi.org/10.1111/j.1468-0009.2012.00662.x)] [Medline: [22709387](https://pubmed.ncbi.nlm.nih.gov/22709387/)]
20. Zieband S, Herxheimer A. How patients' experiences contribute to decision making: illustrations from DIPEX (personal experiences of health and illness). *J Nurs Manag* 2008 May;16(4):433-439. [doi: [10.1111/j.1365-2834.2008.00863.x](https://doi.org/10.1111/j.1365-2834.2008.00863.x)] [Medline: [18405260](https://pubmed.ncbi.nlm.nih.gov/18405260/)]
21. Shaffer VA, Hulsey L, Zikmund-Fisher BJ. The effects of process-focused versus experience-focused narratives in a breast cancer treatment decision task. *Patient Educ Couns* 2013 Nov;93(2):255-264. [doi: [10.1016/j.pec.2013.07.013](https://doi.org/10.1016/j.pec.2013.07.013)] [Medline: [23962673](https://pubmed.ncbi.nlm.nih.gov/23962673/)]
22. Ormel I, Magalhaes M, Josephson D, Tracey L, Law S. How to know what to know: information challenges for women in the diagnostic phase of breast cancer. *Patient Educ Couns* 2021 Jan;104(1):179-185 [FREE Full text] [doi: [10.1016/j.pec.2020.06.030](https://doi.org/10.1016/j.pec.2020.06.030)] [Medline: [32646774](https://pubmed.ncbi.nlm.nih.gov/32646774/)]
23. Mobasheri MH, Johnston M, King D, Leff D, Thiruchelvam P, Darzi A. Smartphone breast applications - what's the evidence? *Breast* 2014 Oct;23(5):683-689. [doi: [10.1016/j.breast.2014.07.006](https://doi.org/10.1016/j.breast.2014.07.006)] [Medline: [25153432](https://pubmed.ncbi.nlm.nih.gov/25153432/)]
24. Blow AJ, Swiecicki P, Haan P, Osuch JR, Symonds LL, Smith SS, et al. The emotional journey of women experiencing a breast abnormality. *Qual Health Res* 2011 Oct;21(10):1316-1334. [doi: [10.1177/1049732311405798](https://doi.org/10.1177/1049732311405798)] [Medline: [21511978](https://pubmed.ncbi.nlm.nih.gov/21511978/)]
25. Smit A, Coetzee BJ, Roomaney R, Bradshaw M, Swartz L. Women's stories of living with breast cancer: a systematic review and meta-synthesis of qualitative evidence. *Soc Sci Med* 2019 Feb;222:231-245. [doi: [10.1016/j.socscimed.2019.01.020](https://doi.org/10.1016/j.socscimed.2019.01.020)] [Medline: [30665063](https://pubmed.ncbi.nlm.nih.gov/30665063/)]
26. Canadian Health Experiences Research Network. 2021. URL: <https://healthexperiences.ca/> [accessed 2021-05-17]
27. Gale NK, Heath G, Cameron E, Rashid S, Redwood S. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. *BMC Med Res Methodol* 2013 Sep 18;13:117 [FREE Full text] [doi: [10.1186/1471-2288-13-117](https://doi.org/10.1186/1471-2288-13-117)] [Medline: [24047204](https://pubmed.ncbi.nlm.nih.gov/24047204/)]
28. Kelly L, Zieband S, Jenkinson C. Measuring the effects of online health information: scale validation for the e-Health Impact Questionnaire. *Patient Educ Couns* 2015 Nov;98(11):1418-1424 [FREE Full text] [doi: [10.1016/j.pec.2015.06.008](https://doi.org/10.1016/j.pec.2015.06.008)] [Medline: [26162953](https://pubmed.ncbi.nlm.nih.gov/26162953/)]
29. Lu H, Xie J, Gerido LH, Cheng Y, Chen Y, Sun L. Information needs of breast cancer patients: theory-generating meta-synthesis. *J Med Internet Res* 2020 Jul 28;22(7):e17907 [FREE Full text] [doi: [10.2196/17907](https://doi.org/10.2196/17907)] [Medline: [32720899](https://pubmed.ncbi.nlm.nih.gov/32720899/)]
30. Halbach SM, Ernstmann N, Kowalski C, Pfaff H, Pfortner T, Wesselmann S, et al. Unmet information needs and limited health literacy in newly diagnosed breast cancer patients over the course of cancer treatment. *Patient Educ Couns* 2016 Sep;99(9):1511-1518. [doi: [10.1016/j.pec.2016.06.028](https://doi.org/10.1016/j.pec.2016.06.028)] [Medline: [27378079](https://pubmed.ncbi.nlm.nih.gov/27378079/)]
31. Hanna L, Grothaus K, Peterson M, Bertram S. Breast cancer survivors' perceptions of the delivery of lymphedema education in the United States. *J Women's Health Phys Ther* 2017;41(3):137-144. [doi: [10.1097/JWH.0000000000000083](https://doi.org/10.1097/JWH.0000000000000083)]
32. Cheung KL, Durusu D, Sui X, de Vries H. How recommender systems could support and enhance computer-tailored digital health programs: a scoping review. *Digit Health* 2019 Jan 24;5:A [FREE Full text] [doi: [10.1177/2055207618824727](https://doi.org/10.1177/2055207618824727)] [Medline: [30800414](https://pubmed.ncbi.nlm.nih.gov/30800414/)]
33. Shaffer VA, Zikmund-Fisher BJ. All stories are not alike: a purpose-, content-, and valence-based taxonomy of patient narratives in decision aids. *Med Decis Making* 2013 Jan;33(1):4-13. [doi: [10.1177/0272989X12463266](https://doi.org/10.1177/0272989X12463266)] [Medline: [23065418](https://pubmed.ncbi.nlm.nih.gov/23065418/)]
34. DIPEX International. URL: <https://dipexinternational.org/> [accessed 2021-05-18]

## Abbreviations

**DCIS:** ductal carcinoma in situ

**HERS:** Health Experiences and Real Stories

**SMHC:** Saint Mary's Hospital Center

*Edited by G Eysenbach; submitted 05.08.20; peer-reviewed by H Harder, M Lozano-Lozano; comments to author 04.10.20; revised version received 26.11.20; accepted 13.04.21; published 02.06.21.*

*Please cite as:*

*Ormel I, Onu CC, Magalhaes M, Tang T, Hughes JB, Law S*

*Using a Mobile App-Based Video Recommender System of Patient Narratives to Prepare Women for Breast Cancer Surgery: Development and Usability Study Informed by Qualitative Data*

*JMIR Form Res 2021;5(6):e22970*

*URL: <https://formative.jmir.org/2021/6/e22970>*

*doi: [10.2196/22970](https://doi.org/10.2196/22970)*

*PMID: [34076582](https://pubmed.ncbi.nlm.nih.gov/34076582/)*

©Ilja Ormel, Charles C Onu, Mona Magalhaes, Terence Tang, John B Hughes, Susan Law. Originally published in JMIR Formative Research (<https://formative.jmir.org>), 02.06.2021. This is an open-access article distributed under the terms of the Creative Commons Attribution License (<https://creativecommons.org/licenses/by/4.0/>), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Formative Research, is properly cited. The complete bibliographic information, a link to the original publication on <https://formative.jmir.org>, as well as this copyright and license information must be included.

Original Paper

# Multicultural Adaptation of Mighty Girls for Widespread Dissemination: Pilot Study, App Development and Usability Testing, and Gauging Parent Support With Focus Groups

Anne E Norris<sup>1,2</sup>, FAAN, PhD; Roxana Delcampo Thalasinis<sup>3</sup>, AS; Michael L Hecht<sup>3,4</sup>, DPhil

<sup>1</sup>REAL Prevention, LLC, Oviedo, FL, United States

<sup>2</sup>School of Nursing and Health Studies, University of Miami, Coral Gables, FL, United States

<sup>3</sup>REAL Prevention, LLC, Clifton, NJ, United States

<sup>4</sup>Department of Communication Arts and Science, Penn State University, State College, PA, United States

**Corresponding Author:**

Anne E Norris, FAAN, PhD

REAL Prevention, LLC

817 Kingsbridge Dr

Oviedo, FL, 32765

United States

Phone: 1 4074161727

Email: [anne@real-prevention.com](mailto:anne@real-prevention.com)

## Abstract

**Background:** Taking evidence-based interventions to scale is a challenge for prevention science. Mighty Girls is an evidence-based sexual health intervention program that combines classroom sessions with novel, cutting-edge technology (digital puppetry). The program was developed for 7th grade Latinas, but US school and community demographics rarely allow interventions targeting a single ethnic group. Additionally, digital puppetry is costly to scale up, and parent disapproval often prevents successful dissemination of adolescent sexual health programs. Intervening steps along the scaling-up pathway are needed to adapt the program prior to scaling up for dissemination.

**Objective:** The aims of this study were to create a multicultural adaptation of the Mighty Girls program using a mobile app that is less costly to disseminate and is acceptable to parents of 7th grade girls.

**Methods:** This study used a three-phase process to adapt Mighty Girls into Mighty Teens. All phases used purposive (nonprobability) sampling of low-income, multicultural, urban metropolitan groups (7th grade girls and their parents) within central Florida. Phase 1 involved two videotaped implementations of a multicultural adaptation of the classroom sessions, one involving focus groups (N=14) and the other serving as a single-group pretest-posttest pilot study (N=23). Phase 2 involved development of a narrative cell phone app prototype, which was subjected to usability testing (N=25). App usability and engagement were assessed qualitatively (observation, focus group, open-ended questions) and quantitatively. Phase 3 used focus groups to assess parent support for the program (N=6). Qualitative data were analyzed using descriptive content analysis. Quantitative data were analyzed using descriptive statistics and paired *t* tests.

**Results:** Qualitative findings supported classroom sessions being multicultural, and identified simple changes to improve engagement and learning. Quantitative findings from the second classroom session implementation pilot study indicated a significant pre-post difference in intention to delay sexual intercourse ( $P=.04$ ). App usability and appeal were supported by a System Usability Scale score of 76 (exceeding 68 per the industry standard) and 83% (20/24) of participants agreeing they would recommend the app to friends. Parents (mothers) expressed only positive regard for program goals, and classroom session and app activities.

**Conclusions:** This study adapted Mighty Girls into an engaging, easier-to-disseminate, multicultural program, termed Mighty Teens, that uses a narrative-generating app to support behavior change, and is likely to be accepted by parents of 7th grade girls. This study also provides evidence of the preliminary effectiveness of Mighty Teens classroom sessions. The sampling method and sample size were appropriate for adaptation, but research involving a more representative US sample is needed to confirm multicultural fit, parent receptivity, and program effectiveness. Study implications include integrating app use throughout the classroom sessions to build narrative-generating skills across the program and increasing the number of narratives produced, which should in turn increase the program's behavior change potency.

**KEYWORDS**

implementation science; mobile apps; peer influence; early intervention; adolescent health

## ***Introduction***

Taking evidence-based interventions to scale is a challenge for prevention science [1,2] because scaling up interventions for widespread dissemination is not always straightforward [3]. Scaling up is particularly challenging in sexual health interventions with traditional support from the literature focused on monocultural tailoring [4,5] and the focus of the US National Institutes of Health on innovation. Although these are certainly worthy goals, they are often at odds with achieving scale, particularly for school-based programs. Additionally, political and ideological issues, especially parent disapproval [6], can create barriers to dissemination [7,8]. Failure to consider these issues prior to scaling up for widespread dissemination can threaten the successful dissemination of evidence-based programs [9].

The purpose of this paper is to illustrate the steps taken to adapt Mighty Girls, an evidence-based sexual health intervention

program [10], prior to scaling it up for widespread dissemination within US public school systems. Mighty Girl's program design is guided by a theoretical framework that integrates adolescent development theory [11], social cognitive theory [12], and narrative engagement theory [13]. The first two theories define program goals: delaying initiation of intercourse by building efficacy and skills in decision-making, goal-setting, risk evaluation, and resistance to peer pressure and media messages implying teen sex as a common behavior. By contrast, the narrative engagement theory defines the overarching program strategy: using narrative-generating activities to (a) build program skills, and (b) combine and imbed skill knowledge and program messages in memory. The resulting Mighty Girls program includes 6 classroom sessions and a computer game, DRAMA-RAMA, that generates a first-person narrative about responding to peer pressure in a simulated early adolescent world (Textbox 1).

**Textbox 1.** Mighty Girls program components and corresponding components in the Mighty Teens adaptation.

Sessions began with “Mighty Moments,” a kinesthetic learning experience of relationally competent resistance communication skills developed by the second author. Session objectives are listed with the original (Mighty Girls) program session title. Objectives were retained in the adaptation with minor modifications.

**Choices & Results (split into two sessions in Mighty Teens: Goals and Choices & Results)**

- Identify personal goals (modified as “Goals” in Mighty Teens)
- Understand the results of everyday choices (modified as “Choices & Results” in Mighty Teens)
- Relate choices and results to goals (modified as “Choices & Results” in Mighty Teens)

**What’s Risky? (maintained as “What’s Risky?” in Mighty Teens)**

- Explain why some behaviors could be considered risky
- Identify potential results of choosing to engage in risky behaviors
- Discuss what increases or decreases the risk of a specific behavior
- Identify what behaviors are risky for oneself

**The Avoid Skill (modified as “Avoid & Leave” in Mighty Teens)**

- Define Avoid Skill
- List 3 methods for avoiding an uncomfortable or risky situation
- Avoid the Mighty Girls way: being considerate, confident, and convincing

**The Refuse Skill (modified as “Refuse & Explain” in Mighty Teens)**

- Explain differences between aggressive, passive, and assertive communication
- Demonstrate matching voice and body language using Refuse Skill
- Refuse the Mighty Girl way: being considerate, confident, and convincing

**Media Influences (modified as “Challenging Media Messages” in Mighty Teens)**

- Explain purpose of media
- Think critically about advertisements and TV show messages
- Identify positive and negative messages about girls and women in the media
- Identify ways in which teens on popular TV shows are different from and similar to teens in real life

**Wrap-up & Review**

- Model results-based choices
- Demonstrate Mighty communication: using considerate, confident, and convincing words and body language.

**Tech Component to Support and Sustain Behavior Change (modified as a cell phone app in Mighty Teens)**

- Digital puppetry computer game, DRAMA-RAMA

The Avoid Skill and The Refuse Skill sessions were adapted from “keepin’ it REAL” [14]. Other sessions were cocreated by the first and second authors.

Mighty Girls has three features, which the nonadoption, abandonment, scale-up, spread, and sustainability (NASSS) framework identifies as likely to result in failure to scale up and disseminate [9]. First, the program was developed for Latinas. This monocultural focus is at odds with successful dissemination within US public school systems given US school and community demographics [15]. Additionally, research findings argue for greater effectiveness of multicultural, relative to monocultural, program interventions in general [16] and within US school settings in particular [17,18]. Second, DRAMA-RAMA relies on human-in-the-loop technology (digital puppetry) [10]. Advances in artificial intelligence are

not yet sufficient to reduce this cost (current personnel and equipment costs estimated at US \$20,000 per school), making the intervention not sustainable within US public school systems. An alternative, less costly narrative-generating technological component such as a smartphone app would address this sustainability barrier. Third, it is wise to gauge potential parent support for any school-based sexual health program [6], particularly one that uses a smartphone app [19], early in the scaling-up process when changes are easier to accommodate.



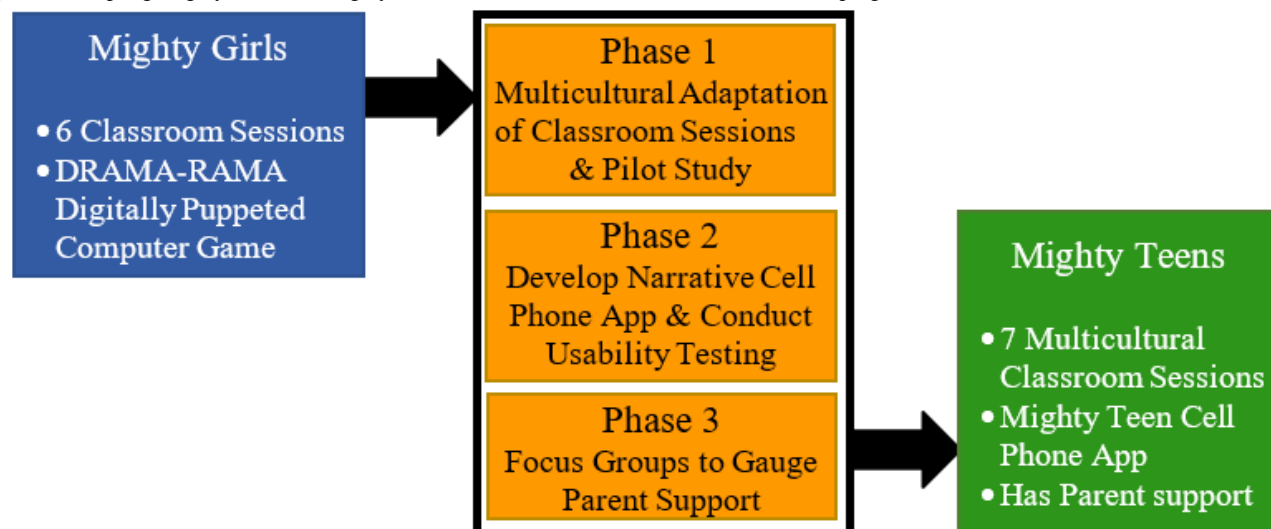
## Methods

### Overview

All three phases of program adaptation (Figure 1) used purposive [20] (nonprobability) sampling of groups living in a low-income,

multicultural, urban metropolitan area within central Florida. Recruitment and study procedures were approved by the Prevention Strategies LLC Institutional Review Board and participating school district. Below, we present information specific to each phase, one phase at a time.

**Figure 1.** Adapting Mighty Girls into Mighty Teens, a more scalable and easier to disseminate program.



### Phase 1: Multicultural Adaptation of Classroom Sessions and Pilot Study

#### Design

Phase 1 used an iterative process involving consultation and two implementations of the classroom sessions, with the second implementation serving as a pilot study. After each iteration, the classroom sessions were revised.

Three changes to program materials were made in preparation for phase 1. First, session slide sets were revised to ensure representation of a variety of cultural/ethnic groups. Second, content on narrative writing was added to the final “Wrap-up & Review” session. Third, ordering of the Avoid Skill and Refuse Skill sessions was reversed relative to their positioning in the original program. This last change was driven by insights from implementing the original program [10]. Both sessions were adapted from an efficacious, early-adolescent substance use prevention program, “keepin’ it REAL” [14], which stands for the relationally competent resistance communication skills Refuse, Explain, Avoid, and Leave. Only Refuse and Avoid were taught in Mighty Girls because formative work indicated that Explain could elicit more peer pressure by inviting peers to argue [21], and Leave could not be used in DRAMA-RAMA.

#### Consultation

Consultants included a female middle school staff member and three adult women in their early 20s (two African American women and one biracial African American/Native American woman). The latter were recruited as research assistants through Indeed, a worldwide employment website for job listings. These young women all lived in the same low-income, multicultural, urban metropolitan area in which the study was being performed. We specifically empowered them by emphasizing during recruitment and task directions that they brought a unique and

valuable expertise critical to the success of the research effort (this message was repeated throughout phase 1 and phase 2 for all tasks involving these women). They were tasked with reviewing the Mighty Girls classroom session program manual and slide sets for language, terminology, and image inclusivity (ie, not heterosexist or specific to a particular ethnic group) and making recommendations.

#### Participants, Procedures, and Measures

Participants in both implementations were girls enrolled in the 7th grade (aged 11-14 years) at two multiethnic middle schools in an urban metropolitan area within central Florida. No participant had difficulty speaking, reading, or writing in English, and on average used only English, or English more than other languages, for these activities (ie, high level of acculturation). Participants of implementation 1 were recruited at a low-income (67% reduced/free lunch, in accordance with criteria to be designated as a “Title I” school: 65% of students/families qualify directly for supplemental nutrition assistance program, homeless, migrant, Medicaid, or foster care as verified by the state) middle school with 80% minority enrollment. Two girls dropped out after session 4 due to repeated disruptive behavioral issues. Participants of implementation 2 were recruited at a second low-income (52% reduced/free lunch) school with 69% minority enrollment (top 5% of state schools for enrollment diversity). Participants at both schools were recruited with: (1) flyers posted at the school; (2) a message sent out via phone by the principal to parents of 7th grade girls; and (3) the three research assistants discussing the study and handing out study packets during 7th grade lunch (packets contained the principal’s letter of support, parental consent forms, and screening form assessing parents’ culture/ethnicity and child’s English language fluency).

Each implementation involved a two-person multicultural teaching team consisting of either the first or third author in the teaching role and one of the three research assistants in the teaching assistant role (ie, Hispanic or non-Hispanic White teacher paired with African American or multiethnic [African American/Native American] teaching assistant). This team also acted as participant observers who made postsession notes about the session they had taught, identifying what worked and did not work, and providing feedback on the cultural relevance of the wording and examples used to explain concepts.

Teaching assistant role training involved completing session activities in the role of a participant, and provided an opportunity to try out a training approach that combined two 2-hour face-to-face sessions with a “homework” assignment similar to what might be used for training when the program is taken to scale. All three research assistants spontaneously reported how much they liked their training, particularly the “homework” (using communication techniques with friends and family).

Both implementations were videotaped. The first implementation involved postsession focus groups, and the second was a one-group, pretest-posttest pilot study (not powered for significance).

### **First Implementation**

Participants at the first school completed a brief demographic questionnaire immediately prior to the first session that assessed age; birth country; race and ethnicity; acculturation (use of first language relative to English for those who spoke more than one language) [22,23]; and whether lunch was free, reduced in price, or full price.

Each Mighty Teens classroom session was delivered and then followed by a short focus group led by the teaching team. Focus group questions were displayed on slides. Participants wrote responses on large pieces of paper posted on walls or on anonymous index cards, depending on the question. They then voted (ie, agreed/disagreed) on themes identified in comments written publicly and anonymously, and responded to probes for more details or new thoughts emerging in response to other teens’ comments.

### **Second Implementation/Pilot Study**

In lieu of focus groups, participants at the second school completed a paper-and-pencil pretest immediately prior to the first session (also containing the same demographic items used in the first implementation) and completed a posttest immediately after the last session. All measures had been pretested or used with this age group previously [10,24].

The pretest and posttest contained a short self-efficacy scale, along with items assessing resistance and sexual intentions, and intention to postpone sexual intercourse. The 9-item self-efficacy scale comprised 5 items from the 12-item measure reported by DiIorio et al [25] (eg, say “no” to sex even if the other person says they will break up with you if you don’t have sex) and 4 items created by the first author to assess self-efficacy regarding specific program resistance behaviors [10]. These 4 items were: (1) stop someone who is pressuring you to do sexual things without making them angry, (2) leave a party or dance

club where sexual things are going on without being made fun of, (3) avoid situations where you know other people will be making out, and (4) say no in a serious way and stick to it when someone you like is pressuring you to do sexual things. Response options range from 1 to 4 with labels for endpoints and midpoints (1=not at all sure; 3=moderately sure; 5=completely sure). Higher scores indicate greater resistance self-efficacy. Cronbach  $\alpha$  was .84.

All intention items used the same response options: definitely not (1), probably not (2), probably yes (3), and definitely yes (4). Higher scores indicate greater intention. Psychometric analysis argued for treating intention types as measures of separate constructs, not part of a single multi-item intentions scale. Resistance intentions were assessed by a question related to a particular response strategy when asked “to do something you do not want to do.” Response strategies included: not resisting (go along with what they want me to do), resisting by using relationally competent communication strategies (4 items, including suggest doing something else;  $\alpha=.62$ ), or resisting by using a nonrelationally competent strategy (tell them I don’t want to because it’s stupid). Kirby et al’s [26] 3-item sexual intention measure was used to assess willingness to engage in sexual intercourse (eg, I would have sex now to keep someone I cared about romantically as a boyfriend/girlfriend); Cronbach  $\alpha$  was .79. Intention to postpone sexual intercourse was assessed with a single item: I want to wait to have sex until I am older.

### **Data Analysis**

Demographic responses were summarized with descriptive statistics. A paired *t* test was used to assess pretest-posttest differences in self-efficacy, resistance and sexual intentions, and intention to postpone sexual intercourse (second implementation only).

The first and second authors reviewed classroom session videos (both implementations) for signs of engagement, restlessness, and confusion. Engagement was defined as girls raising their hands to participate, smiling, looking at the teaching team or slide presentation when not engaged in a task, working on tasks, or easily redirected from chatting with peer(s) back to the main discussion and remaining attentive. Restlessness was defined as fidgeting, repeatedly talking with peer(s) and not easily redirected back to the task, complaining about the activity, being bored, or not having fun. Confusion was defined as a facial expression in which the nose and forehead were scrunched up in a type of frown, or complaints about being confused or not understanding task directions.

The first author also reviewed and performed a descriptive content analysis [27] of the teaching team postsession notes (both implementations) and postsession focus group videos (implementation 1 only). Content (eg, sentence or section of notes; participant response or portion of response if expressing multiple ideas) was sorted into one of three categories: (1) liking or positive, (2) disliking or negative, and (3) confusing or not clear. Improvement suggestions noticed in this process were also marked. Next, information within categories and improvement suggestions were each reviewed for themes and multiple instances, summarized, and then discussed with the study team.

## Phase 2: Development of a Narrative Cell Phone App and Usability Testing

### Design

Phase 2 began with app development that culminated in usability testing. The app prototype was initially developed for Android phones given Pew Foundation reports [28] indicating greater Android use by low-income families living in the urban metropolitan area within central Florida in which this research was being performed. However, the next iteration of the app will be built for both Android and iPhone cell phones.

Two theories guided app development. First, the theory of fun [29] stresses the importance of engagement for app uptake, and defines engagement as the result of positive affect, fun, low predictability, novelty, and the right amount of challenge (not too little or too much) experienced while interacting with the app. Second, narrative engagement theory [13] stresses the centrality of engagement to behavior change. According to this theory, engagement mediates overall effectiveness of narrative

creation, a phenomenon that builds self-efficacy through cognitive rehearsal [12] while simultaneously imbedding intervention messages (eg, concepts) in a narrative [13]. App use was planned for nonschool settings (eg, home, public library), necessitating a simple and intuitive interface. Additionally, the interface needed to guide users in creating their own “Mighty Teens” electronic story of resistance (similar to the events that occurred with DRAMA-RAMA in the Mighty Girls program). Stories were to be recorded, mirroring natural storytelling.

Both the app and a secure, password-protected dashboard (backend accessible to administration staff) were developed using a collaborative approach, involving the authors and Margaret Broucek, Principal of Tapp.technology who was a phase 2 technology partner (Textbox 2). Tapp.technology iteratively created screen designs in response to feedback from the authors and the three research assistants, arriving at the designs used to create the prototype for usability testing (Figure 2).

**Textbox 2.** Required prototype features and functionalities.

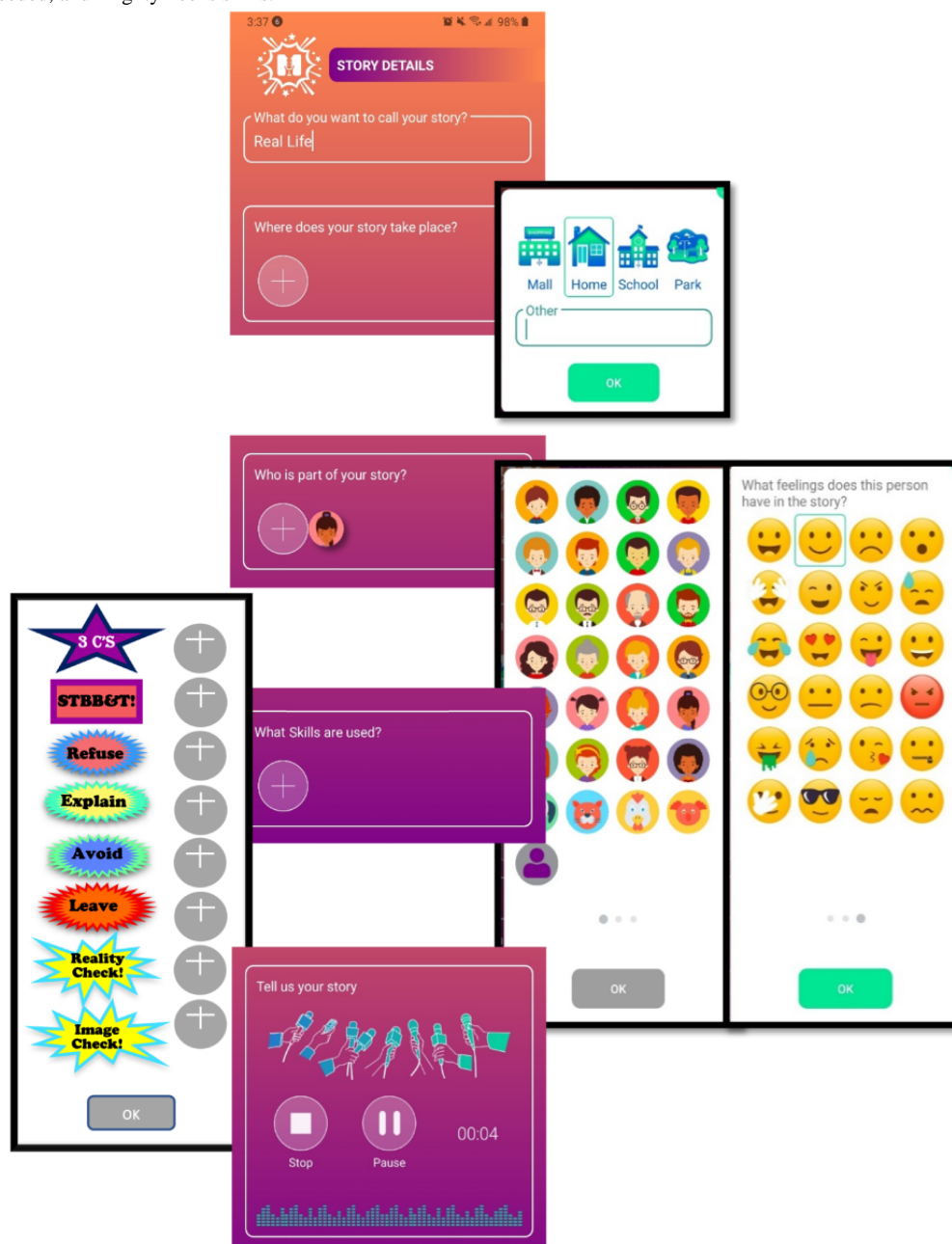
#### Mighty Teens app

- Intuitive interface with minimal text or direction
- Record oral story. Text input only required for naming story
- Present users with icons representing places, characters and their emotions, and Mighty Teens skills from which to select
- Provide users with button to click to access definitions of individual Mighty Teens skills
- Provide users with a button to click to record story while viewing selected icon places, people and their emotions, and Mighty Teens skills
- Allow users to listen to their story, and submit, rerecord, or delete it
- Send user stories using secure encrypted transmission to Mighty Teens dashboard

#### Mighty Teens Dashboard

- Secure, password-protected
- Allow direct entry and edit of information into sortable fields with controlled access to such privileges
- Usernames grouped by implementer and implementation school/clinic site
- Implementation school/clinic site with street, address, state, and zip code information, and grouped by organization
- Store usernames, app access codes, addresses, and story submissions
- Assign various levels of access to all stored information

**Figure 2.** Mighty Teens app prototype story-creating screen with pop-ups allowing selection of places, characters with as many emotions (represented as emoticons) as needed, and Mighty Teens skills.



### Participants and Procedures

Phase 1 participants were invited to participate in usability testing as part of their study participation. However, some were unable to attend due to transportation issues or schedule conflicts (eg, needed for sport team practice), resulting in a sample of 25 participants. Almost all participants (92%, 23/25) created and recorded at least one story. Two participants interacted with the app but did not record (or deleted recordings of) their stories. One of these participants did not want anyone to listen to her story. It is unclear if the other had difficulty with the recording feature or felt similarly. Although 25 girls participated in app testing, only 24 completed written assessments of usability and engagement.

Usability testing was performed at each school involved in phase 1 with hot spots, approximately 1 month apart. Participants

accessed the app using either their own Android cell phone or a “testing” cell phone provided by the research team.

When participants arrived at their respective school, they were split into two groups with each group assigned to a different classroom. Once in their classroom, participants were split into dyads and a research team member was assigned to observe each dyad. Those that finished early were free to record additional stories. Research team members took ethnographic field notes describing participants’ verbal and nonverbal behaviors during app use, but were unable to see the participants’ screens unless shown to them. Research team members debriefed immediately after testing. Notes from this meeting became part of the ethnographic field notes.

After using the app, the girls completed written assessments of usability and engagement. Following this, a brief focus group



discussion was held with the first or second author in the role of facilitator and a member of the research team in the role of cofacilitator/notetaker.

## Measures

### Quantitative Measures

Self-reported usability was assessed with an adaptation of the System Usability Scale [30] in which the word “system” was replaced with “app,” and wordiness and reading level were reduced to make items more accessible to teens. For example, the original item “I think that I would like to use this system frequently” was revised to “I would use this app a lot.” Response options (strongly disagree, disagree, neutral, agree, strongly agree) were unchanged.

Consistent with the original scoring process [30], responses were assigned a value of 0 (strongly disagree) to 4 (strongly agree) with even-numbered items reverse-scored, and scores were summed with the result multiplied by 2.5 to create a usability score ranging from 0 to 100. Cronbach  $\alpha$  for the adapted measure was .80. Validity was supported by correlations with the app being interesting ( $r=0.60$ ,  $P=.002$ ), task difficulty ( $r=-0.44$ ,  $P=.048$ ), and flow ( $r=0.45$ ,  $P=.03$ ).

Usability was also assessed with an open-ended question asking what could be done to improve the app, and task difficulty was assessed with a closed-ended question: “It was hard to think of an idea to use for the Mighty Teens app.” Response options were strongly disagree (1), disagree (2), agree (3), and strongly agree (4).

Self-reported engagement was measured with 6 items adapted from those used in DRAMA-RAMA development by replacing the word “game” with “app” and referring to writing stories instead of interacting with game characters [10]. A single item assessed whether the app was fun to use. A 5-item Likert scale consisted of the following items: three items describing the app experience (fun way to create a story, interesting, boring [recorded]), one item asking about using the app for a school assignment, and one item asking about recommending the app to friends. Response options ranged from strongly disagree (0) to strongly agree (3), without a neutral midpoint.

### Qualitative Measures

Ethnographic field notes were used to assess usability and engagement presence and issues. Research team members were trained to collect these notes and used a checklist as a guide to verify that they had commented on all assessment domains. The checklist prompted assessment of (a) verbal and nonverbal signs of positive and negative affect, and (b) problems with usability indicated by participants having completed the storytelling task (eg, long delays, facial expressions of frustration, asking questions).

Focus group interviews consisted of open-ended questions that asked for general impressions, likes and dislikes, and recommendations for improvement. These questions were followed by requests for feedback on specific screens or parts of screens.

## Data Analysis

Ethnographic field notes, focus group notes, and participant responses to the open-ended usability question were analyzed using descriptive content analysis [27], similar to phase 1. However, the first author sorted units into categories, and then identified and presented a summary of themes represented by these categories to the usability testing team, along with copies of the raw qualitative data. The summary was finalized in the resulting discussion.

Participant stories were coded for narrative structure and reference to Mighty Teens program skills using two dichotomous (0, 1) variables. Narrative structure was defined as three complete components (1). A reference to a Mighty Teens program skill (1) required the participant to describe a character correctly using (or teaching another character to use) at least one skill. It was not necessary to use the exact program name for the skill. However, not referencing a skill or naming one without any application were both coded as no reference (0). Interrater agreement was 100%.

## Phase 3: Focus Groups to Gauge Parent Support

### Participants, Procedures, and Measures

Mothers and fathers of 7th grade girls involved in the second implementation were invited to participate in a focus group (a) by flyers included in the study packets given out to their daughters, and (b) during the parental consent process for their daughters' participation. No fathers expressed interest in participating or were involved in the consenting process.

Scheduling of focus group participation coincided with the first national lockdown in response to the COVID-19 pandemic. Parents were distracted, under distress, with other activities competing for their attention, complicating consenting and scheduling (eg, parents who had previously expressed interest did not return phone calls). Scheduling and COVID-19 accommodations resulted in two focus groups involving 6 mothers as participants.

Focus groups were conducted using Zoom conference technology, which was challenging because the participants seemed unfamiliar with Zoom and video conferences in general. However, the facilitator (second author) was able to assist by phone, and familiarize participants with the process and importance of confidentiality and privacy once they opened Zoom.

Focus group interviews consisted of open-ended questions about (1) what the parents had heard about Mighty Teen classroom sessions or the app from their daughters, and (2) the parents' feelings about and challenges related to their daughters' use of apps and cell phones. Information about classroom session topics and activities, and about the app was provided once parents shared what they had heard. Feedback was then solicited, followed by specific probing related to their daughters' use of the app, her doing so privately, and supervision preferences and concerns.



## Data Analysis

Descriptive statistics are used to summarize the mothers' ethnicities. Focus group recordings were transcribed verbatim and analyzed using descriptive content analysis [27], similar to phases 1 and 2. However, the first and second authors independently sorted units into positive/negative categories and

summarized themes within the categories. No differences in categorization or meaning of theme labels were noted.

## Results

### Participant Characteristics

Participant demographic characteristics for all three study phases are provided in Table 1.

**Table 1.** Demographic characteristics of participants by study phase.

| Characteristic  | Phase 1: Implementation |            | Phase 2: Usability testing<br>(N=25) | Phase 3: Parent focus groups<br>(N=6) |
|---|-------------------------|------------|--------------------------------------|---------------------------------------|
|   | 1 (n=14)                | 2 (n=23)   |                                      |                                       |
| Age (years), median (range)   | 13 (12-14)              | 13 (11-14) | 13 (11-14)                           | — <sup>a</sup>                        |
| Qualifies for reduced/free lunch, n (%)   | 11 (85)                 | 16 (70)    | 19 (76)                              | N/A <sup>b</sup>                      |
| <b>Cultural/ethnic group, n (%)</b>   |                         |            |                                      |                                       |
| African American  | 5 (36)                  | 5 (22)     | 8 (32)                               | 2 (33) <sup>c</sup>                   |
| Arab American   | 0 (0)                   | 1 (4)      | 1 (4)                                | 0 (0)                                 |
| Bahamian/Black Caribbean  | 2 (14)                  | 2 (9)      | 2 (8)                                | 1 (17) <sup>c</sup>                   |
| Haitian   | 0 (0)                   | 4 (17)     | 3 (12)                               | 1 (17) <sup>c</sup>                   |
| Hispanic/Latino   | 4 (29)                  | 5 (22)     | 5 (20)                               | 1 (17) <sup>d</sup>                   |
| Indo-American   | 1 (7)                   | 1 (4)      | 1 (4)                                | 0 (0)                                 |
| Non-Hispanic White  | 1 (7)                   | 2 (9)      | 2 (8)                                | 1 (17) <sup>d</sup>                   |
| Multicultural (African American and Haitian; African American and Hispanic/Latino; Navajo and Non-Hispanic White; Bahamian and Haitian) | 1 (7)                   | 3 (13)     | 3 (12)                               | 0 (0)                                 |
| US (mainland)-born, n (%)   | 11 (79)                 | 20 (87)    | 21 (85%)                             | —                                     |
| High level of acculturation, n (%)  | 12 (86)                 | 20 (87)    | 22 (88%)                             | —                                     |

<sup>a</sup>Data not collected.

<sup>b</sup>N/A: not applicable.

<sup>c</sup>Part of same focus group.

<sup>d</sup>Part of same focus group.

### Phase 1: Multicultural Adaptation of Classroom Sessions

#### Consultation

The consultants recommended taking more time in session 1 to explain the program, and making two changes to increase program language inclusivity: (1) replace “girls” with “teens” (including in the program title); and (2) use nongender-specific names and pronouns to avoid gender identity and sexual orientation biases. These changes were recommended to make teens feel included regardless of gender identity or sexual orientation. The only exception was in the Media Influences session, where the focus on how girls and women are depicted in advertisements was viewed as valuable. The three young adult consultants also reported (without prompting) how much they liked the program and wished it had been offered to them when they were in middle school, lending support for its multicultural potential.

### Implementations

#### Overview

Review of classroom session videos and teaching impression notes from both implementations failed to identify instances indicating a lack of multiculturalism in terminology or directions, including those related to resisting peer pressure. For example, expressions of confusion tended to be made by multiple teens who were not more likely to be of a particular cultural/ethnic group than other participants. Moreover, the teaching teams of implementations 1 and 2 failed to report any instances of program content, directions, or examples feeling “off,” “needing to be translated,” and similar. Below, we discuss the implementation-specific findings.

#### First Implementation

Analyses of focus group and classroom session videos, and teaching impression notes identified two pedagogical issues and one opportunity to fine-tune the content. First, participants appeared to be confused when identifying goals in session 1,

indicating that more time was needed for teaching this content, resulting in the decision to split this session in two, with the first objective retained in the new Goals session and the remaining two objectives addressed in the new Choices & Results session (Textbox 1). Second, fidgeting and restlessness were noted during the session 3 content when the resistant communication skill Refuse was presented, indicating a need for physically active learning (eg, having the class stand and share in acting out the Refuse skill). Aside from these issues, all other disengagements could be linked to one or two participants with a preexisting peer conflict documented in teaching impression notes. Third, review of Refuse and Avoid session videos led to a discussion with the teaching team that resulted in (a) adding a clear definition of Explain, but restricting it to a type of vague explanation that is difficult for peers to argue with (eg, “I’m not into that”); and (b) defining Leave as a response that can be combined with Refuse, Explain, or Avoid. In the original program, this content has been presented more as a type of Refuse or Avoid skill but with little emphasis. As a result of this change, session objectives were slightly modified to include defining and applying Explain and Leave, respectively, and session titles were modified to “Refuse & Explain” and “Avoid & Leave.”

## Second Implementation and Pilot Study

The teaching team reported that splitting session 1 into two different sessions increased class discussion time and allowed for the goal content to be covered more slowly, improving participants’ grasp of this content. Review of videos indicated that any confusion initially present declined over the period in which the goal content was presented. Similarly, fidgeting and restlessness during the Refuse skill content presentation appeared to be eliminated by increasing the physical learning of this skill. Nevertheless, the teaching team reported that, overall, it was difficult to deliver all content within 45 minutes and still have sufficient time for discussion. This was particularly true for sessions 4 and 5, which had been revised to include content on Explain and Leave, respectively, and also for session 7 to which content on narrative writing had been added. In other words, all three sessions need to be revisited to streamline/reduce their content.

Engagement was evident across all sessions. Any disengagement could again be linked to a preexisting peer conflict noted in the teaching impression notes.

Quantitative analyses identified a significant pre-post increase in intention to delay sexual intercourse ( $t_{14} = -2.26$ ,  $P = .04$ ). No significant pre-post increases in resistance self-efficacy ( $P = .71$ ) or resistance intentions ( $P \geq .30$ ), or decreases in sexual intentions ( $P \geq .17$ ) were observed.

## Phase 2: Narrative Cell Phone App Usability Testing

### *Qualitative and Quantitative Measures*

We could not detect any substantive differences between the results obtained for the two usability testing sessions. Hence, results presented herein are combined across sessions. The observed time to complete a task ranged from 6.30 to 13 minutes (median 6.67). The prototype did not track the time spent between opening the app and submitting a story, and teens were

offered the opportunity to record their stories outside if they did not want to be overheard. Hence, the observed time to complete a task may be confounded with the time spent visiting with friends, a behavior observed at the same time the recording was presumed to be occurring, arguing for it being a “high-end” estimate of the actual time required.

Only 24% (6/25) of the participants created a story with a beginning, middle, and end, and less than half of the participants (44%, 11/25) created a story in which Mighty Teens skills were used. The stories reflected both same and opposite sex orientations, consistent with the tailoring expected in self-generated narratives.

### *Usability*

The System Usability Scale score was 76 despite 55% (12/22) of the participants agreeing that it was hard to think of an idea to use for the Mighty Teens app. Content analysis of open-ended question responses and focus group notes indicated that about half of the participants wanted the app to have a tutorial, more directions, or prompts, whereas about half felt that it was “simple,” “easy,” or “very straightforward.”

Analysis of ethnographic field notes described some participants as frowning and stopping, as if concentrating, and others clearly stuck at the initial step of identifying a title until told they could use “My Story” as the title if they wanted to. Regardless, these participants quickly transitioned to a rush of tapping and swiping with brighter affect, and focus group notes indicated that all but one participant (disgruntled by a preexisting peer conflict) were pleased with their experience. Nevertheless, many did not like how their recorded voice sounded.

Slightly more than a third (9/24, 38%) of the participants stated in their written responses to the usability open-ended question that there was nothing needed to improve the app (eg, “no,” “nope,” “nothing”). Less than half (11/24, 46%) made one or more comments concerning actual or desired app features, and 17% (4/24) made no comments.

Descriptive content analysis of responses to the usability open-ended question ethnographic field notes or focus group notes identified ways to improve usability (Textbox 3). Triangulation of these data sources indicated that a majority of participants (80%, 20/25) were frustrated or disappointed that they could not type their story. In contrast, 20% (5/25) expressed joy and astonishment that they could record (they had expected text entry) and had quickly begun using the app with gusto. However, this latter group agreed in the focus groups that text entry would be useful if a teen was concerned about being overheard, or was mute or stuttered.

Four unsubmitted stories were found in the testing phones after the session supported participants’ suggestion to add confirmation of a successful story submission. Additionally, the focus group discussion helped clarify other usability improvements. For example, all participants wanted the character set to be more representative but some also felt that the numbers of icons in the current character set was overwhelming, arguing for customizing over expanding the existing set.

Similarly, the importance of adding an “other” category for character emotions was emphasized by comments indicating that participants considered qualities such as courageous, shy, and determined to be emotions. In contrast, comments regarding

places suggested adding both icons (eg, corner store, fast food place, “jumping place” [a place for teen parties with trampolines]) and an “other” option to accommodate places that might be more regional or seasonal (eg, pool, beach).

**Textbox 3.** App improvement categories and themes identified in descriptive content analysis.

#### Usability improvement categories and themes

- Allow both recording and text entry of stories.
- Label emoticons (cannot tell what some of the faces mean).
- Improve ability to select story elements:
  - Allow multiple selections without exiting and reentering screen.
  - Increase differentiation between skill versus skill definition selection (add a question mark for definition).
- Improve ability to delete characters.
- Make “controls” (pause, record, submit) on recording screen clear.
- Confirm story submission, so you know it worked.
- Increase choices and/or allow more customization:
  - Current character set not sufficiently representative (nobody looked like me).
  - Add selection of various different intensities of particular emotions (eg, a little angry, extremely angry).
  - Add more places.
  - Add “other” option for emotions and places similar to what is available for characters.
- Change to blue and red colors if app to be used by both boys and girls at some point; current colors are “girly.”

#### Engagement improvement categories and themes

- Make possible to anonymously share and chat about stories to help other teens or obtain feedback on how story creator responded (or could have responded) to a particular situation.
- Increase the fun:
  - Add emoticons floating across login page.
  - Have app “read back” in a male or female voice, according to user’s choice.
  - Animate stories (have characters act out story).

### Engagement

Descriptive content analysis indicated smiling, intense focus, and constant interaction with the app for 23 out of 25 (92%) participants with these same participants asking if they could use the app to make multiple stories. At least 4 out of 23 (17%) participants who requested this option did so in the time available with one participant creating 4 stories.

The word “fun” was used multiple times in all focus groups to describe the app; 83% (20/24) of participants reported they would recommend the app to their friends. Mean Fun and Like scores were 3.0 (SD 0.75) and 3.2 (SD 0.60), respectively, indicating that the participants agreed that the app was fun and liked using it. Additionally, both ethnographic and focus group notes indicated that participants found selecting icons for

characters, character emotions, and places very appealing. Selecting emotions was stated as a “favorite part.”

Analysis of open-ended question and focus group data identified changes that could increase engagement (Textbox 3). One such change (sharing and chatting about stories with other teens) appeared part of a larger theme of wanting the app to have a purpose; otherwise, “why should we use it?”

### Phase 3: Focus Groups Gauging Parent Support

Descriptive content analysis of focus group transcripts indicated no obvious group differences, and no ethnic or racial differences. Hence, results for each group are combined with participants referred to as mothers because no fathers participated (Table 2). There were no negative comments about any aspect of the program.

**Table 2.** Themes identified in parent focus groups.

| Theme  | Exemplar quote <sup>a</sup>  |
|--|--|
| Mothers liked program goals and content          | "...she [referring to daughter] was just saying, 'You got to be careful when you're on social media, because you don't know who you're talk to who they are.'...I was Okay, she must have mentioned it because of the session...now they're having a session and all of a sudden, they know what to do so, that I did appreciate." |
| Mothers liked the Mighty Teens app               | "What I find different about yours versus the others is that she can either make up a story or use her own story...The other thing that I find that your app is interesting about is the fact that it brings in emotions, which I don't think the others do that. I like the emotional aspect of your app."                        |
| Mothers want Mighty Teens app use monitored      | "Sometimes they're not willing to talk about it themselves...if they shared something like that in a story, then it may put up a red flag: 'Hey, this person needs help.'"   |
| Sharing is a benefit to daughter and other teens | "I think if it's in a controlled environment, as far as your company or whomever, I think that will be something that is great for the kids to share whether it's a fictitious or whether it's a true story...to kind of make awareness to other children..."  |

<sup>a</sup>Each exemplar quote is from a different focus group participant. Participant race or ethnicity is not reported to protect confidentiality.

## Discussion

Scaling up culturally tailored sexual health interventions can be challenging and not always straightforward [3]. This study addressed three barriers that the NASSS framework [9] argued would impede successfully scaling up and disseminating the Mighty Girls program: lack of multiculturalism, cost, and parent receptivity. Phase 1 used an iterative process involving consultation, focus groups, and pretest-posttest evaluation to produce a multicultural adaptation of the classroom sessions and a new program name, Mighty Teens. The iterative process increased program language inclusivity with respect to gender identity, sexual orientation, and culture/ethnicity, consistent with best practices for creating multicultural programs [16]. Phase 1 also provided preliminary support for efficacy of the multicultural Mighty Teens classroom sessions.

Phase 2 used a combination of qualitative and quantitative methods to evaluate app usability and engagement potential. The usability score (76) exceeded the minimum industry standard (68) for minimum or average usability [31]. Additionally, the app enabled users to self-tailor their narratives to the level of sexual orientation, which was not possible using the original program's technical component. The app is less costly to disseminate than the Mighty Girls DRAMA-RAMA game, and potentially more powerful, because it affords a greater level of tailoring [13].

Finally, phase 3 parent focus groups demonstrated not only parent receptivity but also positive regard for the Mighty Teens program. This argues for the program's ability to surmount the political and ideological issues surrounding sex education that typically impede sexual health program dissemination and uptake [6-8].

Looking across the findings from all three phases of this study, two themes stand out. First, the study findings suggest that Mighty Teens has high engagement potential. This argues for program success and impact because engagement predicts program participation [32], learning [33], and behavior change [13]. Second, both mothers and daughters liked and valued a narrative-generating app that allows teens to (a) select emotions

for characters in a story and (b) share their stories with peers in a monitored environment. Although it is unclear if fathers would feel similarly, mother-daughter agreement suggests parents would support their daughters' app use in the home environment. This conclusion is also consistent with the technology acceptance model's premise that user value for particular app functionalities is critical to app acceptance and uptake [34].

This study did have limitations. Participants were purposively selected to represent various cultural and ethnic groups living within a low-income, urban metropolitan area within central Florida, and sample sizes were small, preventing us from statistical evaluation of possible cultural or ethnic differences. All parent focus group participants had previously consented to their daughters' participation in a sexual health program, and may have been more likely to approve of sex education in general, as well as this program. Further, only mothers participated in the parent focus groups. However, research shows that fathers often defer to mothers when it comes to their daughters' sexual health [35], and our sampling methods were suitable for adaptation purposes. Nevertheless, more cultural/ethnic differences might emerge in larger samples. Hence, we will evaluate both multicultural fit and parent receptivity in a future efficacy trial involving a more representative US sample.

Despite these limitations, this study illustrates how program developers can adapt a program prior to scaling up for dissemination so that clear barriers to implementation by targeted user organizations (ie, public schools) are addressed. Our three-phase approach models the use of specific guidelines and best practices for creating cultural [36] and multicultural adaptations [16] of evidence-based preventive interventions. For example, we involved a multicultural team of consultants (school counselor and three young adult women) familiar with and representative of a multicultural community. Our three young adult women were all intimately involved with the process of adapting the intervention in phases 1 and 2 in their roles as research assistants, and were empowered to shape this process. Our pilot study, usability testing, and parent focus groups provided data regarding intervention acceptability and efficacy as well as feasibility. Moreover, the empowered role



of our research assistants illustrates how to extend the principle of coproduction of public health interventions from intervention development to adaptation of an existing evidence-based intervention [37].

Additionally, the study findings provide clear directions for three app-related program improvements. First, there are clearly two different teen subgroups that need to be accommodated: those that prefer to record a story and those that prefer to use text. Second, story creation can be a difficult task for this age group. More support for structuring stories, including a prompt to use a Mighty Teens skill, needs to be designed into the app. Our findings suggest that either narrative writing is not consistently taught in 7th grade, despite being part of the US 7th grade common core standards [38], or, if it is taught, the content and related skills can be challenging for early adolescents to master. The ability of a sexual health program to support learning of an academic skill should increase the program's appeal to parents and public schools, thereby facilitating dissemination [6]. Third, the app should be introduced earlier and used to build narrative-generating skills

over the course of the program, opening up possibilities for classroom activities to move into the app, and creating more time for class discussion. This change also enhances relevance and synergy between the app and classroom session activities, and increases the number of narratives participants create. Meanwhile, increasing the number of narratives increases Mighty Teens behavior change potency [13].

In conclusion, this paper describes a three-phase process for adapting an evidence-based monocultural sexual health program to increase the ease and success of scaling up and dissemination. Specifically, this process (a) created a multicultural version of the classroom sessions (phase 1); (b) replaced a costly technological component with a less costly easier-to-disseminate narrative-generating cell phone app (phase 2); and (c) obtained preliminary parent support for the adaptation, including their child's use of the program's app component (phase 3). Findings generated by this process provide preliminary support for Mighty Teens program efficacy, and insights for increasing program engagement, potency, and perceived value.

## Acknowledgments

Funding for this research was provided by a SBIR Phase 1 award from the National Institute of Nursing Research (R43 NR018977) to MLH. The authors wish to acknowledge the assistance of Annie Pezalla with manuscript preparation.

## Conflicts of Interest

MLH is President of REAL Prevention LLC, owns the intellectual property rights to the intervention, and will market it in the future. AEN and RDT are former employees of REAL Prevention LLC. Commercialization of Mighty Teens and its derivatives results in shared revenues involving REAL Prevention LLC, RDT, and AEN.

## References

1. Milat AJ, Newson R, King L, Rissel C, Wolfenden L, Bauman A, et al. A guide to scaling up population health interventions. *Public Health Res Pract* 2016 Jan 28;26(1):e2611604. [doi: [10.17061/phrp2611604](https://doi.org/10.17061/phrp2611604)] [Medline: [26863167](https://pubmed.ncbi.nlm.nih.gov/26863167/)]
2. Indig D, Lee K, Grunseit A, Milat A, Bauman A. Pathways for scaling up public health interventions. *BMC Public Health* 2017 Aug 01;18(1):68 [FREE Full text] [doi: [10.1186/s12889-017-4572-5](https://doi.org/10.1186/s12889-017-4572-5)] [Medline: [28764785](https://pubmed.ncbi.nlm.nih.gov/28764785/)]
3. Barker PM, Reid A, Schall MW. A framework for scaling up health interventions: lessons from large-scale improvement initiatives in Africa. *Implement Sci* 2016 Jan 29;11:12 [FREE Full text] [doi: [10.1186/s13012-016-0374-x](https://doi.org/10.1186/s13012-016-0374-x)] [Medline: [26821910](https://pubmed.ncbi.nlm.nih.gov/26821910/)]
4. Bowring AL, Wright CJC, Douglass C, Gold J, Lim MSC. Features of successful sexual health promotion programs for young people: findings from a review of systematic reviews. *Health Promot J Austr* 2018 Apr;29(1):46-57. [doi: [10.1002/hpja.3](https://doi.org/10.1002/hpja.3)] [Medline: [29700941](https://pubmed.ncbi.nlm.nih.gov/29700941/)]
5. Lustria MLA, Cortese J, Gerend MA, Schmitt K, Kung YM, McLaughlin C. A model of tailoring effects: A randomized controlled trial examining the mechanisms of tailoring in a web-based STD screening intervention. *Health Psychol* 2016 Nov;35(11):1214-1224. [doi: [10.1037/hea0000399](https://doi.org/10.1037/hea0000399)] [Medline: [27441869](https://pubmed.ncbi.nlm.nih.gov/27441869/)]
6. Wiley DC, Plesons M, Chandra-Mouli V, Ortega M. Managing sex education controversy deep in the heart of Texas: a case study of the North East Independent School District (NEISD). *Am J Sex Educ* 2019 Nov 18;15(1):53-81. [doi: [10.1080/15546128.2019.1675562](https://doi.org/10.1080/15546128.2019.1675562)]
7. Hall WJ, Jones BLH, Witkemper KD, Collins TL, Rodgers GK. State policy on school-based sex education: a content analysis focused on sexual behaviors, relationships, and identities. *Am J Health Behav* 2019 May 01;43(3):506-519. [doi: [10.5993/AJHB.43.3.6](https://doi.org/10.5993/AJHB.43.3.6)] [Medline: [31046882](https://pubmed.ncbi.nlm.nih.gov/31046882/)]
8. Sex and HIV education. Guttmacher Institute. 2021 May 01. URL: <https://www.guttmacher.org/state-policy/explore/sex-and-hiv-education> [accessed 2021-05-12]
9. Greenhalgh T, Wherton J, Papoutsis C, Lynch J, Hughes G, A'Court C, et al. Beyond adoption: a new framework for theorizing and evaluating nonadoption, abandonment, and challenges to the scale-up, spread, and sustainability of health and care technologies. *J Med Internet Res* 2017 Nov 01;19(11):e367 [FREE Full text] [doi: [10.2196/jmir.8775](https://doi.org/10.2196/jmir.8775)] [Medline: [29092808](https://pubmed.ncbi.nlm.nih.gov/29092808/)]



10. Norris AE, Hughes C, Hecht M, Peragallo N, Nickerson D. Randomized trial of a peer resistance skill-building game for Hispanic early adolescent girls. *Nurs Res* 2013;62(1):25-35 [FREE Full text] [doi: [10.1097/NNR.0b013e318276138f](https://doi.org/10.1097/NNR.0b013e318276138f)] [Medline: [23150043](https://pubmed.ncbi.nlm.nih.gov/23150043/)]
11. Do KT, Prinstein MJ, Telzer EH. Neurobiological susceptibility to peer influence in adolescence. In: Kadosh KC, editor. *The handbook of developmental cognitive neuroscience*. New York: Oxford University Press; Oct 2020.
12. Schunk DH, DiBenedetto MK. Motivation and social cognitive theory. *Contemp Educ Psychol* 2020 Jan;60:101832. [doi: [10.1016/j.cedpsych.2019.101832](https://doi.org/10.1016/j.cedpsych.2019.101832)]
13. Miller-Day M, Hecht ML. Narrative means to preventative ends: a narrative engagement framework for designing prevention interventions. *Health Commun* 2013;28(7):657-670 [FREE Full text] [doi: [10.1080/10410236.2012.762861](https://doi.org/10.1080/10410236.2012.762861)] [Medline: [23980613](https://pubmed.ncbi.nlm.nih.gov/23980613/)]
14. Hecht ML, Shin Y, Pettigrew J, Miller-Day M, Krieger JL. Designed cultural adaptation and delivery quality in rural substance use prevention: an effectiveness trial for the keepin' it REAL curriculum. *Prev Sci* 2018 Nov;19(8):1008-1018 [FREE Full text] [doi: [10.1007/s11121-018-0937-y](https://doi.org/10.1007/s11121-018-0937-y)] [Medline: [30056616](https://pubmed.ncbi.nlm.nih.gov/30056616/)]
15. Vespa J, Armstrong D, Medina L. Demographic turning points for the United States: Population projections for 2020 to 2060. Report Number P25-1144. United States Census Bureau. Washington, DC: US Department of Commerce, Economics and Statistics Administration, USCB; 2020 Feb. URL: <https://www.census.gov/library/publications/2020/demo/p25-1144.html> [accessed 2021-05-12]
16. Clauss-Ehlers CS, Chiriboga DA, Hunter SJ, Roysircar G, Tummala-Narra P. APA multicultural guidelines executive summary: ecological approach to context, identity, and intersectionality. *Am Psychol* 2019;74(2):232-244. [doi: [10.1037/amp0000382](https://doi.org/10.1037/amp0000382)] [Medline: [30762387](https://pubmed.ncbi.nlm.nih.gov/30762387/)]
17. Shin Y, Miller-Day M, Hecht ML, Krieger JL. Entertainment-education videos as a persuasive tool in the substance use prevention intervention "keepin' it REAL". *Health Commun* 2018 Jul;33(7):896-906 [FREE Full text] [doi: [10.1080/10410236.2017.1321163](https://doi.org/10.1080/10410236.2017.1321163)] [Medline: [28586239](https://pubmed.ncbi.nlm.nih.gov/28586239/)]
18. Taylor CS, Nolan SB. Classroom assessment and diversity. In: Banks JA, Banks CAM, editors. *Multicultural education: issues and perspectives*, 10th Edition. Hoboken, NJ: John Wiley & Sons; Oct 2019:306-328.
19. Anderson M. How parents feel about—and manage—their teens' online behavior and screen time. Pew Research Center. 2019 Mar 22. URL: <https://www.pewresearch.org/fact-tank/2019/03/22/how-parents-feel-about-and-manage-their-teens-online-behavior-and-screen-time/> [accessed 2021-05-12]
20. Etikan I, Musa SA, Alkassim RS. Comparison of convenience sampling and purposive sampling. *Am J Theor Appl Stat* 2016 Jan 05;5(1):1-4. [doi: [10.11648/j.ajtas.20160501.11](https://doi.org/10.11648/j.ajtas.20160501.11)]
21. Norris AE, Aroian KJ, Warren S, Wirth J. Interactive performance and focus groups with adolescents: the power of play. *Res Nurs Health* 2012 Dec;35(6):671-679 [FREE Full text] [doi: [10.1002/nur.21509](https://doi.org/10.1002/nur.21509)] [Medline: [22949032](https://pubmed.ncbi.nlm.nih.gov/22949032/)]
22. Norris AE, Ford K, Bova CA. Psychometrics of a brief acculturation scale for Hispanics in a probability sample of urban Hispanic adolescents and young adults. *Hisp J Behav Sci* 2016 Jul 25;18(1):29-38. [doi: [10.1177/07399863960181004](https://doi.org/10.1177/07399863960181004)]
23. Norris AE, Phillips RE, Kang HP. Evaluation of a generic brief acculturation scale in a sample of male enlisted naval personnel. *Clin Nurse Spec* 2008;22(4):172-178. [doi: [10.1097/01.NUR.0000311705.38404.14](https://doi.org/10.1097/01.NUR.0000311705.38404.14)] [Medline: [18596485](https://pubmed.ncbi.nlm.nih.gov/18596485/)]
24. Norris AE, Torres-Thomas S, Williams ET. Adapting cognitive interviewing for early adolescent Hispanic girls and sensitive topics. *Hisp Health Care Int* 2014;12(3):111-119 [FREE Full text] [doi: [10.1891/1540-4153.12.3.111](https://doi.org/10.1891/1540-4153.12.3.111)] [Medline: [25239207](https://pubmed.ncbi.nlm.nih.gov/25239207/)]
25. DiIorio C, Resnicow K, Thomas S, Wang DT, Dudley WN, Van Marter DF, et al. Keepin' it R.E.A.L.: program description and results of baseline assessment. *Health Educ Behav* 2002 Feb 30;29(1):104-123. [doi: [10.1177/109019810202900110](https://doi.org/10.1177/109019810202900110)] [Medline: [11822548](https://pubmed.ncbi.nlm.nih.gov/11822548/)]
26. Kirby D, Korpi M, Barth RP, Cagampang HH. The impact of the postponing sexual involvement curriculum among youths in California. *Fam Plan Perspect* 1997 May;29(3):100-108. [doi: [10.2307/2953331](https://doi.org/10.2307/2953331)]
27. Graneheim UH, Lindgren B, Lundman B. Methodological challenges in qualitative content analysis: A discussion paper. *Nurse Educ Today* 2017 Sep;56:29-34. [doi: [10.1016/j.nedt.2017.06.002](https://doi.org/10.1016/j.nedt.2017.06.002)] [Medline: [28651100](https://pubmed.ncbi.nlm.nih.gov/28651100/)]
28. Smith A. Smartphone ownership 2013. Pew Research Center Internet & Technology. 2013 Jun 05. URL: <https://www.pewresearch.org/internet/2013/06/05/smartphone-ownership-2013/> [accessed 2021-05-12]
29. Koster R. *Theory of fun for game design*. 2nd edition. Sebastopol, CA: O'Reilly Media, Inc; 2014.
30. Lewis JR. The System Usability Scale: past, present, and future. *Int J Hum-Comput Interact* 2018 Mar 30;34(7):577-590. [doi: [10.1080/10447318.2018.1455307](https://doi.org/10.1080/10447318.2018.1455307)]
31. Bangor A, Kortum PT, Miller JT. An empirical evaluation of the System Usability Scale. *Int J Hum-Comput Interact* 2008 Jul 30;24(6):574-594. [doi: [10.1080/10447310802205776](https://doi.org/10.1080/10447310802205776)]
32. Hansen WB, Fleming CB, Scheier LM. Self-reported engagement in a drug prevention program: individual and classroom effects on proximal and behavioral outcomes. *J Prim Prev* 2019 Feb;40(1):5-34 [FREE Full text] [doi: [10.1007/s10935-018-00532-1](https://doi.org/10.1007/s10935-018-00532-1)] [Medline: [30631997](https://pubmed.ncbi.nlm.nih.gov/30631997/)]
33. Roorda DL, Jak S, Zee M, Oort FJ, Koomen HMY. Affective teacher-student relationships and students' engagement and achievement: A meta-analytic update and test of the mediating role of engagement. *School Psychol Rev* 2017 Sep 01;46(3):239-261. [doi: [10.17105/SPR-2017-0035.V46-3](https://doi.org/10.17105/SPR-2017-0035.V46-3)]

34. Tao D, Wang T, Wang T, Zhang T, Zhang X, Qu X. A systematic review and meta-analysis of user acceptance of consumer-oriented health information technologies. *Comput Hum Behav* 2020 Mar 01;104:106147. [doi: [10.1016/j.chb.2019.09.023](https://doi.org/10.1016/j.chb.2019.09.023)]
35. Widman L, Choukas-Bradley S, Noar SM, Nesi J, Garrett K. Parent-adolescent sexual communication and adolescent safer sex behavior: a meta-analysis. *JAMA Pediatr* 2016 Jan;170(1):52-61 [FREE Full text] [doi: [10.1001/jamapediatrics.2015.2731](https://doi.org/10.1001/jamapediatrics.2015.2731)] [Medline: [26524189](https://pubmed.ncbi.nlm.nih.gov/26524189/)]
36. Bernal G, Adames C. Cultural adaptations: conceptual, ethical, contextual, and methodological issues for working with ethnocultural and majority-world populations. *Prev Sci* 2017 Aug;18(6):681-688. [doi: [10.1007/s11121-017-0806-0](https://doi.org/10.1007/s11121-017-0806-0)] [Medline: [28573426](https://pubmed.ncbi.nlm.nih.gov/28573426/)]
37. Hawkins J, Madden K, Fletcher A, Midgley L, Grant A, Cox G, et al. Development of a framework for the co-production and prototyping of public health interventions. *BMC Public Health* 2017 Sep 04;17(1):689 [FREE Full text] [doi: [10.1186/s12889-017-4695-8](https://doi.org/10.1186/s12889-017-4695-8)] [Medline: [28870192](https://pubmed.ncbi.nlm.nih.gov/28870192/)]
38. English Language Arts Standards » Writing » Grade 7. Common Core State Standards Initiative. Washington DC: National Governors Association Center for Best Practices, Council of Chief State School Officers; 2010. URL: <http://www.corestandards.org/ELA-Literacy/W/7/> [accessed 2020-05-12]

## Abbreviations

**NASSS:** nonadoption, abandonment, scale-up, spread, and sustainability

*Edited by G Eysenbach; submitted 10.10.20; peer-reviewed by S Rostam Niakan Kalhori, YH Kwan; comments to author 02.11.20; revised version received 18.02.21; accepted 13.04.21; published 02.06.21.*

*Please cite as:*

Norris AE, Thalasin RD, Hecht ML

*Multicultural Adaptation of Mighty Girls for Widespread Dissemination: Pilot Study, App Development and Usability Testing, and Gauging Parent Support With Focus Groups*

*JMIR Form Res* 2021;5(6):e24937

URL: <https://formative.jmir.org/2021/6/e24937>

doi: [10.2196/24937](https://doi.org/10.2196/24937)

PMID: [34076578](https://pubmed.ncbi.nlm.nih.gov/34076578/)

©Anne E Norris, Roxana Delcampo Thalasin, Michael L Hecht. Originally published in JMIR Formative Research (<https://formative.jmir.org>), 02.06.2021. This is an open-access article distributed under the terms of the Creative Commons Attribution License (<https://creativecommons.org/licenses/by/4.0/>), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Formative Research, is properly cited. The complete bibliographic information, a link to the original publication on <https://formative.jmir.org>, as well as this copyright and license information must be included.

Original Paper

# Testing the Feasibility of Sensor-Based Home Health Monitoring (TEC4Home) to Support the Convalescence of Patients With Heart Failure: Pre–Post Study

Kendall Ho<sup>1\*</sup>, MD, FRCPC; Helen Novak Lauscher<sup>1\*</sup>, PhD; Jennifer Cordeiro<sup>1\*</sup>, BA; Nathaniel Hawkins<sup>2</sup>, MBChB, MD, MPH; Frank Scheuermeyer<sup>2</sup>, MD, MHSc; Craig Mitton<sup>3</sup>, PhD; Hubert Wong<sup>4</sup>, PhD; Colleen McGavin<sup>5</sup>, BA, DipED; Dianne Ross<sup>6</sup>, RN, CCN(C); Glory Apantaku<sup>3</sup>, MSc; Mohammad Ehsan Karim<sup>4</sup>, MSc, PhD; Amrit Bhullar<sup>1</sup>, BSc; Riyadh Abu-Laban<sup>2</sup>, MD, MHSc, FRCPC; Suzanne Nixon<sup>2</sup>, BScN, RN, MSN; Tyler Smith<sup>7</sup>, CPA, MBA

<sup>1</sup>Digital Emergency Medicine, University of British Columbia, Vancouver, BC, Canada

<sup>2</sup>University of British Columbia, Vancouver, BC, Canada

<sup>3</sup>Centre for Clinical Epidemiology & Evaluation, University of British Columbia, Vancouver, BC, Canada

<sup>4</sup>Centre for Health Evaluation & Outcome Sciences, University of British Columbia, Vancouver, BC, Canada

<sup>5</sup>BC Support for People & Patient-Oriented Research & Trials, Vancouver, BC, Canada

<sup>6</sup>Vancouver General Hospital, Vancouver, BC, Canada

<sup>7</sup>TELUS Health, Vancouver, BC, Canada

\*these authors contributed equally

**Corresponding Author:**

Kendall Ho, MD, FRCPC  
Digital Emergency Medicine  
University of British Columbia  
818 West 10th Avenue  
2329 West Mall  
Vancouver, BC, V6T 1Z4  
Canada  
Phone: 1 604 822 0327  
Email: [kendall.ho@ubc.ca](mailto:kendall.ho@ubc.ca)

## Abstract

**Background:** Patients with heart failure (HF) can be affected by disabling symptoms and low quality of life. Furthermore, they may frequently need to visit the emergency department or be hospitalized due to their condition deteriorating. Home telemonitoring can play a role in tracking symptoms, reducing hospital visits, and improving quality of life.

**Objective:** Our objective was to conduct a feasibility study of a home health monitoring (HHM) solution for patients with HF in British Columbia, Canada, to prepare for conducting a randomized controlled trial.

**Methods:** Patients with HF were recruited from 3 urban hospitals and provided with HHM technology for 60 days of monitoring postdischarge. Participants were asked to monitor their weight, blood pressure, and heart rate and to answer symptomology questions via Bluetooth sensors and a tablet computer each day. A monitoring nurse received this data and monitored the patient's condition. In our evaluation, the primary outcome was the combination of unscheduled emergency department revisits of discharged participants or death within 90 days. Secondary outcomes included 90-day hospital readmissions, patient quality of life (as measured by Veterans Rand 12-Item Health Survey and Kansas City Cardiomyopathy Scale), self-efficacy (as measured by European Heart Failure Self-Care Behaviour Scale 9), end-user experience, and health system cost-effectiveness including cost reduction and hospital bed capacity. In this feasibility study, we also tested the recruitment strategy, clinical protocols, evaluation framework, and data collection methods.

**Results:** Seventy participants were enrolled into this trial. Participant engagement to monitoring was measured at 94% (N=70; ie, data submitted 56/60 days on average). Our evaluation framework allowed us to collect sound data, which also showed encouraging trends: a 79% reduction of emergency department revisits post monitoring, an 87% reduction in hospital readmissions, and a 60% reduction in the median hospital length of stay (n=36). Cost of hospitalization for participants decreased by 71%, and emergency department visit costs decreased by 58% (n=30). Overall health system costs for our participants showed a 56%

reduction post monitoring (n=30). HF-specific quality of life (Kansas City Cardiomyopathy Scale) scores showed a significant increase of 101% (n=35) post monitoring ( $P<.001$ ). General quality of life (Veterans Rand 12-Item Health Survey) improved by 19% (n=35) on the mental component score ( $P<.001$ ) and 19% (n=35) on the physical component score ( $P=.02$ ). Self-efficacy improved by 6% (n=35). Interviews with participants revealed that they were satisfied overall with the monitoring program and its usability, and participants reported being more engaged, educated, and involved in their self-management.

**Conclusions:** Results from this small-sample feasibility study suggested that our HHM intervention can be beneficial in supporting patients post discharge. Additionally, key insights from the trial allowed us to refine our methods and procedures, such as shifting our recruitment methods to in-patient wards and increasing our scope of data collection. Although these findings are promising, a more rigorous trial design is required to test the true efficacy of the intervention. The results from this feasibility trial will inform our next step as we proceed with a randomized controlled trial across British Columbia.

**Trial Registration:** ClinicalTrials.gov NCT03439384; <https://clinicaltrials.gov/ct2/show/NCT03439384>

(*JMIR Form Res* 2021;5(6):e24509) doi:[10.2196/24509](https://doi.org/10.2196/24509)

## KEYWORDS

telemonitoring; heart failure; home health monitoring; technology; telehealth; emergency care; community care; emergency department; quality of life; self-efficacy

## Introduction

Heart failure (HF) is common, life-limiting, and the leading cause of hospitalization in North America and Europe [1]. Patients with HF are affected by debilitating symptoms and impaired quality of life. The median survival after hospitalization is 2.5 years, while rehospitalization rates exceed 20% at 30 days [1]. Telemonitoring has been proposed to support patients with HF in the community. Clinical studies to date have demonstrated promising but inconsistent evidence for this strategy. A recent meta-analysis of 17 studies of telemonitoring found mixed results with benefits reported in some areas and no significant change in others [2]. Two large randomized controlled trials (RCTs) failed to find a reduction in death or hospitalization [3,4]. These studies did not examine issues such as patients' level of familiarity and adoption of these technologies [3], or integration of technology-enabled monitoring in the context of convalescent care [4]. The Telemedical Interventional Management in Heart Failure II (TIM-HF2) trial demonstrated significant reductions in all-cause mortality and days lost due to unplanned cardiovascular hospitalization 1 year after monitoring [4]. Further, a meta-analysis concluded that a subpopulation of patients with HF recently discharged from hospital within 28 days of admission benefited preferentially from home telemonitoring and showed reduced mortality and all-cause hospitalizations [5]. Further trials of home telemonitoring for patients with HF are required to clarify these findings and their underlying factors.

Telehealth for Emergency-Community Continuity of Care Connectivity via Home Telemonitoring (TEC4Home) is a 4-year research initiative to evaluate the efficacy of home health monitoring (HHM) as an integrated component of health care delivery to support the transition of patients with HF from hospital to home. The initiative consists of a feasibility study followed by a pragmatic, multicenter, RCT [6]. The purpose of this paper is to report the results of the feasibility study conducted in preparation for the RCT, to test the clinical and technical monitoring protocols in hospital and community settings, and to refine the evaluation framework. We hypothesized that the study procedures would be acceptable to

both patients and providers; that the evaluation framework would capture useful metrics for outcome evaluation; and that the results would suggest a trend toward decreasing 90-day emergency department (ED) revisits and hospital admission rates, enhancing quality of life, improving self-efficacy, and reducing health care costs for patients and the health care system.

## Methods

### Recruitment Procedures

The feasibility study was an unblinded trial. Participants were prospectively recruited from EDs and inpatient units at 3 large urban hospital sites in British Columbia from November 2016 to July 2017. As this study was designed to assess the feasibility of the study protocol and refine procedures with a purposive sample gleaned from the feasibility study sites, no power calculation was conducted. Rather, the sample size was estimated from the recruitable number of patients with HF presenting at the ED sites based on administrative data with HF diagnosis and factoring in estimation of eligibility and attrition rates.

The inclusion criteria were as follows: one or more typical clinical HF symptoms; one or more typical clinical HF signs; one or more objective measures of HF, such as brain natriuretic peptide elevation or chest x-ray findings; currently receiving diuretic therapy; and age of 19 years or above. The exclusion criteria were as follows: inability to complete study procedures; no access to a reliable phone for communicating with a nurse; coronary or structural heart intervention during admission that would alter the course of HF convalescence with medical therapies alone; patients not expecting to present back to hospital for further deterioration, such as those wanting to die at home (see [Multimedia Appendix 1](#) for the patient participant eligibility criteria of the feasibility).

Potential participants were first identified via referrals from hospital ED staff and screening hospital ED lists. Throughout recruitment, the study team expanded referral streams to include hospital in-patient wards to increase recruitment numbers. Eligible patients were contacted in the hospital when possible



or immediately after discharge. Participants completed the consent process and were enrolled within 7 days from hospital discharge.

This study obtained ethics and associated approvals (no. H16-01076) from the regions where the 3 hospitals operate: University of British Columbia (UBC), Vancouver Coastal Health, and Interior Health Authorities.

### HHM Intervention

The HHM device kits were provided by TELUS Health (technology partner). The kit included a touch screen tablet computer and Bluetooth-connected sensors that included a blood pressure cuff, a pulse oximeter, and a weighing scale. Upon enrollment and after patients returned home, monitoring nurses aimed to contact all participants within 1-3 days by telephone. Nurses trained to provide monitoring during the study period were seconded from cardiac clinics and had extensive experience managing patients with HF. During the first call, the nurse confirmed eligibility and scheduled the delivery of the HHM device kit. Kits were provided free of charge for 60 days and were delivered and set up in participants' homes by a technician. The protocol sought to have kits delivered within 7 days of discharge from the hospital; however, this varied depending on the individual patient's scheduling preference.

Participants were taught how to use the device kit by the technicians at the time of delivery and were observed submitting their first set of biometric measurements (ie, blood pressure, oxygen saturation, pulse, and weight) and answering 10-12 yes-or-no questions regarding symptoms (eg, "I feel more short of breath today") in the technician's presence. Participants were then asked to continue daily submissions of 1 set of this data per day for the next 60 days. The monitoring nurse sent an enrollment letter to the participant's primary care provider (PCP) and other health care team members (eg, specialists), if appropriate, to notify them of their patients' participation in the monitoring program and research study. PCPs or specialists were also asked to review and change the default monitoring limits of the patients (eg, blood pressure, heart rate limits, or oxygen saturation levels) to customize to patients' needs if required. Dry target weight was also requested if known.

Monitoring data were reviewed by a single monitoring nurse Monday through Friday between 8:00 AM and 4:00 PM (excluding statutory holidays) via a web-based dashboard. The primary monitoring nurse performing the monitoring was a cardiac specialty nurse with over 20 years of experience working in cardiac care settings, such as a heart function clinic.

The platform listed and flagged patient measurements falling outside of predefined default (or customized) values (eg, weight gain of more than 5 lbs in 2 days), changes in symptoms, or missed data submissions. Alerts were flagged as red/severe (eg, systolic blood pressure < 85 mm Hg or >160 mm Hg) or yellow/caution (eg, systolic blood pressure 85-89 mm Hg or 141-160 mm Hg). The monitoring nurse followed up by telephone with the participants on all concerning flags and alerts. The monitoring nurse was authorized to advise the patient on better managing their condition and to provide education on management of the patient's condition. For medication changes,

the monitoring nurse would connect with the most responsible physician (eg, PCP) of the patient to facilitate these changes. In addition, the monitoring nurse would connect with other specialists with whom the patient was attached, if needed. For urgent situations, such as severe shortness of breath, the monitoring nurse was advised to direct the patient to their closest urgent care center or to call 911. Interventions that resulted from consultations between patients and monitoring nurses were documented in monitoring nurses' notes, and summaries were shared via fax with the participants' PCP every 2 weeks or as needed. The nurse also provided HF self-management education including advance care planning discussions to participants over the telephone, referring to a binder of HF self-management materials provided to participants upon enrollment into the study. Participants were discharged from the monitoring program after 60 days with a final report summarizing the monitoring data sent to the PCP. Participants were contacted again 30 days after discharge from the HHM program by telephone to complete a follow-up survey and to obtain their feedback on the HHM monitoring program.

### Primary and Secondary Outcomes

Key metrics were drawn from the Triple Aim Plus framework [7], and both quantitative and qualitative data were collected from patient participants, participants' PCPs, and the monitoring nurses. The primary outcome was the combination of unscheduled ED revisits in discharged participants within 90 days of discharge or all-cause death. Secondary outcomes included hospital readmission, patient participant health status (eg, quality of life, self-efficacy), end-user experience, and health system cost-effectiveness (including cost reduction and hospital bed capacity).

### Data Collection

#### *Patient Participant Experience and Outcomes*

Administrative data and data regarding patient participant experience and 90-day outcomes were collected via presurveys (at the time of consent) and postsurveys (30 days after monitoring discharge), with participants serving as their own controls.

Participants completed presurveys at enrollment and postsurveys from home via mail or over the telephone. The surveys, as outlined below, comprised multiple validated scales to assess pre-to-post changes in quality of life, self-efficacy, and health care utilization.

The Veterans Rand 12-Item Health Survey (VR-12) was included to measure health-related quality of life (general) [8,9]. The scale assesses 8 domains of health to produce a physical component and a mental component score.

The Kansas City Cardiomyopathy Scale (KCCQ-12) measures HF-specific quality of life [10]. The shortened 12-item scale assesses "patient-reported symptoms, function and quality of life for patients with heart failure." Agreement between the KCCQ-12 and the full KCCQ 23-item scale, which it is derived from, has previously been tested and results in a construct validity of 0.93-0.96 in quality of life scores, 0.97 in physical limitation scores, 0.98 in social limitation scores, and 0.98-0.99



in summary scores. Test-retest reliability calculations of KCCQ-12 have resulted in scores ranging from a 0.76 to 0.91 correlation across all domains. Scoring is calculated on a 100-point scale, with a higher score indicating a better overall health status.

The European Heart Failure Self-Care Behaviour Scale 9 (EHFScBs-9) was employed to assess self-care self-efficacy [11]. Internal reliability of this scale has been previously tested with a test score of 0.80 [11]. This scale consists of a 9 to 45-point scale, with lower scores indicating better self-care. For this trial, the method of standardizing the score to a 0-100 scale was used to make interpretation easier [12].

The My Healthcare Utilization Survey was included, as it assesses health care resource utilization and can collect information about the type and frequency of health-related services used within a specified time period. This scale was developed for this trial in collaboration with the UBC School of Population and Public Health

The System Usability Scale (postsurvey only) was also used, as it can evaluate the usability of a technology-based application [13]. The scale is scored on a 0 to 100-point scale, with higher scores representing better usability.

Basic demographic data (presurvey only) were also collected from participants and included age, sex, education level, and ethnicity.

Optional interviews were offered to all patient participants who completed the 90-day follow-up survey to gather additional feedback about their overall experience.

### **Health Care Provider Experience**

After study completion, the monitoring nurses were interviewed to explore their overall experience with the monitoring model, the benefits and challenges, and suggestions for improvement (see [Multimedia Appendix 2](#) for the monitoring nurse interview protocol).

Participants' PCPs were invited to provide feedback regarding the HHM intervention's impact on care delivery and workload through surveys, which were faxed to them (see [Multimedia Appendix 3](#) for the primary care physician survey protocol).

### **Statistical Analysis**

#### **Patient Participant Experience and Outcomes**

Survey data were entered into a Research Electronic Data Capture (REDCap) database [14,15] hosted at the Centre for Health Evaluation & Outcome Sciences (CHEOS) and were analyzed using R statistical package version 3.5.3 (R Foundation for Statistical Computing). The pre-to-postsurveys were coded and scored according to the validated scales' instructions, and paired *t* tests were used to assess pre-to-post difference across the outcome measures. The results are described as means with SD for parametric data and medians with IQRs for nonparametric data.

Pre-post analysis of administrative data was performed using Microsoft Excel (Microsoft Corporation). To determine pre-post change, we calculated the absolute risk reduction. Pre- and

posthealth care costs and impacts were calculated using the self-reported health care utilization surveys. To calculate out-of-pocket costs, we used participants' self-reported data on expenses related to their health condition, which included information on drugs, aids to daily living, housekeeping or home care, and transportation to and from medical appointments.

Interviews with patient participants about the overall experience were recorded and transcribed verbatim. Transcripts were coded, and content analysis was performed to summarize the interviews into themes (see [Multimedia Appendix 4](#) for the patient participant interview analysis codebook).

### **Health Care Provider Experience**

Survey and interview data collected from the monitoring nurses and the PCPs were summarized using content analysis to draw out themes and recommendations to guide future HHM implementations. Interview data were recorded and transcribed verbatim. Transcripts were coded and summarized by 2 researchers (AB and an undergraduate student) into main themes, including level of satisfaction for providing care, communication with participants, impact, and areas for improvement (see [Multimedia Appendix 5](#) for the monitoring nurse interview analysis codebook).

## **Results**

### **Recruitment**

From October 2016 to June 2017, 519 patients who met the criterion of presenting to the hospital with shortness of breath were referred and screened for further HF eligibility screening: 219 met the study eligibility criteria for HF, and 70 were enrolled. Out of these 70, 47 (67%) participants completed the enrollment survey and thus provided demographic information. The median age of these participants was 75 years (range: 44-93 years), 24/47 (51%) participants identified as male, 36/47 (76%) identified as White (of European descent), and 45/47 (96%) identified English as their language of preference for health care matters.

The top 3 reasons for nonparticipation included patients declining, patients not meeting clinical eligibility criteria, and inability to provide informed consent (see [Multimedia Appendix 6](#) for a summary of the most common reasons for patients not participating). Of the 121 patients who declined to participate, most did not provide a reason (see [Multimedia Appendix 7](#) for a summary of reasons provided by eligible patients who declined to participate).

Of the 70 participants, 47 completed and returned the enrollment survey, 49 completed and returned the 90-day survey, and 35 completed and returned both the enrollment and 90-day survey. The subsamples providing data for each area of analysis are specified in the following section.

### **HHM Adherence**

Participants were expected to be in the monitoring system for 60 days, submitting data once per day. Actual monitoring adherence (ie, the actual days data were entered) averaged 56 days across our sample, which is a 94% adherence rate based on the 60 days of baseline expectation.

Satisfaction with the monitoring platform as measured by the System Usability Scale [13] resulted in a mean score of 80.0 and a median of 81.4 on a 100-point scale (n=49).

## Patient Participant Experience and Outcomes

### Health Care Utilization

Administrative data were available for 2 of the 3 participating sites that included 36 of the 70 participants (51%). ED visits, rehospitalizations, and length of stay all decreased for these

participants. Furthermore, the overall duration of rehospitalization decreased (see Table 1).

There was a 71% reduction in hospitalization costs ( $P<.001$ ), along with a 58% reduction in ED visit costs, although the latter did not reach statistical significance. PCP and specialist costs were similar in the pre-post analysis.

For the 30 participants (43%) who completed survey items included in the cost analysis, we estimated a 49% reduction in out-of-pocket costs (Table 2).

**Table 1.** Administrative data of change in ED visits, hospital admissions, and length of stay (n=36).

| Data type                             | 90 days pre-TEC4Home <sup>a</sup> | 90 days post-TEC4Home | Pre-post change (%) |
|---------------------------------------|-----------------------------------|-----------------------|---------------------|
| ED <sup>b</sup> visits                | 66                                | 14                    | -79                 |
| Hospital admissions                   | 54                                | 7                     | -87                 |
| Length of stay (days), total (median) | 440 (5.0)                         | 71 (8.0)              | -84 (60)            |

<sup>a</sup>TEC4Home: Telehealth for Emergency-Community Continuity of Care Connectivity via Home Telemonitoring.

<sup>b</sup>ED: emergency department.

**Table 2.** Per-patient aggregate health care utilization cost.

| Cost type  | Mean pre-TEC4home <sup>a</sup> cost (US\$) | Mean post-TEC4home cost (US\$) | Cost reduction (US\$), n (95% CI) | Pre-post change (%) |
|--|--|--------------------------------|-----------------------------------|---------------------|
| ED <sup>b</sup> visits cost <sup>c</sup>                       | 618  | 262                            | -376 (-87 to 799)                 | -58                 |
| PCP <sup>d</sup> visits cost <sup>e</sup>                      | 126  | 129                            | 3 (-52 to 47)                     | 2                   |
| LoS <sup>f</sup> cost (ie, overall hospital cost) <sup>g</sup> | 10,792                                     | 3091                           | -7701 (-3772 to 11,631)           | -71                 |
| Specialist visits <sup>h</sup>                                 | 160  | 132                            | -28 (-72 to 128)                  | -18                 |
| Patient-reported out-of-pocket cost                            | 357  | 185                            | -175 (-49 to -395)                | -49                 |

<sup>a</sup>TEC4Home: Telehealth for Emergency-Community Continuity of Care Connectivity via Home Telemonitoring.

<sup>b</sup>ED: emergency department.

<sup>c</sup>Costs calculated based on standard outpatient cost from the Canadian Institute for Health Information: US \$314.15.

<sup>d</sup>PCP: primary care provider.

<sup>e</sup>Standard PCP visits cost obtained from the Ministry of Health Medical Services Commission payment schedule.

<sup>f</sup>LoS: length of stay.

<sup>g</sup>Per diem ward (1 night in hospital) from the Canadian Institute for Health Information: US \$1520.20.

<sup>h</sup>Special visits cost obtained from the Ministry of Health Medical Services Commission payment schedule.

### Participant Experience and Outcomes

For the 35 participants who reported a complete set of pre- and postoutcomes, disease-specific quality of life demonstrated the

greatest improvement, and mental and physical general quality of life also significantly improved (Table 3). No significant change occurred in HF self-care behavior.

**Table 3.** Patient-reported outcomes pre- and post-TEC4Home.

| Patient-reported outcome   | Pre-TEC4Home <sup>a</sup> (score out of 100) | Post-TEC4Home (score out of 100) | Pre–post change, mean (95% CI) | Pre–post change (%) | P value |
|--|--|----------------------------------|--------------------------------|---------------------|---------|
| Heart failure–specific quality of life (KCCQ-12 <sup>b</sup> )       | 33.4   | 67.1                             | 33.7 (40.05-23.84)             | 100.8               | <.001   |
| Health-related quality of life (VR-12 <sup>c</sup> mental component) | 43.1   | 51.4                             | 8.3(12.48-4.08)                | 19.2                | <.001   |
| Health-related quality of life (VR-12 physical component)            | 26.7   | 31.7                             | 5.0 (0.83-8.12)                | 18.7                | .02     |
| Heart failure self-care behavior (EHFScBs-9 <sup>d</sup> )           | 70.2   | 74.3                             | 4.1 (14.59-3.48)               | 5.84                | .22     |

<sup>a</sup>TEC4Home: Telehealth for Emergency-Community Continuity of Care Connectivity via Home Telemonitoring.

<sup>b</sup>KCCQ-12: Kansas City Cardiomyopathy Scale.

<sup>c</sup>VR-12: Veterans Rand 12-Item Health Survey.

<sup>d</sup>EHFScBs-9: European Heart Failure Self-Care Behaviour Scale 9.

### Participant Experience

Participants who completed the postsurvey were invited to take part in a telephone interview to discuss their experiences further: 11 out of the 49 participants (22%) who completed the postsurvey participated in telephone interviews to further discuss their experiences in the study. The findings are summarized in [Textbox 1](#). Most notably, they described TEC4Home as contributing to a sense of safety and security after the transition from the hospital:

*I wasn't afraid to come home [from the hospital]...it actually brought me a lot of comfort and security once I came home.*

Participants also expressed that they felt more involved in their own care as a result of participating in the home monitoring intervention:

*The TEC4Home program taught me how valuable it is [to monitor my condition]*

**Textbox 1.** Summarized findings from patient interview feedback by themes.

|  |
|--|
| <p><b>Project satisfaction</b></p> <ul style="list-style-type: none"> <li>Overall, all (11/11) participants described being pleased with their participation in the project.</li> </ul> <p><b>Experience</b></p> <ul style="list-style-type: none"> <li>Most (9/11) reported ease of use with the technology and training provided.</li> <li>Most (8/11) expressed they were content with the support and education provided by the monitoring nurse.</li> <li>All (11/11) expressed feeling more involved in their own care.</li> </ul> <p><b>Perceived impact</b></p> <ul style="list-style-type: none"> <li>A few (3/11) participants expressed that they perceived that their primary care provider appreciated the regular patient reports (most participants felt that the program did not impact the relationship, positively or negatively, with their primary care provider in any significant way).</li> </ul> <p><b>Challenges</b></p> <ul style="list-style-type: none"> <li>A few (3/11) participants expressed some technical difficulties with the equipment (eg, blood pressure cuff ripped, blood pressure cuff not fitting properly, oximeter not working, weight scale not accurate).</li> <li>Some (4/11) participants wished the monitoring was a 7-day support service.</li> </ul> |
|--|

### Health Care Provider Experience

Interviews were also conducted with the 2 monitoring nurses and covered satisfaction, patient–care provider interactions, procedures and usability, and perceived impact. Findings are summarized in [Textbox 2](#). Monitoring nurses emphasized that

they perceived positive impacts on participants quality of life and confidence:

*Patients were definitely more engaged with their self-management. They're able to report changes in their symptoms and their weights and things like that.*

PCPs were invited to participate in surveys, but we did not receive any responses from them.

**Textbox 2.** Summarized findings from monitoring nurse feedback by theme. Monitoring nurse feedback (n=2).

#### Satisfaction

- Both (2/2) monitoring nurses expressed satisfaction with the project and their experiences working with patient participants.

#### Patient-care provider interactions

- Monitoring nurses expressed satisfaction with the level of care they were able to provide through the program.
- The nurses described how some primary care providers were more responsive than others but that the overall coordination of care improved because of her communications with nurse practitioners at the HF clinics, home care clinicians, and specialist physicians.

#### Procedures and usability

- The remote patient monitoring clinician station interface could have been more streamlined.
- Graphical visualizations of patients' biometric data were mentioned as an area of improvement.
- Consenting of patients too early led to dropout or ineligibility issues later on.
- For the HF protocol, questions could be modified to understand the patient's condition relative to the previous day (eg, "Is your shortness of breath the same, better or worse today?").

#### Impact

- The clinicians expressed a perceived impact on their patients in quality of life and self-management and confidence.

## Discussion

This TEC4Home feasibility study, a precursor to the full TEC4Home RCT to follow, focused on exploring 3 key issues: (1) Would the study procedures be acceptable to both patients and providers? (2) Would the evaluation framework capture useful metrics for outcome evaluation? (3) Did the results suggest a trend toward HHM improving the care of patients with HF?

### Insights From the Results of the Feasibility Study

The purpose and scope of this feasibility study were not designed to determine the efficacy of HHM. Nevertheless, we observed important trending of the data showing benefits across all 3 domains of the Triple Aim Plus framework. Most importantly, fewer patients had unscheduled ED revisits, fewer were readmitted to hospital, and the overall length of hospitalization decreased. In terms of quality of life, participants reported improved scores for both HF and general questionnaires. Furthermore, in economic terms, a cost consequence analysis showed that in all health care utilization factors measured, TEC4Home participants demonstrated decreased cost to the health system and decreased out-of-pocket costs. Finally, both participants and providers felt an improved experience in managing the patient's HF.

The observation that our participants felt better while being monitored was similar to clinical case series and studies demonstrating high participant satisfaction when patients with HF were monitored at home [16]. Critically, our positive results differ from those of previous studies that suggested no benefit [3,4]. We hypothesize that TEC4Home was designed to support a patient in the postdischarge period for 60 days, which may be a reason for our promising results. Our study also measured participants' quality of life and end-user experience, and both were found to increase. These findings have not been frequently reported in the literature.

### Acceptability of the Conduct of Research

This study, conducted in 3 urban sites in British Columbia, enrolled motivated patients. Of the 219 patients fulfilling eligibility criteria, only 70 patients enrolled, resulting in a recruitment rate of 32.0%. It would, therefore, be important to increase identification, recruitment, and enrollment of eligible patients. One challenge experienced was attempting to recruit patients at the height of their exacerbation in the ED. Indeed, other studies have encountered similar challenges in recruiting from the ED with common difficulties, such as time-consuming health record searches, limited research nurse support, and lack of face-to-face communication between patient and researcher [17]. The results we provide in Table 1 helped us to understand some of the factors that led to eligible patients declining participation, such as not feeling well enough to participate and not feeling comfortable using HHM or having someone to help them use it.

We presented these findings to our research study patient advisory committee and collectively developed the following ways to improve recruitment of eligible patients: increase engagement with the hospital staff members to raise awareness of TEC4Home to improve referral rates of potential patients, and identify optimal times to approach patients during patients' hospital stays (eg, when they begin to feel better) or being careful to avoid recruiting while in the ED, especially when patients are being admitted to hospital.

The feasibility study also helped us to devise the following refinements to recruitment procedures: refining recruiter materials, including brochures, videos on how to use the HHM tool kit, and other materials to demystify study procedures and pique the participants' interest; reviewing and clarifying the eligibility criteria with recruiters so they can conduct the screening and enrolment of patients more effectively; and establishing an ongoing support-and-feedback loop for site recruiters to promote consistent understanding and support for patient engagement.

Although a before–after analysis using administrative data is appropriate for a feasibility study, a more definitive trial design with a true control comparison is required. One site was unable to provide administrative data. Further, the discrepancy in responses and return rates between administrative data and survey data will be addressed in the RCT with an emphasis on provincial databases being the definitive source for our primary outcome.

Our results suggests that participants are generally able to perform self-monitoring routinely over 2 months postdischarge from the hospital. Our participants submitted data on nearly 95% of days, which compares favorably to similar studies. A recent telemonitoring feasibility study with patients with type 2 diabetes mellitus found lower adherence rates compared to our trial [18]. We further found the success rate of presurvey completion to be 67% (47/70), postsurvey completion to be 70% (49/70), and pre- and postsurvey completion by the same participants to be 50% (35/70). We identified ways, such as using scheduled reminders, to increase survey returns in our RCT.

Comments from patients in the survey revealed that those who persisted in using the HHM found the experience very helpful to support their self-management. Technology usability was another area that needed improvement—how to make the equipment more user friendly. Survey comments from monitoring clinicians were also highly useful to improving the types of data we needed to include in the dashboard, the workflow of monitoring nurses when contacting participants and their PCP, and how often the monitoring report summary should be sent to PCPs. We were unable to obtain feedback from participants' PCPs in this feasibility study and needed to understand the reasons for it. We conducted a focus group with the PCPs to explore this issue prior to conducting the full RCT.

## Evaluation Framework

This study allowed us to examine our data collection procedures and scope. Overall, our evaluation framework was able to guide the collection of metrics to assess the outcomes that we would

like to measure: patient outcome, end-user experiences, and health system cost-effectiveness. The data we collected helped us determine the primary outcome differences before and after monitoring, a basis for hospital utilization and cost comparisons, and end-user experiences based on the validated scales that we selected. This study also guided us in improving the scope of data we would be collecting, such as additional provincial databases covering clinical baseline measures to learn more about our participants at enrollment (eg, severity of illness, comorbidities), more health care utilization indicators (eg, specialized medical services), health care system and patient costs (eg, prescription drugs dispensed), and vital statistics that include accurate and more detailed mortality data. Additionally, the lack of data from a control comparison is a true limitation of any feasibility study design and will be addressed in the upcoming RCT. We also lengthened the period of data collection from just 90 days before and after enrollment to include 3 additional 3-month periods, up to 1 year before and after enrollment to provide insight into long-term effects. A shift from the VR-12 to the EuroQol-5D (EQ-5D) quality of life assessment tool will allow for the calculation of quality-adjusted life-year analysis. All of these refinements based on the feasibility results were implemented in the second phase of TEC4Home, a large-scale RCT designed to further examine home health monitoring across 22 British Columbia hospitals from urban, regional, and rural communities.

## Conclusions

This feasibility study better prepared us for a planned multicenter RCT by helping us understand how best to engage patients in eligibility assessment, recruitment, and retention and how to refine our evaluation framework and metrics collection. Furthermore, analysis of the data we collected provided encouragement that HHM can be beneficial for patients with HF post discharge. Findings from this feasibility study provided practical lessons that allowed us to conduct the multicenter RCT as well as identify early positive signals of the benefits of HHM for patients with HF.

## Acknowledgments

Funding was provided by the Canadian Institute for Health Research, eHealth Innovations Partnership Program, the Michael Smith Foundation for Health Research, and the BC Ministry of Health Strategic Initiative Funding in a partnership between the UBC Digital Emergency Medicine Research Unit and the technology partner TELUS Health.

This manuscript is submitted on behalf of the TEC4Home Community, a multidisciplinary community of policy makers, physicians, epidemiologists, statisticians, and researchers from British Columbia.

The publication costs for this article have been covered by Canada Health Infoway Inc., a non-profit corporation funded by the Government of Canada. The funders had no role in study design, data collection, and analysis, or decision to publish the manuscript.

## Conflicts of Interest

KH is a full professor in UBC Faculty of Medicine leading the Digital Emergency Medicine Unit and, as part of his academic salary from UBC, his academic research work is on digital health technologies including the subject matter in this paper. This TEC4Home project is funded by grants from the Canadian Institutes of Health Research, the Michael Smith Foundation for Health Research, the BC Ministry of Health, TELUS Health, and private donations from the VGH & UBC Hospital Foundation. With the exception of the Health Professional Investigator Award from the Michael Smith Foundation for Health Research, from which KH received partial funding support through the UBC Department of Emergency Medicine for his research salary earnings, all



other grants and supports are to fund the implementation and evaluation of this project without benefiting KH directly. TS is an employee of TELUS Health, the technology partner for TEC4Home, which has been compensated for providing the hardware and software for the project as well as for professional services support.

TS is an employee of TELUS Health, the technology partner for TEC4Home, which has been compensated for providing the hardware and software for the project as well as for professional services support.

---

#### Multimedia Appendix 1

Feasibility study patient participant eligibility criteria.

[[DOCX File, 16 KB](#) - [formative\\_v5i6e24509\\_app1.docx](#) ]

---

#### Multimedia Appendix 2

Monitoring nurse interview protocol.

[[DOCX File, 15 KB](#) - [formative\\_v5i6e24509\\_app2.docx](#) ]

---

#### Multimedia Appendix 3

Primary care physician survey protocol.

[[DOCX File, 15 KB](#) - [formative\\_v5i6e24509\\_app3.docx](#) ]

---

#### Multimedia Appendix 4

Patient participant interview analysis code book.

[[DOCX File, 13 KB](#) - [formative\\_v5i6e24509\\_app4.docx](#) ]

---

#### Multimedia Appendix 5

Monitoring nurse interview analysis code book.

[[DOCX File, 13 KB](#) - [formative\\_v5i6e24509\\_app5.docx](#) ]

---

#### Multimedia Appendix 6

Summary of most common reasons (not exhaustive) for patients not participating.

[[DOCX File, 15 KB](#) - [formative\\_v5i6e24509\\_app6.docx](#) ]

---

#### Multimedia Appendix 7

Summary of reasons provided by eligible patients who declined to participate.

[[DOCX File, 12 KB](#) - [formative\\_v5i6e24509\\_app7.docx](#) ]

---

## References

1. Ambrosy AP, Fonarow GC, Butler J, Chioncel O, Greene SJ, Vaduganathan M, et al. The global health and economic burden of hospitalizations for heart failure: lessons learned from hospitalized heart failure registries. *J Am Coll Cardiol* 2014 Apr 1;63(12):1123-1133 [[FREE Full text](#)] [doi: [10.1016/j.jacc.2013.11.053](#)] [Medline: [24491689](#)]
2. Brahmabhatt D, Cowie M. Remote management of heart failure: an overview of telemonitoring technologies. *Cardiac Failure Review* 2019 May 01;86-92 [[FREE Full text](#)] [doi: [10.15420/cfr.2019.5.3](#)] [Medline: [31179018](#)]
3. Chaudhry SI, Mattern JA, Curtis JP, Spertus JA, Herrin J, Lin Z, et al. Telemonitoring in patients with heart failure. *N Engl J Med* 2010 Dec 9;363(24):2301-2309 [[FREE Full text](#)] [doi: [10.1056/NEJMoa1010029](#)] [Medline: [21080835](#)]
4. Koehler F, Koehler K, Prescher S, Kirwan BA, Wegscheider K, Vettorazzi E, et al. Mortality and morbidity 1 year after stopping a remote patient management intervention: extended follow-up results from the telemedical interventional management in patients with heart failure II (TIM-HF2) randomised trial. *Lancet Digit Health* 2020 Jan;2(1):e16-e24 [[FREE Full text](#)] [doi: [10.1016/S2589-7500\(19\)30195-5](#)] [Medline: [33328035](#)]
5. Kitsiou S, Paré G, Jaana M. Effects of home telemonitoring interventions on patients with chronic heart failure: an overview of systematic reviews. *J Med Internet Res* 2015;17(3):e63 [[FREE Full text](#)] [doi: [10.2196/jmir.4174](#)] [Medline: [25768664](#)]
6. TEC4Home Healthcare Innovation Community. Supporting heart failure patient transitions from acute to community care with home telemonitoring technology: a protocol for a provincial randomized controlled trial (TEC4Home). *JMIR Res Protoc* 2016 Dec 18;5(4):e198 [[FREE Full text](#)] [doi: [10.2196/resprot.5856](#)] [Medline: [27977002](#)]
7. Berwick DM, Nolan TW, Whittington J. The triple aim: care, health, and cost. *Health Aff (Millwood)* 2008;27(3):759-769 [[FREE Full text](#)] [doi: [10.1377/hlthaff.27.3.759](#)] [Medline: [18474969](#)]
8. Kazis LE, Selim A, Rogers W, Ren XS, Lee A, Miller DR. Dissemination of methods and results from the veterans health study: final comments and implications for future monitoring strategies within and outside the veterans healthcare system. *J Ambul Care Manage* 2006;29(4):310-319. [doi: [10.1097/00004479-200610000-00007](#)] [Medline: [16985389](#)]

9. Kazis LE, Miller DR, Skinner KM, Lee A, Ren XS, Clark JA, et al. Applications of methodologies of the Veterans Health Study in the VA healthcare system: conclusions and summary. *J Ambul Care Manage* 2006;29(2):182-188. [doi: [10.1097/00004479-200604000-00011](https://doi.org/10.1097/00004479-200604000-00011)] [Medline: [16552327](#)]
10. Spertus JA, Jones PG. Development and validation of a short version of the Kansas City Cardiomyopathy Questionnaire. *Circ Cardiovasc Qual Outcomes* 2015 Sep;8(5):469-476 [FREE Full text] [doi: [10.1161/CIRCOUTCOMES.115.001958](https://doi.org/10.1161/CIRCOUTCOMES.115.001958)] [Medline: [26307129](#)]
11. Jaarsma T, Arestedt KF, Mårtensson J, Dracup K, Strömberg A. The European Heart Failure Self-care Behaviour scale revised into a nine-item scale (EHFScB-9): a reliable and valid international instrument. *Eur J Heart Fail* 2009 Jan;11(1):99-105 [FREE Full text] [doi: [10.1093/eurjhf/hfn007](https://doi.org/10.1093/eurjhf/hfn007)] [Medline: [19147463](#)]
12. Vellone E, Jaarsma T, Strömberg A, Fida R, Årestedt K, Rocco G, et al. The European Heart Failure Self-care Behaviour Scale: new insights into factorial structure, reliability, precision and scoring procedure. *Patient Educ Couns* 2014 Jan;94(1):97-102. [doi: [10.1016/j.pec.2013.09.014](https://doi.org/10.1016/j.pec.2013.09.014)] [Medline: [24148605](#)]
13. Brooke J. SUS - A quick and dirty usability scale. In: Jordan PW, Thomas B, McClelland IL, Weerdmeester B, editors. *Usability evaluation in industry*. London, United Kingdom: Taylor & Francis Ltd; Jul 01, 1996:189-194.
14. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform* 2009 Apr;42(2):377-381 [FREE Full text] [doi: [10.1016/j.jbi.2008.08.010](https://doi.org/10.1016/j.jbi.2008.08.010)] [Medline: [18929686](#)]
15. Harris PA, Taylor R, Minor BL, Elliott V, Fernandez M, O'Neal L, REDCap Consortium. The REDCap consortium: Building an international community of software platform partners. *J Biomed Inform* 2019 Jul;95:103208 [FREE Full text] [doi: [10.1016/j.jbi.2019.103208](https://doi.org/10.1016/j.jbi.2019.103208)] [Medline: [31078660](#)]
16. Ware P, Ross HJ, Cafazzo JA, Boodoo C, Munnery M, Seto E. Outcomes of a heart failure telemonitoring program implemented as the standard of care in an outpatient heart function clinic: pretest-posttest pragmatic study. *J Med Internet Res* 2020 Feb 08;22(2):e16538 [FREE Full text] [doi: [10.2196/16538](https://doi.org/10.2196/16538)] [Medline: [32027309](#)]
17. Price D, Edwards M, Carson-Stevens A, Cooper A, Davies F, Evans B, et al. Challenges of recruiting emergency department patients to a qualitative study: a thematic analysis of researchers' experiences. *BMC Medical Research Methodology* 2020 Jun 01:151 [FREE Full text] [doi: [10.1186/s12874-020-01039-2](https://doi.org/10.1186/s12874-020-01039-2)] [Medline: [32522265](#)]
18. Shaw RJ, Yang Q, Barnes A, Hatch D, Crowley MJ, Vorderstrasse A, et al. Self-monitoring diabetes with multiple mobile health devices. *J Am Med Inform Assoc* 2020 May 01;27(5):667-676 [FREE Full text] [doi: [10.1093/jamia/ocaa007](https://doi.org/10.1093/jamia/ocaa007)] [Medline: [32134447](#)]

## Abbreviations

**CHEOS:** Centre for Health Evaluation & Outcome Sciences

**ED:** emergency department

**EHFScBs-9:** European Heart Failure Self-Care Behaviour Scale 9

**EQ-5D:** EuroQol-5D

**KCCQ-12:** Kansas City Cardiomyopathy Scale

**HF:** heart failure

**HHM:** home health monitoring

**PCP:** primary healthcare provider

**RCT:** randomized controlled trial

**REDCap:** Research Electronic Data Capture

**Tec4Home:** Telehealth for Emergency-Community Continuity of Care Connectivity via Home Telemonitoring

**TIM-HF2:** Telemedical Interventional Management in Heart Failure II

**UBC:** University of British Columbia

**VR-12:** Veterans Rand 12-Item Health Survey

*Edited by G Eysenbach; submitted 22.09.20; peer-reviewed by Y Shahar, P Ware, CY Yeh; comments to author 02.11.20; revised version received 18.12.20; accepted 16.03.21; published 03.06.21.*

*Please cite as:*

Ho K, Novak Lauscher H, Cordeiro J, Hawkins N, Scheuermeyer F, Mitton C, Wong H, McGavin C, Ross D, Apantaku G, Karim ME, Bhullar A, Abu-Laban R, Nixon S, Smith T

Testing the Feasibility of Sensor-Based Home Health Monitoring (TEC4Home) to Support the Convalescence of Patients With Heart Failure: Pre-Post Study

*JMIR Form Res* 2021;5(6):e24509

URL: <https://formative.jmir.org/2021/6/e24509>

doi: [10.2196/24509](https://doi.org/10.2196/24509)

PMID: [34081015](https://pubmed.ncbi.nlm.nih.gov/34081015/)

©Kendall Ho, Helen Novak Lauscher, Jennifer Cordeiro, Nathaniel Hawkins, Frank Scheuermeyer, Craig Mitton, Hubert Wong, Colleen McGavin, Dianne Ross, Glory Apantaku, Mohammad Ehsan Karim, Amrit Bhullar, Riyadh Abu-Laban, Suzanne Nixon, Tyler Smith. Originally published in JMIR Formative Research (<https://formative.jmir.org>), 03.06.2021. This is an open-access article distributed under the terms of the Creative Commons Attribution License (<https://creativecommons.org/licenses/by/4.0/>), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Formative Research, is properly cited. The complete bibliographic information, a link to the original publication on <https://formative.jmir.org>, as well as this copyright and license information must be included.

Original Paper

# Expanding the Reach of Research: Quantitative Evaluation of a Web-Based Approach for Remote Recruitment of People Who Hear Voices

Benjamin Buck<sup>1</sup>, PhD; Ayesha Chander<sup>1</sup>, MRes; Rachel M Brian<sup>1</sup>, MPH; Weichen Wang<sup>2</sup>, ME; Andrew T Campbell<sup>2</sup>, PhD; Dror Ben-Zeev<sup>1</sup>, PhD

<sup>1</sup>Behavioral Research in Technology and Engineering (BRiTE) Center, Department of Psychiatry and Behavioral Sciences, University of Washington, Seattle, WA, United States

<sup>2</sup>Department of Computer Science, Dartmouth College, Hanover, NH, United States

**Corresponding Author:**

Benjamin Buck, PhD

Behavioral Research in Technology and Engineering (BRiTE) Center

Department of Psychiatry and Behavioral Sciences

University of Washington

1959 NE Pacific Street

Seattle, WA, 98195

United States

Phone: 1 206 221 8518

Email: [buckbe@uw.edu](mailto:buckbe@uw.edu)

## Abstract

**Background:** Similar to other populations with highly stigmatized medical or psychiatric conditions, people who hear voices (ie, experience auditory verbal hallucinations [AVH]) are often difficult to identify and reach for research. Technology-assisted remote research strategies reduce barriers to research recruitment; however, few studies have reported on the efficiency and effectiveness of these approaches.

**Objective:** This study introduces and evaluates the efficacy of technology-assisted remote research designed for people who experience AVH.

**Methods:** Our group developed an integrated, automated and human complementary web-based recruitment and enrollment apparatus that incorporated Google Ads, web-based screening, identification verification, hybrid automation, and interaction with live staff. We examined the efficacy of that apparatus by examining the number of web-based advertisement impressions (ie, number of times the web-based advertisement was viewed); clicks on that advertisement; engagement with web-based research materials; and the extent to which it succeeded in representing a broad sample of individuals with AVH, assessed through the self-reported AVH symptom severity and demographic representativeness (relative to the US population) of the sample recruited.

**Results:** Over an 18-month period, our Google Ads advertisement was viewed 872,496 times and clicked on 11,183 times. A total amount of US \$4429.25 was spent on Google Ads, resulting in 772 individuals who experience AVH providing consent to participate in an entirely remote research study (US \$0.40 per click on the advertisement and US \$5.73 per consented participant) after verifying their phone number, passing a competency screening questionnaire, and providing consent. These participants reported high levels of AVH frequency (666/756, 88.1% daily or more), distress (689/755, 91.3%), and functional interference (697/755, 92.4%). They also represented a broad sample of diversity that mirrored the US population demographics. Approximately one-third (264/756, 34.9%) of the participants had never received treatment for their AVH and, therefore, were unlikely to be identified via traditional clinic-based research recruitment strategies.

**Conclusions:** Web-based procedures allow for time saving, cost-efficient, and representative recruitment of individuals with AVH and can serve as a model for future studies focusing on hard-to-reach populations.

(*JMIR Form Res* 2021;5(6):e23118) doi:[10.2196/23118](https://doi.org/10.2196/23118)

**KEYWORDS**

digital health; research procedures; recruitment; mobile phone

## Introduction

### Background

Auditory verbal hallucinations (AVH; or *voices*), or erroneous perceptions of speech, are a hallmark symptom of schizophrenia spectrum disorders (SSDs). They are experienced by 5% to 28% of the general population [1-4], including many people with a range of psychiatric diagnoses as well as many people who are otherwise considered healthy. In their most severe form, AVH are linked to anxiety, depression, and functional impairment [5,6]. AVH present unique challenges for research. First, individuals with SSDs who hear voices are considered a hard-to-reach population or a group that faces geographical, social, or economic barriers to participation [7,8]. SSDs are overrepresented in economically deprived and socially isolated groups [9,10], and treatment resources for them are scarce [11]. Many have no contact with mental health providers [12-14]. Others are reluctant to engage with the mental health system because of concerns about stigma [15], disagreement with diagnosis [16,17], or negative attitudes toward services [18]. Second, common clinical research practices often fail to access individuals with less severe or non-clinical AVH. Most individuals with AVH do not meet the criteria for an SSD; they often present with a range of diagnoses, including major depressive disorder, bipolar disorder, or may have never received a diagnosis at all [19,20]. Due to their reduced impact and increased independent coping skills, individuals with nonclinical AVH may be less likely to engage in research through traditional clinical settings. They may also opt against self-identifying because of concerns about stigma [21].

Digital technologies may help address these barriers. The average American adult is estimated to spend 3 hours and 48 minutes per day on a smartphone, tablet, or computer, with the majority of that time (62%) spent on the internet and using an app on a smartphone [22]. More than 1 in 3 adults report that they have gone on the internet to better understand a health condition [23]. Although smartphone ownership tends to lag behind the general population, many individuals with serious mental illnesses report owning a smartphone [24], and this number has rapidly increased over the past two decades [25]. Individuals with SSDs report similar levels of health-related internet and web-based engagement [26] and are willing to engage in a variety of research or clinical activities on the web, including assessments [27,28], interventions [29-31], and peer communication [32,33]. Web-based approaches allow participants to covertly self-identify and thus could reduce the impact of stigma on research participation [34]. Furthermore, the COVID-19 pandemic has revealed additional vulnerabilities in in-person research recruitment procedures. During the pandemic, many of these activities have halted; however, research engagement through digital technology can continue while remaining adherent to physical distancing guidelines.

One particularly promising approach to address these issues is the use of technology-assisted remote research. This term describes a constellation of web-based tools (eg, advertisements posted in search engine results and email listservs) that require no face-to-face interactions with prospective participants and

thus obviate many of the barriers common in traditional research. These differ from traditional recruitment methodologies that require partnerships with partner organizations with brick-and-mortar locations or other recruitment tools such as flyers. These efficient and cost-effective [35,36] tools have been used to recruit research participants from several psychiatric populations, including people with depression [35], bipolar disorder [36], and suicidality [37]. These tools may be specifically well suited to address the extant challenges in recruiting and engaging individuals who experience AVH. As it is not situated within a health care system, technology-assisted remote research may be less susceptible to overrepresenting individuals engaged in treatment. It also potentially removes economic and social barriers faced by hard-to-reach populations (eg, time constraints and travel time) and allows for anonymous participation, thus reducing the impact of stigma.

Web-based methodologies are not without challenges. Research has examined the extent to which web-based research participants (eg, users of web-based platforms such as Amazon Mechanical Turk) are representative of the general population [38-40]. Others have raised concerns about participants' *gaming* or earning payments without honest and effortful participation [41]. For example, participants may attempt to complete web-based studies multiple times by masking their identifiers (eg, name and email address). Few studies have presented methods and models to engage difficult-to-reach populations while preserving the security, privacy, and validity of research data.

### Objectives

In this paper, we report on the use of a technology-assisted remote research approach designed to recruit people who experience AVH. These procedures combine public-facing technologies (eg, Google Ads) with automated digital tools (eg, coding scripts to filter prospective participants) and available remote human support to efficiently recruit a difficult-to-reach population while preserving data security and quality. We describe the structure of that system and report several metrics assessing its performance, including (1) the number of web-based advertisement impressions (ie, number of times the web-based advertisement was viewed); (2) clicks on that advertisement; (3) engagement with web-based research materials; and (4) the extent to which it succeeded at representing a broad sample of individuals with AVH, assessed through self-reported AVH symptom severity and demographic representativeness (relative to the US population) of the sample recruited.

## Methods

### Overview

These digital tools were built for a primary study described elsewhere examining the real-time, real-place phenomenology of AVH [42]. This involved downloading and carrying a smartphone app for a 30-day study period that deployed brief ecological momentary assessment questionnaires and captured data through smartphone sensors. Study inclusion criteria included speaking English, being 18 years or older, living in



the United States, experiencing AVH at least once per week, and ownership of an Android smartphone. Exclusion criteria included previous participation in the study and being unavailable for 30 days of consecutive data collection. The internal review boards at the University of Washington and Dartmouth College approved all the study procedures.

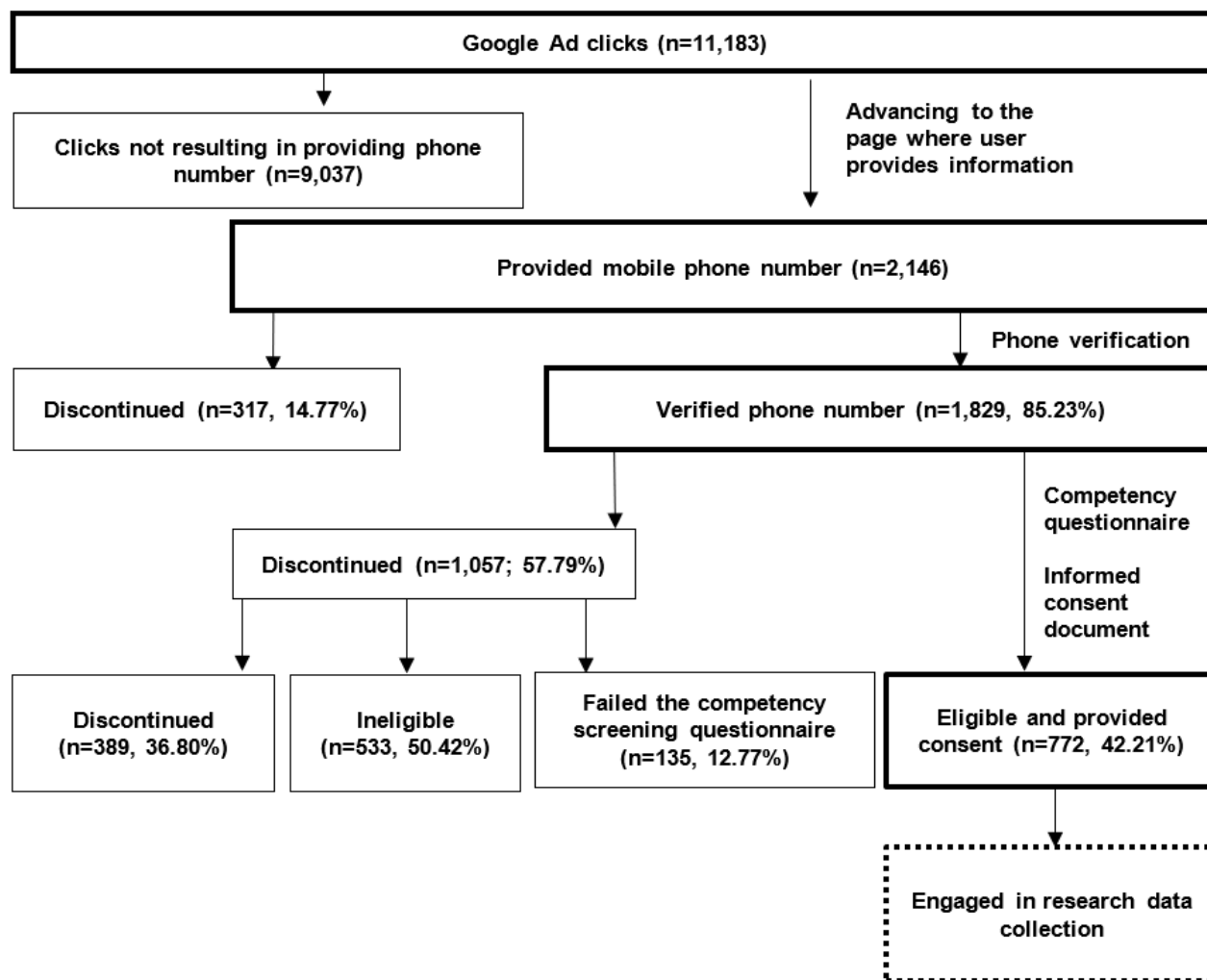
### Google Ads and Keywords

To recruit individuals reporting AVH, we used Google Ads, a system of web-based advertisements wherein advertisements are viewable by individuals who use terms that match preselected keywords provided by the advertiser. Advertisements are designed to resemble a typical Google search result and thus comprise a title, URL, and brief description. In addition to keywords, the system allows for the entry of *negative keywords*, which function in the opposite way, ensuring that the advertisements are not viewable by individuals who search one of the negative keywords. Google Ads records the number of impressions, keywords used, number of clicks linked to the landing page and cost per click, and basic demographics of those who clicked on the advertisement (eg, age, gender, and household income, if reported to Google by the user). For this study, we selected keywords based on several sources: qualitative responses during our early work [43] as well as a rapid review of the academic literature, consultation with researchers focused on serious mental illness, and a review of blogs of people with lived experience. These keywords included descriptors that involved both clinical language (eg, *schizophrenia* and *bipolar disorder*) and nontraditional appraisals of AVH or related terms (eg, *talking to ghosts* and *going crazy*). Positive keywords were allowed to have a *broad match* with search terms, according to which search terms could be reordered or accompanied with other terms. Negative keywords were entered with a *phrase match* setting, according to which the exact phrase must be included in the search for the user to be blocked. Negative keywords were selected to prevent

individuals from attempting to complete the study a second time (eg, *hearing voice research* and *bipolar studies that pay*).

### Web-Based Recruitment Materials

Once users clicked on the advertisement, they were taken to the study landing page that provided written and video descriptions of the study. The consent form was available for download on this page. Participants were instructed to click on a “see if I am eligible” button if they were interested; this button then triggered a pop-up message requesting their email and a valid mobile phone number. This number received a text message with a code that prospective participants had to enter on the study website to gain access to the eligibility questionnaire. Once found eligible, participants were again given access to the consent form to download and review and asked to answer all competency questions correctly within 3 attempts. Participants were excluded if they were unable to complete this step successfully, as they were deemed unable to provide informed consent. Participants were also excluded if they had previously participated in the study. Therefore, the server ran the email and phone numbers provided through the participant database and automatically blocked people with repeat phone numbers from continuing the enrollment process. If participants met eligibility criteria via the screening questions and provided informed consent, their participation in the study officially began (ie, access to baseline assessments and the study app was provided). If at any point their responses indicated that they were ineligible (eg, 3 failed attempts to answer competency questions or previous participation), they were taken to a page where they were thanked for their interest but informed that they were ineligible to participate. Throughout this process, a staff member was available by phone and email for participants to call if the prospective participant faced barriers or had questions. Figure 1 provides an overview of the flow of interested individuals from the landing page to the consent and initiation of the study.

**Figure 1.** Participant flow and attrition at each stage of the web-based engagement procedure.

### Data Security and Validity Procedures

In addition to the phone verification process, other procedures were also used to deter *gamers* or participants aiming to earn payments through duplicate or otherwise dishonest participation. These involved identifying prospective participants based on suspicious digital activity; when such users were identified, a research coordinator contacted them to conduct additional live screening by telephone. We identified this suspicious activity by (1) reviewing their means of access to the study landing page and (2) assessing duplicate emails, phone numbers, and email addresses. First, as a user cannot ensure that a Google Ad will appear in their search terms, it was expected that gamers would attempt to access the study landing page by entering the study URL directly, as opposed to honest participants who would only respond to the link listed in Google Ads. Thus, different links distinguished those who accessed the page via Google Ads versus those who accessed it directly. When a direct arrival initiated the screening process, a research coordinator would receive a notification and conduct additional screening of the prospective participant by phone; they were only allowed to proceed if cleared by the research coordinator. Second, the research coordinator would also receive an automated email if a participant attempted to enter the study with (1) an identical IP (internet protocol) address to a previous participant or (2) an

email address for which characters matched the email of a previously enrolled participant by >90%. The study responses of these suspicious participants were reviewed on an ongoing basis (ie, identifiers and patterns in survey responses) and discussed at subsequent team meetings to determine whether additional screening was warranted by these patterns of responses. Participants were discontinued from the study if it was determined after additional screening that they were attempting to participate in the study for a second time (n=44) or were otherwise dishonest about their eligibility (n=2). No adverse events occurred throughout the course of the study.

## Results

### Overview

The aim of this study is to examine the efficiency and effectiveness of web-based recruitment of individuals who experience AVH, according to a number of metrics, including (1) the number of web-based advertisement impressions (ie, number of times it was viewed) and clicks; (2) engagement with web-based research materials (ie, whether and how participants enrolled); and (3) the extent to which it succeeded in representing a broad sample of individuals with AVH, assessed through self-reported AVH symptom severity and demographic representativeness (relative to the US population).

## Advertisement Impressions and Clicks

Advertisements were posted from February 2018 to September 2019, with a total budget of US \$4429.25. The advertisement was viewed 872,496 times and was clicked on 11,183 times, reaching a click-through rate (clicks per impression) of 1.28% at an average cost of US \$0.40 per click. The cost of a successfully recruited participant, that is, one who completed the screening processes and informed consent portions

completely, was US \$5.74 per person. The top 5 advertisement keywords were *mental illness*, *schizophrenia*, *mental health*, *bipolar*, and *hear voices*. Table 1 presents the number of impressions, clicks, click-through rate, and cost per click by advertisement keyword. Of the individuals who clicked on the advertisement and had available demographic information, most (9896/11,223, 88.18%) clicked on the advertisement through mobile phones, whereas few used desktop computers (700/11,223, 6.24%) or tablets (627/11,223, 5.59%).

**Table 1.** Measures of advertisement engagement for all keywords included to reach people who hear voices<sup>a</sup>.

| Keywords                      | Impressions <sup>b</sup> , n | Clicks, n | Click-through rate (%) | Average cost per click (US \$) | Total cost (US \$) |
|-------------------------------|------------------------------|-----------|------------------------|--------------------------------|--------------------|
| Mental illness                | 188,766                      | 2263      | 1.20                   | 0.42                           | 951.33             |
| Schizophrenia                 | 97,872                       | 1945      | 1.99                   | 0.41                           | 794.19             |
| Mental health                 | 146,438                      | 1753      | 1.20                   | 0.43                           | 757.05             |
| Bipolar                       | 82,815                       | 931       | 1.12                   | 0.44                           | 410.64             |
| Hear voices                   | 59,321                       | 881       | 1.49                   | 0.33                           | 294.16             |
| I hear voices                 | 55,629                       | 815       | 1.47                   | 0.35                           | 286.64             |
| Hearing sounds                | 47,702                       | 610       | 1.28                   | 0.37                           | 226.86             |
| Hearing voices in head        | 22,234                       | 445       | 2.00                   | 0.34                           | 151.06             |
| Mental illness hearing voices | 19,685                       | 422       | 2.14                   | 0.35                           | 148.30             |
| Schizoaffective               | 8787                         | 181       | 2.06                   | 0.39                           | 70.28              |
| Hearing voices disorder       | 9972                         | 175       | 1.75                   | 0.39                           | 67.77              |
| Auditory hallucinations       | 6479                         | 158       | 2.44                   | 0.33                           | 51.59              |
| Hearing things                | 39,836                       | 148       | 0.37                   | 0.33                           | 48.90              |
| Delusional                    | 22,321                       | 130       | 0.58                   | 0.33                           | 42.88              |
| Going crazy                   | 11,880                       | 78        | 0.66                   | 0.33                           | 25.49              |
| Talking to ghosts             | 9904                         | 67        | 0.68                   | 0.37                           | 24.96              |
| Stress relief                 | 21,329                       | 64        | 0.30                   | 0.46                           | 29.12              |
| Spirits talking               | 13,142                       | 58        | 0.44                   | 0.42                           | 24.09              |
| Musical ear syndrome          | 3767                         | 19        | 0.50                   | 0.44                           | 8.39               |
| Am I crazy                    | 1644                         | 19        | 1.16                   | 0.31                           | 5.95               |
| Am I insane                   | 942                          | 12        | 1.27                   | 0.45                           | 5.43               |
| Disembodied voices            | 227                          | 3         | 1.32                   | 0.28                           | 0.84               |
| I'm not crazy                 | 1591                         | 3         | 0.19                   | 0.39                           | 1.18               |
| Hearing voices <sup>c</sup>   | 122                          | 3         | 2.46                   | 0.71                           | 2.15               |
| Voice hearing <sup>c</sup>    | 91                           | 0         | 0                      | 0                              | 0                  |

<sup>a</sup>The total number of impressions was 872,496; the total number of clicks was 11,183; average click-through rate was 1.28%; average cost per click was US \$0.40; and the total cost was US \$4429.25.

<sup>b</sup>An impression is counted each time the advertisement is shown on a search result page.

<sup>c</sup>These keywords were included for only a portion of the study period because of concerns related to repeat study participants searching for and finding the study advertisement.

## Study Enrollment

The flow of interested users from Google Ads through informed consent is shown in Figure 1. Of the 11,183 clicks on the study Google Ad, a total of 2146 individuals provided their mobile phone number to be verified for participation in the study. Of the 2146 participants who provided a phone number, 1829

(85.23%) verified this phone number with a code. Of the 1829 individuals with a verified phone number, 772 (42.21%) provided consent to participate in the study. Most individuals who verified their phone number but did not provide informed consent, did not meet the eligibility criteria (533/1057, 50.43%), whereas the remainder either failed a competency screening

questionnaire (135/1057, 12.77%) or chose not to participate (389/1057, 36.8%).

### Participant AVH Frequency and Severity

Results related to participants' AVH frequency and severity are presented in Table 2. Most individuals who provided consent to participate reported that they had sought treatment for their AVH at some point in their lifetime (492/756, 65.1%) but over one-third had not (264/756, 34.9%). The most common self-reported diagnoses were depression (488/749, 65.2%), bipolar disorder (352/749, 47%), and posttraumatic stress disorder (328/749, 43.8%). Most participants reported hearing voices at least once a day (666/756, 88.1%) and that the voices interfered with their daily activities in some way (697/755, 92.4%), with almost half of the participants reporting "quite a

bit" or "extreme" interference (346/755, 45.9%). Most reported that the voices they hear are distressing (689/755, 91.3%) and more than half reported "quite a bit" or "extreme" distress (416/755, 55.1%). Participants varied in terms of how open they were about these voices with others. Most participants (443/756, 58.6%) had shared their experience of voices with a medical professional. Approximately half of the participants had immediate family members (376/755, 49.8%) or a significant other (350/754, 46.4%) who knew about their experience of voices. One-tenth (75/753, 10%) of the sample reported that no one else knew about their experience of voices. These figures suggest that this remote recruitment strategy successfully engaged a broad continuum of people with AVH experiences, including individuals with significant and severe AVH as well as those who had never engaged in treatment for them.

**Table 2.** Participants' diagnoses, experience, frequency, severity, and behavioral interference of auditory verbal hallucinations.

| Clinical characteristics  | Participants, n (%) |
|---|---------------------|
| <b>Lifetime treatment seeking (n=756)</b>                                   |                     |
| Yes   | 492 (65.1)          |
| No  | 264 (34.9)          |
| <b>Self-reported diagnosis<sup>a</sup></b>                                  |                     |
| Alzheimer or Parkinson disease (n=747)                                      | 4 (0.5)             |
| Bipolar disorder (n=749)  | 352 (47.0)          |
| Depression (n=749)  | 488 (65.2)          |
| Traumatic brain injury (n=746)  | 50 (6.7)            |
| Migraines (n=747)   | 141 (18.9)          |
| Schizoaffective disorder (n=748)  | 210 (28.1)          |
| Schizophrenia (n=749)   | 208 (27.8)          |
| Posttraumatic stress disorder (n=749)                                       | 328 (43.8)          |
| Substance use (n=747)   | 228 (30.5)          |
| Seizures (n=748)  | 54 (7.2)            |
| None of the above (n=749)   | 61 (8.1)            |
| Other (n=772)   | 87 (11.3)           |
| <b>Who knows about your voices?<sup>a</sup></b>                             |                     |
| No one knows (n=753)  | 75 (10.0)           |
| People you know online but not in person (n=756)                            | 63 (8.3)            |
| Medical professionals/primary doctor/therapist (n=756)                      | 443 (58.6)          |
| Significant other (ie, boyfriend, girlfriend, or spouse) (n=754)            | 350 (46.4)          |
| Some of my friends (n=756)  | 333 (44.0)          |
| All my friends (n=755)  | 83 (11.0)           |
| Extended family (n=756)   | 105 (13.9)          |
| Immediate family (n=755)  | 376 (49.8)          |
| <b>How frequently do you hear a voice or voices? (n=756)</b>                |                     |
| No voices   | 2 (0.3)             |
| Less than once day  | 88 (11.6)           |
| Once or twice a day   | 199 (26.3)          |
| Several times a day   | 242 (32.0)          |
| All the time/constantly   | 225 (29.8)          |
| <b>How much do the voices interfere with your daily activities? (n=755)</b> |                     |
| No interference   | 58 (7.7)            |
| A little bit  | 162 (21.5)          |
| Moderately  | 189 (25.0)          |
| Quite a bit   | 187 (24.8)          |
| Extremely interfering   | 159 (21.1)          |
| <b>How distressing are the voices that you hear? (n=755)</b>                |                     |
| No voices are distressing me  | 66 (8.7)            |
| A little bit  | 116 (15.4)          |
| Moderately  | 157 (20.8)          |



| Clinical characteristics | Participants, n (%) |
|--------------------------|---------------------|
| Quite a bit              | 205 (27.2)          |
| Extremely distressing    | 211 (27.9)          |

<sup>a</sup>Participants could select multiple options.

### Participant Demographics and Representativeness

The demographics of the study sample (Table 3) broadly reflect a number of US population trends. The average age of consented participants was 38.14 years (SD 9.86), which closely mirrored the median US age of 38.2 years [44]. In comparison with population estimates, the sample of individuals providing consent included larger percentages of multiple populations that are traditionally underrepresented in research, including Black or African American participants (108/760, 14.2% in our study,

estimated at 12.7% of the US population [45]), multiracial participants (90/760, 11.8% vs 3.4% of the US population [45]), sexual minorities (156/766, 20.3% gay, lesbian, or bisexual vs 5% [46]; 12/771, 1.6% transgender vs 0.6% [47]), and the homeless (69/767, 9.0% vs 0.2% [48]). Other groups appeared underrepresented relative to the general population, including individuals who identified as Asian (9/760, 1.2% vs 5.6% [45]), Hispanic or Latino (101/765, 13.2% vs 18.3% [45]), and male (292/771, 37.9% vs 49.2% [45]).

**Table 3.** Demographics of participants who provided consent to participate.

| Demographic characteristic               | Values       |
|--|--------------|
| Age (years; n=768), mean (SD)            | 38.14 (9.86) |
| <b>Sex or gender (n=771), n (%)</b>      |              |
| Female                                   | 470 (61.0)   |
| Male                                     | 286 (37.1)   |
| <b>Transgender</b>                       | 12 (1.6)     |
| Transgender woman                        | 6 (0.8)      |
| Transgender man                          | 6 (0.8)      |
| Other                                    | 3 (0.4)      |
| <b>Race (n=760), n (%)</b>               |              |
| White                                    | 537 (70.7)   |
| Black or African American                | 108 (14.2)   |
| Pacific Islander                         | 2 (0.3)      |
| American Indian or Alaskan Native        | 14 (1.8)     |
| Asian                                    | 9 (1.2)      |
| More than one race                       | 90 (11.8)    |
| <b>Hispanic (n=765), n (%)</b>           |              |
| Yes                                      | 101 (13.2)   |
| No                                       | 664 (86.8)   |
| <b>Sexual orientation (n=766), n (%)</b> |              |
| Heterosexual or straight                 | 591 (77.2)   |
| Gay or lesbian                           | 50 (6.5)     |
| Bisexual                                 | 106 (13.8)   |
| Other                                    | 19 (2.5)     |
| <b>Housing status (n=767), n (%)</b>     |              |
| Independent or living on my own          | 348 (45.4)   |
| Living with family                       | 313 (40.8)   |
| Assisted or supported living             | 33 (4.3)     |
| Substance treatment institution          | 4 (0.5)      |
| Homeless                                 | 69 (9.0)     |

## Discussion

### Principal Findings

Digital technologies are rapidly reshaping mental health research and services. One particular benefit of these approaches is their capacity to increase the reach of research to underserved populations. Previous work has demonstrated the potential of web-based engagement to facilitate help seeking among individuals at risk for psychosis by linking them to web-based resources about symptoms and treatments (eg, the *Strong365* campaign [49]). This study builds on this earlier work by demonstrating that web-based tools can remotely facilitate research participation of individuals with psychotic symptoms at both clinical and nonclinical levels. The recruited sample reported clinically significant experiences with voices that were frequent, distressing, and functionally interfering, and over one-third had never received treatment for them. Overall, the results suggest that these web-based procedures allow for the efficient, affordable, and representative recruitment of research participants without reliance on a clinical setting.

Web-based digital recruitment methods compare favorably with extant approaches for engaging hard-to-reach populations in several ways. First, such methods appear to reduce costs. Traditional recruitment methods incur several costs in the process of raising interest and awareness of a study, such as increased staff time, flyers, mailings, and presentations to clinical or educational facilities [50]. These needs are obviated through remote recruitment. Our web-based advertisements were viewed by over 870,000 individuals for 18 months for less than US \$4500, a fraction of the cost that such exposure would necessitate using offline approaches. The approach of this study appeared to reduce costs relative to previous work using social media to recruit individuals with psychotic experiences [43]. Second, beyond increasing efficiency, these methods may improve representative sampling when the members of a group face barriers to participation. Research in other health-related populations has demonstrated that digital technologies may address these barriers [7,8,51], in particular, accessing broader geographic regions [52,53] and more diverse respondents [35,54]. This study provides support for these benefits and suggests that they may also reduce barriers specific to individuals on either end of the continuum of AVH severity. Individuals with psychosis are difficult to engage in clinical research, given social isolation and economic hardship [10,12,13]. Those with undiagnosed and untreated AVH may be even more difficult to engage, given a lack of contact with typical clinical research settings as well as potential concerns about self-identifying with stigmatized experiences. This approach appeared to engage participants from both ends of this continuum; one-third of the participants reported never seeking treatment for their voices, a similar proportion reported that they experienced highly distressing voices daily. This finding also provides additional support for the utility of these approaches to engage individuals at risk either in programs that

encourage help seeking [49,55] or in remotely delivered interventions [33]. Although a few examples provide support for the feasibility of these initiatives, future work should examine remote treatment-seeking support and intervention for the psychosis continuum at a population level. Furthermore, notable in these data were the number of participants who were also members of other underrepresented populations, including racial minorities, sexual minorities, and the homeless. Although it remains an open question why these groups are better represented using these methods, it is possible that web-based engagement reduces barriers for underrepresented groups that may face additional intersectional experiences of stigma on top of those related to their mental health concerns alone.

### Limitations

This study had some limitations. Although web-based methods may ameliorate some recruitment biases, they may worsen others. Web-based recruitment strategies rely on participants' ownership and adeptness to use technology to engage. Individuals who lack either may struggle to engage in these new avenues. This may be particularly pronounced among individuals who face economic barriers to several needed services. Most visitors to the research study landing page did not provide informed consent to participate. Specific factors may predict a lack of willingness to persist through automated screening steps (eg, persecutory ideation and cognitive functioning). If this is the case, this could limit the representativeness of the sample. Although our approach successfully engaged members of several typically underrepresented groups, others accounted for smaller proportions than their proportion of the US population, including Hispanic and Asian individuals. The prevalence of AVH in specific racial or ethnic groups is not clear in the academic literature at present; thus, it is not clear from these data whether overrepresentation of these groups relative to population demographic estimates is the result of a greater prevalence of AVH in specific groups, characteristics of our recruitment strategies, or other causes. Overall, however, our results suggest that web-based recruitment methods engage a diverse sample of individuals with AVH experiences.

### Conclusions

Technology-assisted remote research procedures address several barriers that are common in traditional research. Engaging prospective participants outside of typical clinical settings removes existing sampling biases, allowing for greater representation of psychiatric populations. These procedures have also been able to continue despite the halted in-person research activities in light of social distancing measures imposed by the COVID-19 pandemic. This expansion of access and reach has been a principal contribution of digital health technologies, and health care institutions have only just begun to witness their potential impact [56]. Just as digital technologies create considerable opportunities for treatment engagement, such tools can also enhance clinical research.

## Acknowledgments

This study was supported by a grant from the National Institute of Mental Health (R01MH112641). BB is supported by a Mentored Patient-Oriented Research Career Development Award from the National Institute of Mental Health (K23MH122504).

## Conflicts of Interest

DBZ has an intervention content licensing agreement with Pear Therapeutics and has financial interest in FOCUS technology. He has consulted for Trusst Health Inc, eQuility, and Otsuka Pharmaceuticals Ltd. The other authors have no conflicts of interest to disclose.

## References

1. Tien AY. Distribution of hallucinations in the population. *Soc Psychiatry Psychiatr Epidemiol* 1991;26(6):287-292. [doi: [10.1007/bf00789221](https://doi.org/10.1007/bf00789221)]
2. Scott J, Chant D, Andrews G, McGrath J. Psychotic-like experiences in the general community: the correlates of CIDI psychosis screen items in an Australian sample. *Psychol Med* 2005 Nov 23;36(2):231-238. [doi: [10.1017/s0033291705006392](https://doi.org/10.1017/s0033291705006392)]
3. Johns LC, Cannon M, Singleton N, Murray RM, Farrell M, Brugha T, et al. Prevalence and correlates of self-reported psychotic symptoms in the British population. *Br J Psychiatry* 2004 Oct 02;185(4):298-305. [doi: [10.1192/bjp.185.4.298](https://doi.org/10.1192/bjp.185.4.298)] [Medline: [15458989](https://pubmed.ncbi.nlm.nih.gov/15458989/)]
4. Johns LC, Nazroo JY, Bebbington P, Kuipers E. Occurrence of hallucinatory experiences in a community sample and ethnic variations. *Br J Psychiatry* 2002 Feb 02;180(2):174-178. [doi: [10.1192/bjp.180.2.174](https://doi.org/10.1192/bjp.180.2.174)] [Medline: [11823331](https://pubmed.ncbi.nlm.nih.gov/11823331/)]
5. Hoffman R, Varanko M, Gilmore J, Mishara A. Experiential features used by patients with schizophrenia to differentiate 'voices' from ordinary verbal thought. *Psychol Med* 2007 Nov 30;38(8):1167-1176. [doi: [10.1017/s0033291707002395](https://doi.org/10.1017/s0033291707002395)]
6. Freeman D, Garety PA. Connecting neurosis and psychosis: the direct influence of emotion on delusions and hallucinations. *Behav Res Ther* 2003 Aug;41(8):923-947. [doi: [10.1016/s0005-7967\(02\)00104-3](https://doi.org/10.1016/s0005-7967(02)00104-3)]
7. Shaghghi A, Bhopal R, Sheikh A. Approaches to recruiting 'hard-to-reach' populations into re-search: a review of the literature. *Heal Promot Perspect* 2011 Dec 20;1(2):86-94. [doi: [10.5681/hpp.2011.009](https://doi.org/10.5681/hpp.2011.009)]
8. Atkinson R, Flint J. Accessing hidden and hard-to-reach populations: snowball research strategies. *Social Research Update*. 2001. URL: [https://www.researchgate.net/publication/46214232\\_Accessing\\_Hidden\\_and\\_Hard-to-Reach\\_Populations\\_Snowball\\_Research\\_Strategies/link/5540f43a0cf232227314d32/download](https://www.researchgate.net/publication/46214232_Accessing_Hidden_and_Hard-to-Reach_Populations_Snowball_Research_Strategies/link/5540f43a0cf232227314d32/download) [accessed 2021-05-26]
9. Richardson L, Hameed Y, Perez J, Jones PB, Kirkbride JB. Association of environment with the risk of developing psychotic disorders in rural populations: findings from the social epidemiology of psychoses in East Anglia study. *JAMA Psychiatry* 2018 Jan 01;75(1):75-83 [FREE Full text] [doi: [10.1001/jamapsychiatry.2017.3582](https://doi.org/10.1001/jamapsychiatry.2017.3582)] [Medline: [29188295](https://pubmed.ncbi.nlm.nih.gov/29188295/)]
10. McGrath J, Saha S, Welham J, El Saadi O, MacCauley C, Chant D. A systematic review of the incidence of schizophrenia: the distribution of rates and the influence of sex, urbanicity, migrant status and methodology. *BMC Med* 2004 Apr 28;2:13 [FREE Full text] [doi: [10.1186/1741-7015-2-13](https://doi.org/10.1186/1741-7015-2-13)] [Medline: [15115547](https://pubmed.ncbi.nlm.nih.gov/15115547/)]
11. Saxena S, Thornicroft G, Knapp M, Whiteford H. Resources for mental health: scarcity, inequity, and inefficiency. *Lancet* 2007 Sep;370(9590):878-889. [doi: [10.1016/s0140-6736\(07\)61239-2](https://doi.org/10.1016/s0140-6736(07)61239-2)]
12. Schoenbaum M, Sutherland JM, Chappel A, Azrin S, Goldstein AB, Rupp A, et al. Twelve-month health care use and mortality in commercially insured young people with incident psychosis in the United States. *Schizophr Bull* 2017 Oct 21;43(6):1262-1272 [FREE Full text] [doi: [10.1093/schbul/sbx009](https://doi.org/10.1093/schbul/sbx009)] [Medline: [28398566](https://pubmed.ncbi.nlm.nih.gov/28398566/)]
13. Mojtabai R, Fochtmann L, Chang S, Kotov R, Craig TJ, Bromet E. Unmet need for mental health care in schizophrenia: an overview of literature and new data from a first-admission study. *Schizophr Bull* 2009 Jul;35(4):679-695 [FREE Full text] [doi: [10.1093/schbul/sbp045](https://doi.org/10.1093/schbul/sbp045)] [Medline: [19505994](https://pubmed.ncbi.nlm.nih.gov/19505994/)]
14. Doyle R, Turner N, Fanning F, Brennan D, Renwick L, Lawlor E, et al. First-episode psychosis and disengagement from treatment: a systematic review. *Psychiatr Serv* 2014 May 01;65(5):603-611. [doi: [10.1176/appi.ps.201200570](https://doi.org/10.1176/appi.ps.201200570)] [Medline: [24535333](https://pubmed.ncbi.nlm.nih.gov/24535333/)]
15. Fung KM, Tsang HW, Corrigan PW. Self-stigma of people with schizophrenia as predictor of their adherence to psychosocial treatment. *Psychiatr Rehabil J* 2008;32(2):95-104. [doi: [10.2975/32.2.2008.95.104](https://doi.org/10.2975/32.2.2008.95.104)] [Medline: [18840563](https://pubmed.ncbi.nlm.nih.gov/18840563/)]
16. Lincoln TM, Rief W, Westermann S, Ziegler M, Kesting M, Heibach E, et al. Who stays, who benefits? Predicting dropout and change in cognitive behaviour therapy for psychosis. *Psychiatry Res* 2014 May 15;216(2):198-205. [doi: [10.1016/j.psychres.2014.02.012](https://doi.org/10.1016/j.psychres.2014.02.012)] [Medline: [24602992](https://pubmed.ncbi.nlm.nih.gov/24602992/)]
17. Tait L, Birchwood M, Trower P. Predicting engagement with services for psychosis: insight, symptoms and recovery style. *Br J Psychiatry* 2003 Feb 02;182(2):123-128. [doi: [10.1192/bjp.182.2.123](https://doi.org/10.1192/bjp.182.2.123)] [Medline: [12562739](https://pubmed.ncbi.nlm.nih.gov/12562739/)]
18. Schimmelmann BG, Conus P, Schacht M, Mc G, Lambert M. Predictors of service disengagement in first-admitted adolescents with psychosis. *J Am Acad Child Adolesc Psychiatry* 2006 Aug;45(8):990-999. [doi: [10.1097/01.chi.0000223015.29530.65](https://doi.org/10.1097/01.chi.0000223015.29530.65)] [Medline: [16865042](https://pubmed.ncbi.nlm.nih.gov/16865042/)]
19. van Os J, Hanssen M, Bijl RV, Ravelli A. Strauss (1969) revisited: a psychosis continuum in the general population? *Schizophr Res* 2000 Sep 29;45(1-2):11-20. [doi: [10.1016/S0920-9964\(99\)00224-8](https://doi.org/10.1016/S0920-9964(99)00224-8)]

20. van Os J, Linscott RJ, Myin-Germeys I, Delespaul P, Krabbendam L. A systematic review and meta-analysis of the psychosis continuum: evidence for a psychosis proneness-persistence-impairment model of psychotic disorder. *Psychol Med* 2009 Feb;39(2):179-195. [doi: [10.1017/S0033291708003814](https://doi.org/10.1017/S0033291708003814)] [Medline: [18606047](https://pubmed.ncbi.nlm.nih.gov/18606047/)]
21. Gronholm PC, Thornicroft G, Laurens KR, Evans-Lacko S. Mental health-related stigma and pathways to care for people at risk of psychotic disorders or experiencing first-episode psychosis: a systematic review. *Psychol Med* 2017 Aug;47(11):1867-1879. [doi: [10.1017/S0033291717000344](https://doi.org/10.1017/S0033291717000344)] [Medline: [28196549](https://pubmed.ncbi.nlm.nih.gov/28196549/)]
22. Nielsen total audience report, Q1 2018. The Nielsen Company (US), LLC. 2018. URL: <https://www.nielsen.com/wp-content/uploads/sites/3/2019/04/q1-2018-total-audience-report.pdf> [accessed 2020-08-01]
23. Fox S, Duggan M. Pew Research Center. 2013. URL: <https://www.pewresearch.org/internet/2013/01/15/health-online-2013/> [accessed 2020-08-01]
24. Young AS, Cohen AN, Niv N, Nowlin-Finch N, Oberman RS, Olmos-Ochoa TT, et al. Mobile phone and smartphone use by people with serious mental illness. *Psychiatr Serv* 2020 Mar 01;71(3):280-283. [doi: [10.1176/appi.ps.201900203](https://doi.org/10.1176/appi.ps.201900203)] [Medline: [31744429](https://pubmed.ncbi.nlm.nih.gov/31744429/)]
25. Firth J, Cotter J, Torous J, Bucci S, Firth JA, Yung AR. Mobile phone ownership and endorsement of "mHealth" among people with psychosis: a meta-analysis of cross-sectional studies. *Schizophr Bull* 2016 Mar;42(2):448-455. [doi: [10.1093/schbul/sbv132](https://doi.org/10.1093/schbul/sbv132)] [Medline: [26400871](https://pubmed.ncbi.nlm.nih.gov/26400871/)]
26. Gay K, Torous J, Joseph A, Pandya A, Duckworth K. Digital technology use among individuals with schizophrenia: results of an online survey. *JMIR Ment Health* 2016;3(2):e15 [FREE Full text] [doi: [10.2196/mental.5379](https://doi.org/10.2196/mental.5379)] [Medline: [27146094](https://pubmed.ncbi.nlm.nih.gov/27146094/)]
27. Niendam TA, Tully LM, Iosif A, Kumar D, Nye KE, Denton JC, et al. Enhancing early psychosis treatment using smartphone technology: a longitudinal feasibility and validity study. *J Psychiatr Res* 2018 Jan;96:239-246. [doi: [10.1016/j.jpsychires.2017.10.017](https://doi.org/10.1016/j.jpsychires.2017.10.017)] [Medline: [29126059](https://pubmed.ncbi.nlm.nih.gov/29126059/)]
28. Kumar D, Tully LM, Iosif A, Zakskorn LN, Nye KE, Zia A, et al. A mobile health platform for clinical monitoring in early psychosis: implementation in community-based outpatient early psychosis care. *JMIR Ment Health* 2018 Feb 27;5(1):e15 [FREE Full text] [doi: [10.2196/mental.8551](https://doi.org/10.2196/mental.8551)] [Medline: [29487044](https://pubmed.ncbi.nlm.nih.gov/29487044/)]
29. Ben-Zeev D, Kaiser SM, Brenner CJ, Begale M, Duffecy J, Mohr DC. Development and usability testing of FOCUS: a smartphone system for self-management of schizophrenia. *Psychiatr Rehabil J* 2013 Dec;36(4):289-296 [FREE Full text] [doi: [10.1037/prj0000019](https://doi.org/10.1037/prj0000019)] [Medline: [24015913](https://pubmed.ncbi.nlm.nih.gov/24015913/)]
30. Alvarez-Jimenez M, Bendall S, Lederman R, Wadley G, Chinnery G, Vargas S, et al. On the HORYZON: moderated online social therapy for long-term recovery in first episode psychosis. *Schizophr Res* 2013 Jan;143(1):143-149. [doi: [10.1016/j.schres.2012.10.009](https://doi.org/10.1016/j.schres.2012.10.009)] [Medline: [23146146](https://pubmed.ncbi.nlm.nih.gov/23146146/)]
31. Bucci S, Barrowclough C, Ainsworth J, Machin M, Morris R, Berry K, et al. Actissist: proof-of-concept trial of a theory-driven digital intervention for psychosis. *Schizophr Bull* 2018 Sep;44(5):1070-1080. [doi: [10.1093/schbul/sby032](https://doi.org/10.1093/schbul/sby032)] [Medline: [29566206](https://pubmed.ncbi.nlm.nih.gov/29566206/)]
32. Schlosser D, Campellone T, Kim D, Truong B, Vergani S, Ward C, et al. Feasibility of PRIME: a cognitive neuroscience-informed mobile app intervention to enhance motivated behavior and improve quality of life in recent onset schizophrenia. *JMIR Res Protoc* 2016 Apr 28;5(2):e77 [FREE Full text] [doi: [10.2196/resprot.5450](https://doi.org/10.2196/resprot.5450)] [Medline: [27125771](https://pubmed.ncbi.nlm.nih.gov/27125771/)]
33. Schlosser DA, Campellone TR, Truong B, Etter K, Vergani S, Komaiko K, et al. Efficacy of PRIME, a mobile app intervention designed to improve motivation in young people with schizophrenia. *Schizophr Bull* 2018 Dec 20;44(5):1010-1020. [doi: [10.1093/schbul/sby078](https://doi.org/10.1093/schbul/sby078)] [Medline: [29939367](https://pubmed.ncbi.nlm.nih.gov/29939367/)]
34. King R, Bambling M, Lloyd C, Gomurra R, Smith S, Reid W, et al. Online counselling: the motives and experiences of young people who choose the internet instead of face to face or telephone counselling. *Couns Psychother Res* 2006 Sep;6(3):169-174. [doi: [10.1080/14733140600848179](https://doi.org/10.1080/14733140600848179)]
35. Morgan AJ, Jorm AF, Mackinnon AJ. Internet-based recruitment to a depression prevention intervention: lessons from the Mood Memos study. *J Med Internet Res* 2013;15(2):e31 [FREE Full text] [doi: [10.2196/jmir.2262](https://doi.org/10.2196/jmir.2262)] [Medline: [23403043](https://pubmed.ncbi.nlm.nih.gov/23403043/)]
36. Wise T, Arnone D, Marwood L, Zahn R, Lythe K, Young A. Recruiting for research studies using online public advertisements examples from research in affective disorders. *Neuropsychiatr Dis Treat* 2016 Feb;279-285. [doi: [10.2147/ndt.s90941](https://doi.org/10.2147/ndt.s90941)]
37. Liu NH, Contreras O, Muñoz RF, Leykin Y. Assessing suicide attempts and depression among Chinese speakers over the internet. *Crisis* 2014 Sep 01;35(5):322-329 [FREE Full text] [doi: [10.1027/0227-5910/a000261](https://doi.org/10.1027/0227-5910/a000261)] [Medline: [25115490](https://pubmed.ncbi.nlm.nih.gov/25115490/)]
38. Hauser DJ, Schwarz N. Attentive Turkers: MTurk participants perform better on online attention checks than do subject pool participants. *Behav Res Methods* 2016 Mar 12;48(1):400-407. [doi: [10.3758/s13428-015-0578-z](https://doi.org/10.3758/s13428-015-0578-z)] [Medline: [25761395](https://pubmed.ncbi.nlm.nih.gov/25761395/)]
39. Casler K, Bickel L, Hackett E. Separate but equal? A comparison of participants and data gathered via Amazon's MTurk, social media, and face-to-face behavioral testing. *Comp Hum Beh* 2013 Nov;29(6):2156-2160. [doi: [10.1016/j.chb.2013.05.009](https://doi.org/10.1016/j.chb.2013.05.009)]
40. Huff C, Tingley D. "Who are these people?" Evaluating the demographic characteristics and political preferences of MTurk survey respondents. *Res Polit* 2015 Sep 10;2(3):1-12. [doi: [10.1177/2053168015604648](https://doi.org/10.1177/2053168015604648)]
41. Downs J, Holbrook M, Sheng S, Cranor L. Are your participants gaming the system?: screening mechanical turk workers. In: *Proceedings of the SIGCHI Conference on Human Factors in Computing Systems*. 2010 Apr Presented at: CHI '10: CHI Conference on Human Factors in Computing Systems; April, 2010; Atlanta Georgia USA p. 2399-2402. [doi: [10.1145/1753326.1753688](https://doi.org/10.1145/1753326.1753688)]



42. Ben-Zeev D, Buck B, Chander A, Brian R, Wang W, Atkins D, et al. Mobile RDoC: using smartphones to understand the relationship between auditory verbal hallucinations and need for care. *Schizophr Bull Open* 2020 Jan;1(1):sgaa060 [FREE Full text] [doi: [10.1093/schizbullopen/sgaa060](https://doi.org/10.1093/schizbullopen/sgaa060)] [Medline: [33937774](https://pubmed.ncbi.nlm.nih.gov/33937774/)]
43. Crosier BS, Brian RM, Ben-Zeev D. Using Facebook to reach people who experience auditory hallucinations. *J Med Internet Res* 2016 Jun 14;18(6):e160 [FREE Full text] [doi: [10.2196/jmir.5420](https://doi.org/10.2196/jmir.5420)] [Medline: [27302017](https://pubmed.ncbi.nlm.nih.gov/27302017/)]
44. Population estimates show aging across race groups differs. Public Information Office, United States Census Bureau. 2019 Jun 20. URL: <https://www.census.gov/newsroom/press-releases/2019/estimates-characteristics.html> [accessed 2020-08-01]
45. ACS demographic and housing estimates. United States Census Bureau. 2019. URL: <https://data.census.gov/cedsci/table?q=demographics%20and%20housing%20estimates&tid=ACSDP1Y2018.DP05> [accessed 2020-08-01]
46. Smith TW, Davern M, Freese J, Morgan S. General social surveys, 1972-2018. NORC Univ Chicago. URL: [https://gssdataexplorer.norc.umd.edu/trends/Gender & Marriage?measure=sexornt](https://gssdataexplorer.norc.umd.edu/trends/Gender%20&Marriage?measure=sexornt) [accessed 2020-08-01]
47. Flores A, Herman J, Gates G, Brown T. How many adults identify as transgender in the United States? Williams Institute, UCLA School of Law. 2016 Jun. URL: <https://williamsinstitute.law.ucla.edu/publications/trans-adults-united-states/> [accessed 2020-08-01]
48. Henry M, Bishop K, de Sousa T, Shivji A, Watt R. The 2017 Annual Homeless Assessment Report (AHAR) to Congress. The U.S. Department of Housing and Urban Development. 2018 Oct. URL: <https://www.huduser.gov/portal/sites/default/files/pdf/2017-AHAR-Part-2.pdf> [accessed 2020-08-01]
49. Birnbaum ML, Garrett C, Baumel A, Scovel M, Rizvi AF, Muscat W, et al. Using digital media advertising in early psychosis intervention. *Psychiatr Serv* 2017 Nov 01;68(11):1144-1149. [doi: [10.1176/appi.ps.201600571](https://doi.org/10.1176/appi.ps.201600571)] [Medline: [28712355](https://pubmed.ncbi.nlm.nih.gov/28712355/)]
50. Addington J, Epstein I, Reynolds A, Furimsky I, Rudy L, Mancini B, et al. Early detection of psychosis: finding those at clinical high risk. *Early Interv Psychiatry* 2008 Aug;2(3):147-153. [doi: [10.1111/j.1751-7893.2008.00078.x](https://doi.org/10.1111/j.1751-7893.2008.00078.x)]
51. Sadler GR, Lee H, Lim RS, Fullerton J. Recruitment of hard-to-reach population subgroups via adaptations of the snowball sampling strategy. *Nurs Health Sci* 2010 Sep 01;12(3):369-374 [FREE Full text] [doi: [10.1111/j.1442-2018.2010.00541.x](https://doi.org/10.1111/j.1442-2018.2010.00541.x)] [Medline: [20727089](https://pubmed.ncbi.nlm.nih.gov/20727089/)]
52. Fenner Y, Garland SM, Moore EE, Jayasinghe Y, Fletcher A, Tabrizi SN, et al. Web-based recruiting for health research using a social networking site: an exploratory study. *J Med Internet Res* 2012 Feb;14(1):e20 [FREE Full text] [doi: [10.2196/jmir.1978](https://doi.org/10.2196/jmir.1978)] [Medline: [22297093](https://pubmed.ncbi.nlm.nih.gov/22297093/)]
53. Graham AL, Milner P, Saul JE, Pfaff L. Online advertising as a public health and recruitment tool: comparison of different media campaigns to increase demand for smoking cessation interventions. *J Med Internet Res* 2008 Dec 15;10(5):e50 [FREE Full text] [doi: [10.2196/jmir.1001](https://doi.org/10.2196/jmir.1001)] [Medline: [19073542](https://pubmed.ncbi.nlm.nih.gov/19073542/)]
54. Seltzer ED, Stolley MR, Mensah EK, Sharp LK. Social networking site usage among childhood cancer survivors - a potential tool for research recruitment? *J Cancer Surviv* 2014 Sep 16;8(3):349-354 [FREE Full text] [doi: [10.1007/s11764-014-0348-4](https://doi.org/10.1007/s11764-014-0348-4)] [Medline: [24532046](https://pubmed.ncbi.nlm.nih.gov/24532046/)]
55. Birnbaum ML, Rizvi AF, Confino J, Correll CU, Kane JM. Role of social media and the internet in pathways to care for adolescents and young adults with psychotic disorders and non-psychotic mood disorders. *Early Interv Psychiatry* 2017 Dec;11(4):290-295. [doi: [10.1111/eip.12237](https://doi.org/10.1111/eip.12237)] [Medline: [25808317](https://pubmed.ncbi.nlm.nih.gov/25808317/)]
56. Ben-Zeev D. The digital mental health genie is out of the bottle. *Psychiatr Serv* 2020 Dec 01;71(12):1212-1213. [doi: [10.1176/appi.ps.202000306](https://doi.org/10.1176/appi.ps.202000306)] [Medline: [32576123](https://pubmed.ncbi.nlm.nih.gov/32576123/)]

## Abbreviations

**AVH:** auditory verbal hallucinations  
**IP:** internet protocol  
**SSD:** schizophrenia spectrum disorder

*Edited by G Eysenbach; submitted 01.08.20; peer-reviewed by A Wright, C Arnold, T Campellone; comments to author 29.09.20; revised version received 09.10.20; accepted 12.04.21; published 03.06.21.*

### *Please cite as:*

Buck B, Chander A, Brian RM, Wang W, Campbell AT, Ben-Zeev D  
 Expanding the Reach of Research: Quantitative Evaluation of a Web-Based Approach for Remote Recruitment of People Who Hear Voices  
*JMIR Form Res* 2021;5(6):e23118  
 URL: <https://formative.jmir.org/2021/6/e23118>  
 doi:[10.2196/23118](https://doi.org/10.2196/23118)  
 PMID:[34081011](https://pubmed.ncbi.nlm.nih.gov/34081011/)



©Benjamin Buck, Ayesha Chander, Rachel M Brian, Weichen Wang, Andrew T Campbell, Dror Ben-Zeev. Originally published in JMIR Formative Research (<https://formative.jmir.org>), 03.06.2021. This is an open-access article distributed under the terms of the Creative Commons Attribution License (<https://creativecommons.org/licenses/by/4.0/>), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Formative Research, is properly cited. The complete bibliographic information, a link to the original publication on <https://formative.jmir.org>, as well as this copyright and license information must be included.

Original Paper

# Health Perceptions and Adopted Lifestyle Behaviors During the COVID-19 Pandemic: Cross-National Survey

Nandi Krishnamurthy Manjunath<sup>1</sup>, PhD; Vijaya Majumdar<sup>1</sup>, PhD; Antonietta Rozzi<sup>2</sup>, MA; Wang Huiru<sup>3</sup>, PhD; Avinash Mishra<sup>4</sup>, PhD; Keishin Kimura<sup>5</sup>; Raghuram Nagarathna<sup>1</sup>, MD; Hongasandra Ramarao Nagendra<sup>1</sup>, PhD

<sup>1</sup>Swami Vivekananda Yoga Anusandhana Samsthana University, Bengaluru, India

<sup>2</sup>Sarva Yoga International, Sarzana SP, Italy

<sup>3</sup>Shanghai Jiao Tong University, Shanghai, China

<sup>4</sup>Vivekananda Yoga China, Shanghai, China

<sup>5</sup>Japan Yoga Therapy Society, Yonago City, Japan

**Corresponding Author:**

Vijaya Majumdar, PhD

Swami Vivekananda Yoga Anusandhana Samsthana University

#19, Eknath Bhavan, Gavipuram Circle

KG Naga

Bengaluru, 560019

India

Phone: 91 08026995163

Email: [vijaya.majumdar@svyasa.edu.in](mailto:vijaya.majumdar@svyasa.edu.in)

## Abstract

**Background:** Social isolation measures are requisites to control viral spread during the COVID-19 pandemic. However, if these measures are implemented for a long period of time, they can result in adverse modification of people's health perceptions and lifestyle behaviors.

**Objective:** The aim of this cross-national survey was to address the lack of adequate real-time data on the public response to changes in lifestyle behavior during the crisis of the COVID-19 pandemic.

**Methods:** A cross-national web-based survey was administered using Google Forms during the month of April 2020. The settings were China, Japan, Italy, and India. There were two primary outcomes: (1) response to the health scale, defined as perceived health status, a combined score of health-related survey items; and (2) adoption of healthy lifestyle choices, defined as the engagement of the respondent in any two of three healthy lifestyle choices (healthy eating habits, engagement in physical activity or exercise, and reduced substance use). Statistical associations were assessed with linear and logistic regression analyses.

**Results:** We received 3371 responses; 1342 were from India (39.8%), 983 from China (29.2%), 669 from Italy (19.8%), and 377 (11.2%) from Japan. A differential countrywise response was observed toward perceived health status; the highest scores were obtained for Indian respondents (9.43, SD 2.43), and the lowest were obtained for Japanese respondents (6.81, SD 3.44). Similarly, countrywise differences in the magnitude of the influence of perceptions on health status were observed; perception of interpersonal relationships was most pronounced in the comparatively old Italian and Japanese respondents ( $\beta=.68$  and  $.60$ , respectively), and the fear response was most pronounced in Chinese respondents ( $\beta=.71$ ). Overall, 78.4% of the respondents adopted at least two healthy lifestyle choices amid the COVID-19 pandemic. Unlike health status, the influence of perception of interpersonal relationships on the adoption of lifestyle choices was not unanimous, and it was absent in the Italian respondents (odds ratio 1.93, 95% CI 0.65-5.79). The influence of perceived health status was a significant predictor of lifestyle change across all the countries, most prominently by approximately 6-fold in China and Italy.

**Conclusions:** The overall consistent positive influence of increased interpersonal relationships on health perceptions and adopted lifestyle behaviors during the pandemic is the key real-time finding of the survey. Favorable behavioral changes should be bolstered through regular virtual interpersonal interactions, particularly in countries with an overall middle-aged or older population. Further, controlling the fear response of the public through counseling could also help improve health perceptions and lifestyle behavior. However, the observed human behavior needs to be viewed within the purview of cultural disparities, self-perceptions, demographic variances, and the influence of countrywise phase variations of the pandemic. The observations derived from a short lockdown period are preliminary, and real insight could only be obtained from a longer follow-up.

**KEYWORDS**

health behavior; self-report; cross-national survey; COVID-19; behavior; perception; lifestyle; nutrition; real-time

## Introduction

The World Health Organization (WHO) declared the outbreak of COVID-19 a pandemic on March 11, 2020 [1]. As of March 24, 2020, the most affected regions in the world were the Western Pacific region (China, the Republic of Korea, Japan, etc), with a total of 96,580 reported confirmed cases, and the European region (Italy, Spain, Germany, the United Kingdom, etc), which accounted for a total of 195,511 positive cases [2]. There was a global panic due to the shifting of the COVID-19 epicenters from China to Europe, mainly Italy, which reported the worst outcomes up to March 25, 2020 (69,176 reported cases and the maximum number of COVID-19 deaths of 6820) [2].

Global disease outbreaks impact varied aspects of physical and mental health, even suicidality [3-5]. As observed in the infectious disease epidemic of severe acute respiratory syndrome (SARS) in 2003, exposure to new pathogens can manifest as a qualitatively distinct mental impact [6]. Social isolation measures (large-scale quarantines, long-term home confinements, and nationwide lockdowns) [7-11], although essential for controlling viral spread, go against the inherent human instinct of social relationships [12,13]. If these measures are implemented for a long duration, they can be detrimental to mental health, as observed in recent reports from China and Vietnam [14-17], and they are expected to result in modification of people's lifestyle behaviors, such as increased adoption of unhealthy dietary habits and sedentary behavior. These changes can exacerbate the burden of the "pandemics" of behavioral and cardiovascular diseases that already prevail in modern societies [18,19]. The latest trends of re-emergences of such infectious disease outbreaks merit timely preparedness involving community engagement and focus on healthy lifestyle behaviors [20,21]. Although the mental impact of the COVID-19 pandemic is being addressed in a timely fashion [22,23], the associated real-time influences on people's health perceptions and lifestyle choices remain underresearched [24,25]. Careful consideration of the demographic and cultural impact of tailored public health intervention strategies on human behavior is also greatly needed when designing such strategies. Here, we report the findings of a cross-national survey that aimed to generate rapid perspectives on the status of health-related perceptions and their influence on the likelihood of adoption of healthy lifestyle choices during the COVID-19 pandemic. The settings were China and Japan, two nations in the Western Pacific region that were greatly impacted by COVID-19; Italy, from the European region; and India, a highly populous South Asian country that was a potential threat region at the time of the survey [2,7-9,11].

## Methods

### Sampling and Data Collection

Given the restricted mobility restrictions and confinement due to the COVID-19 lockdown, we conducted a

cross-sectional survey using a web-based platform. We disseminated the survey through the circulation of a Google Form via institutional websites and private social media networks, such as Facebook and WhatsApp. We also used the group email lists of a few social organizations, universities, academic institutions, and their interconnections to share the questionnaire links, which further facilitated the snowball sampling. The respondents were residents of China, Japan, Italy, and India who were aged 18 years or older. We anonymized the data to preserve and protect confidentiality. The study was approved by the institutional review boards and institutional ethics committees of the respective nations: Swami Vivekananda Yoga Anusandhana Samsthana (SVYASA), India; Sarva Yoga International, Italy; Shanghai Jiao Tong University, China; and Japan Yoga Therapy Society, Japan. Respondents were informed about the objectives of the survey and the anonymity of their responses. Informed consent was obtained through a declaration of the participants of their voluntary participation, the confidentiality of the data, and the use of the collected information for research purposes only. The survey period was April 3-28, 2020. Once submitted, the responses were directly used for the analysis, and revisions of the responses were not allowed.

### Questionnaire Structure

We chose a short format for the questionnaire, with 19 questions to facilitate rapid administration. The first set of questions (Q1-Q5) were related to the respondents' demographic details: age, gender, country of residence, working status, and the presence of any chronic illness or disability diagnosed by a physician. The next set (Q6-Q14) contained perception-related questions on self-rated physical and mental health, sleep quality, coping ability, energy status (a psychological state defined as an individual's potential to perform mental and physical activity [26,27]), coping flexibility, and perceptions related to interpersonal relationships as well as the fear of the pandemic. The questions were phrased as statements, with responses recorded on 3- or 5-point scales. For example, the respondents were requested to self-rate their mental and physical health status with the questions "How do you rate your physical health at present as" and "How do rate your mental health at present as" with answer modalities of (1) excellent, (2) very good, (3) good, (4) average, and (5) poor. These single-item self-health assessment questions are validated tools used in national surveys and epidemiological studies to assess health perceptions among individuals, strongly related to various morbidities, and mortality, and they have been validated across various ethnicities [28-33]. A further set of questions (Q15-Q19) focused on items related to the respondents' recent lifestyle behavior choices: eating habits, engagement in physical activity or exercise, and substance use. Permitted responses for these behavior-related questions were either yes or no. For eating habits, the respondents provided self-rated scores for their time of eating; nourishment related to intake of vegetables and fibers; and daily

intake of “junk food” (described as packaged and processed sweets or salty snacks); the combined scores were dichotomized into “good” (score  $\geq 3$ ) and “poor” (score  $\leq 2$ ).

## Data Analysis

An exploratory factor analysis using the principal axis factoring and varimax rotation suggested that three factors were present in the data. Items related to health perceptions were used to form a scale for perceived health status (the health scale); the scores were represented as mean (SD). For the remaining two factors, we could not form scales, as they scored Cronbach  $\alpha$  values  $< .6$ ; instead, we used the most relevant single item to represent the factor. The two primary outcomes of the study were the health scale and the adoption of healthy lifestyle choices. The health scale was derived as mentioned above; further health scale scores were categorized based on tertile distribution into low (poor), middle (average), and high (good) scores. Adoption of healthy lifestyle choices was defined as the engagement of the respondent in any two of three healthy lifestyle choices (eating habits, substance use, and exercise). Multivariate linear and logistic regression analyses were used

to test the influence of the perceptions and the personal variables on the primary outcomes. Most of the items in the survey were recorded as 3-point responses. Hence, to achieve homogeneity in the analyses of the survey items, the 5-point Likert responses of the self-rated health items, excellent, very good, good, average, and poor, were collapsed into three categories: (1) very good/excellent, (2) good, and (3) average/poor. Analysis of variance was used to assess comparisons between continuous variables, and  $P < .05$  was considered significant. Chi-square analysis was used for cross-country comparisons for categorical variables.

## Results

The aim of this survey was to understand the cross-national psychosocial and behavioral impact of the lockdowns and social isolations imposed due to the COVID-19 pandemic. We received 3370 responses: 1342 from India (39.8%), 983 from China (29.2%), 669 from Italy (19.8%), and 377 from Japan (11.2%). The demographic profiles of the respondents are presented in Table 1.

**Table 1.** Countrywise representation of the personal characteristics of the survey participants.

| Variable                        | Overall (N=3371) | India (n=1342) | China (n=983) | Japan (n=377) | Italy (n=669) | P value <sup>a</sup> |
|---------------------------------|------------------|----------------|---------------|---------------|---------------|----------------------|
| Age (years), mean (SD)          | 36.04 (15.54)    | 29.42 (12.29)  | 29.77 (11.98) | 53.49 (9.35)  | 48.43 (13.65) | <.001                |
| <b>Age group (years), n (%)</b> |                  |                |               |               |               | <.001                |
| 18-24                           | 1200 (35.6)      | 685 (51.0)     | 490 (49.8)    | 1 (0.3)       | 31 (4.7)      |                      |
| 25-34                           | 503 (14.9)       | 267 (19.9)     | 152 (15.5)    | 4 (1.1)       | 84 (12.5)     |                      |
| 35-54                           | 1176 (34.9)      | 330 (24.6)     | 314 (32.0)    | 217 (57.5)    | 309 (46.2)    |                      |
| 55-64                           | 330 (9.8)        | 40 (3.0)       | 21 (2.1)      | 98 (26.0)     | 169 (25.2)    |                      |
| >65                             | 162 (4.8)        | 20 (1.5)       | 6 (0.6)       | 57 (15.1)     | 76 (11.4)     |                      |
| Female gender, n (%)            | 2535 (75.2)      | 880 (65.6)     | 802 (81.6)    | 348 (92.0)    | 506 (75.6)    | <.001                |
| Working, n (%)                  | 1709 (50.7)      | 582 (43.4)     | 406 (41.3)    | 335 (89.0)    | 395 (59.0)    | <.001                |
| Has a chronic illness, n (%)    | 647 (19.2)       | 169 (12.6)     | 84 (8.5)      | 151 (40.0)    | 314 (46.9)    | <.001                |

<sup>a</sup>Cross-country comparisons for categorical variables were conducted using chi-square analysis. Analysis of variance was conducted to assess comparisons among the continuous variable of age. A  $P$  value  $< .05$  was considered significant.

The mean age of the respondents was 36.04 years (SD 15.54) (Table 1); the average age of the Indian and Chinese respondents (29.42 years, SD 12.29, and 29.77 years, SD 11.98, respectively) was lower than that of the Japanese and Italian respondents (53.49 years, SD 9.35, and 48.43 years, SD 3.65, respectively). Overall, there was a higher representation of the female gender (2535/3371, 75.2%). Japan had the highest representation of women (348/377, 92.0%) and working people (335/377, 89.0%) (Table 1). Italy and Japan had the highest representations of respondents with a known status of chronic illness (314/669, 46.9%, and 151/377, 40.0%, respectively).

Table 2 shows the countrywise status of the perceptions of health and psychosocial factors reported in response to the ongoing outbreak of COVID-19. The health status score was highest for Indian respondents (9.43, SD 2.43) and lowest for Japanese respondents (6.81, SD 3.44). Overall, 846/3371 (25.1%) of the respondents had good health status; Japanese and Chinese respondents had the highest representation of low health status

(236/377, 62.6%, and 562/983, 57.2%, respectively). Sleep quality was perceived well by the majority of Indians (917/1342, 68.3%), and the majority of Japanese and Chinese respondents perceived their sleep quality as average/poor (264/377, 70%, and 554/983, 56.3%, respectively). Italian respondents had almost equal representations of good and average sleep qualities. Coping abilities during social isolation were perceived as good by 1264/3371 (37.5%) of the overall population, with the countrywise trend of India (672/1342, 50.1%) > Italy (283/669, 42.3%) > Japan (131/377, 34.8%) > China (178/983, 18.1%). Fear response was almost equally distributed in positive or intermediate categories for most of the country respondents, except for Italians, among whom the intermediate or partial fear response was the most evident (469/669, 70.1%). Coping flexibility responses were very similar across all the countries except Japan, wherein the majority of respondents (317/377, 84.1%) reported experiencing little challenging response to sudden changes in living norms. Responses to interpersonal

relationships followed the trend of India (733/1342, 54.6%) > Japan (183/377, 48.5%) > Italy (287/669, 42.9%) > China (337/983, 34.3%). Adopted lifestyle behavior yielded the trend of India (1129/1342, 83.9%) > Italy (361/669, 54.0%) > China (436/983, 44.4%) > Japan (137/377, 36.2%).

Based on the regression analysis on the perceived health status, female respondents had a 0.14 lower score compared to male respondents (Table 3). Participants with a positive history of chronic illness and those who were not working also had lower health status scores, by 0.11 and 0.04, respectively, compared to their counterparts. Increased personal relationships and positive fear response were associated with increases in health status across all the countries, particularly Japan, which showed the highest value of  $\beta$  (.60). For Indian respondents, an increase

in age was significantly associated with increase in health status by a score of 0.12.

Increased interpersonal relationships was a significant predictor of adoption of health lifestyle choices across the respondents in all the countries except for Italy (adjusted OR 1.93, 95% CI 0.65-5.79) (Table 4). Positive perception of fear was significantly associated with likelihood of adoption of healthy lifestyle choices only in Indian respondents (adjusted OR 2.41, 95% CI 1.18-4.96). Perceived health status categories were significantly associated with the likelihood of adoption of healthy lifestyle choices across all the countries; most prominently, high health status increased adoption of healthy lifestyle choices by approximately 6-fold in China and Italy.



**Table 2.** Countrywise representation of perceptions and behavioral changes among the survey respondents related to the COVID-19 outbreak.

| Perception or behavior and response  | Overall (N=3371) | India (n=1342) | China (n=983) | Japan (n=377) | Italy (n=669) | P value <sup>a</sup> |
|--|------------------|----------------|---------------|---------------|---------------|----------------------|
| <b>First factor<sup>b</sup></b>  |                  |                |               |               |               |                      |
| <b>Health status, mean (SD)</b>  | 8.26 (3.36)      | 9.43 (2.43)    | 7.09 (2.92)   | 6.81 (3.44)   | 8.43 (2.56)   | .01                  |
| High, n (%)  | 846 (25.1)       | 556 (41.4)     | 71 (7.2)      | 69 (18.3)     | 150 (22.4)    |                      |
| Medium, n (%)  | 1062 (31.5)      | 413 (30.8)     | 350 (35.6)    | 72 (19.1)     | 225 (33.6)    |                      |
| Low, n (%)   | 1463 (43.4)      | 413 (30.8)     | 562 (57.2)    | 236 (62.6)    | 294 (43.9)    |                      |
| <b>Self-rated physical health, n (%)</b>   |                  |                |               |               |               | <.001                |
| Excellent/very good  | 1357 (40.2)      | 629 (46.9)     | 467 (47.5)    | 88 (23.3)     | 173 (25.9)    |                      |
| Good   | 1283 (38.1)      | 573 (42.7)     | 200 (20.3)    | 135 (35.8)    | 375 (56.0)    |                      |
| Poor/average   | 731 (21.7)       | 140 (10.4)     | 316 (32.1)    | 154 (40.8)    | 121 (18.1)    |                      |
| <b>Self-rated mental health, n (%)</b>   |                  |                |               |               |               | <.001                |
| Excellent/very good  | 944 (28.0)       | 645 (48.1)     | 0 (0)         | 93 (24.7)     | 206 (30.8)    |                      |
| Good   | 1670 (49.5)      | 535 (39.9)     | 642 (65.3)    | 122 (32.4)    | 371 (55.4)    |                      |
| Poor/average   | 757 (22.5)       | 162 (12.1)     | 341 (34.7)    | 162 (43.0)    | 92 (13.8)     |                      |
| <b>Self-rated sleep quality, n (%)</b>   |                  |                |               |               |               | <.001                |
| Good   | 1787 (53.0)      | 917 (68.3)     | 429 (43.6)    | 113 (29.9)    | 328 (49.0)    |                      |
| Average  | 1305 (38.7)      | 354 (26.4)     | 477 (48.5)    | 234 (62.1)    | 240 (35.9)    |                      |
| Poor   | 279 (8.3)        | 71 (5.3)       | 77 (7.8)      | 30 (8.0)      | 101 (15.1)    |                      |
| <b>Self-rated coping abilities, n (%)</b>  |                  |                |               |               |               | <.001                |
| Good   | 1264 (37.5)      | 672 (50.1)     | 178 (18.1)    | 131 (34.8)    | 283 (42.3)    |                      |
| Average  | 1492 (44.3)      | 539 (40.1)     | 516 (52.5)    | 139 (36.8)    | 298 (44.5)    |                      |
| Poor   | 615 (18.2)       | 131 (9.8)      | 289 (29.4)    | 107 (28.5)    | 88 (13.2)     |                      |
| <b>Second factor, n (%)</b>  |                  |                |               |               |               |                      |
| <b>Fear/anxiety related to COVID-19<sup>c</sup></b>                                |                  |                |               |               |               | <.001                |
| Not at all (positive)  | 1380 (40.9)      | 628 (46.8)     | 470 (47.8)    | 157 (41.6)    | 125 (18.7)    |                      |
| Partially (intermediate)   | 1829 (54.3)      | 662 (49.3)     | 485 (49.3)    | 213 (56.5)    | 469 (70.1)    |                      |
| Extremely (negative)   | 162 (4.8)        | 52 (3.9)       | 28 (2.8)      | 7 (1.9)       | 75 (11.2)     |                      |
| <b>Self-perception of low energy</b>   |                  |                |               |               |               | <.001                |
| Never  | 1449 (43.0)      | 667 (49.7)     | 282 (28.7)    | 239 (63.4)    | 261 (39.0)    |                      |
| Sometimes  | 1835 (54.5)      | 641 (47.8)     | 672 (68.4)    | 132 (35.0)    | 390 (58.3)    |                      |
| All the time   | 87 (2.6)         | 34 (2.5)       | 29 (3.0)      | 6 (1.6)       | 18 (2.7)      |                      |
| <b>Challenging response to sudden changes in living norms (coping flexibility)</b> |                  |                |               |               |               | <.001                |
| Least/not at all/little  | 845 (25.1)       | 436 (32.5)     | 221 (22.5)    | 44 (11.7)     | 144 (21.5)    |                      |
| Little   | 1454 (43.1)      | 417 (31.1)     | 411 (41.8)    | 317 (84.1)    | 309 (46.2)    |                      |
| Extremely/somewhat   | 1072 (31.8)      | 489 (36.4)     | 351 (35.7)    | 16 (4.2)      | 216 (32.3)    |                      |
| <b>Third factor, n (%)</b>   |                  |                |               |               |               |                      |
| <b>Interpersonal relationships<sup>c</sup></b>                                     |                  |                |               |               |               | <.001                |
| Increased  | 1540 (45.7)      | 733 (54.6)     | 337 (34.3)    | 183 (48.5)    | 287 (42.9)    |                      |
| Not changed  | 1572 (46.6)      | 533 (39.7)     | 550 (56.0)    | 179 (47.5)    | 310 (46.3)    |                      |

| Perception or behavior and response  | Overall (N=3371) | India (n=1342) | China (n=983) | Japan (n=377) | Italy (n=669) | <i>P</i> value <sup>a</sup> |
|--|------------------|----------------|---------------|---------------|---------------|-----------------------------|
| Reduced  | 259 (7.7)        | 76 (5.7)       | 96 (9.8)      | 15 (4.0)      | 72 (10.8)     |                             |
| <b>Motivating influence of COVID-19 on lifestyle</b>                         |                  |                |               |               |               | <.001                       |
| Completely   | 1175 (34.8)      | 605 (45.1)     | 217 (22.1)    | 132 (35.0)    | 221 (33.0)    |                             |
| Partially  | 1919 (57.0)      | 641 (47.8)     | 695 (70.7)    | 223 (59.2)    | 360 (53.8)    |                             |
| Not at all   | 277 (8.2)        | 96 (7.1)       | 71 (7.2)      | 22 (5.8)      | 88 (13.2)     |                             |
| <b>Adoption of ≥2 healthy lifestyle choices</b>                              | 2643 (78.4)      | 1126 (83.9)    | 750 (76.3)    | 283 (75.1)    | 485 (72.5)    | <.001                       |
| Adoption of healthy eating behavior  | 1801 (53.4)      | 867 (64.6)     | 436 (44.4)    | 137 (36.3)    | 361 (54.0)    | <.001                       |
| Decreased dependency on and use of tobacco, alcohol, or any other substances | 3173 (94.1)      | 1277 (95.2)    | 918 (93.4)    | 355 (94.1)    | 623 (93.1)    | <.001                       |
| Increased engagement in exercise or similar activities                       | 2280 (67.6)      | 910 (67.8)     | 672 (68.4)    | 272 (72.1)    | 426 (63.7)    | <.001                       |

<sup>a</sup>Cross-country comparisons for categorical variables were conducted using chi-square analysis; all the *P* values were significant.

<sup>b</sup>An exploratory factor analysis using principal axis factoring and varimax rotation suggested that there were 3 factors present in the data. The first factor consisted of health-related perceptions; composite scores for perceived health were generated as summative scores of the included items.

<sup>c</sup>For the remaining 2 factors, scales could not be formed; rather, the single items that were thought to best summarize the respective factors were considered for further association analyses.

**Table 3.** Multivariate linear regression analysis ( $\beta$  coefficients, standard errors, and *t* and *P* values) of the association between health status, personal variables, and perceptions.

| Predictors  | Overall |      |          |          | India   |      |          |          | China   |      |          |          | Japan   |      |          |          | Italy   |      |          |          |
|---|---------|------|----------|----------|---------|------|----------|----------|---------|------|----------|----------|---------|------|----------|----------|---------|------|----------|----------|
|   | $\beta$ | SE   | <i>t</i> | <i>P</i> | $\beta$ | SE   | <i>t</i> | <i>P</i> | $\beta$ | SE   | <i>t</i> | <i>P</i> | $\beta$ | SE   | <i>t</i> | <i>P</i> | $\beta$ | SE   | <i>t</i> | <i>P</i> |
| <b>Demographic variables</b>                              |         |      |          |          |         |      |          |          |         |      |          |          |         |      |          |          |         |      |          |          |
| Age   | .14     | .001 | 5.12     | <.001    | .12     | .001 | 3.74     | <.001    | .07     | .001 | 1.79     | .07      | .08     | .002 | 1.55     | 0.12     | -.07    | 0.02 | -0.66    | .51      |
| <b>Gender (reference: male)</b>                           |         |      |          |          |         |      |          |          |         |      |          |          |         |      |          |          |         |      |          |          |
| Female  | -.14    | .012 | -7.51    | <.001    | -.09    | .014 | -3.24    | <.001    | -.01    | .023 | -0.35    | .72      | .01     | .064 | -0.30    | 0.77     | <.001   | 0.52 | -0.03    | .97      |
| <b>Working status (reference: working)</b>                |         |      |          |          |         |      |          |          |         |      |          |          |         |      |          |          |         |      |          |          |
| Not working   | -.04    | .013 | -2.04    | .04      | -.01    | .015 | -0.32    | .75      | -.02    | .023 | -0.54    | .59      | -.04    | .056 | -0.71    | 0.48     | -.03    | 0.55 | -0.36    | .72      |
| <b>Chronic illness (reference: no)</b>                    |         |      |          |          |         |      |          |          |         |      |          |          |         |      |          |          |         |      |          |          |
| Yes   | -.11    | .015 | -5.63    | <.001    | -.16    | .020 | -6.12    | <.001    | -.06    | .031 | -2.04    | .04      | -.14    | .035 | -2.81    | 0.01     | -.09    | 0.47 | -0.96    | .34      |
| <b>Perceptions</b>  |         |      |          |          |         |      |          |          |         |      |          |          |         |      |          |          |         |      |          |          |
| <b>Interpersonal relationships (reference: decreased)</b> |         |      |          |          |         |      |          |          |         |      |          |          |         |      |          |          |         |      |          |          |
| Increased   | .37     | .021 | 10.76    | <.001    | .38     | .028 | 6.48     | <.001    | .21     | .031 | 4.12     | <.001    | .60     | .085 | 4.86     | <.001    | .27     | 0.68 | 2.17     | .03      |
| No change   | .14     | .021 | 4.15     | <.001    | .21     | .029 | 3.71     | <.001    | .05     | .029 | 1.08     | .28      | .33     | .084 | 2.66     | 0.01     | .019    | 0.66 | 1.56     | .12      |
| <b>Fear response (reference: poor)</b>                    |         |      |          |          |         |      |          |          |         |      |          |          |         |      |          |          |         |      |          |          |
| Positive  | .54     | .030 | 10.84    | <.001    | .59     | .033 | 8.69     | <.001    | .71     | .052 | 8.02     | <.001    | .54     | .138 | 2.72     | 0.01     | .50     | 1.02 | 3.03     | <.001    |
| Fair  | .29     | .030 | 5.82     | <.001    | .35     | .033 | 5.22     | <.001    | .38     | .051 | 4.35     | <.001    | .26     | .137 | 1.30     | 0.20     | .30     | 0.97 | 1.77     | .08      |

**Table 4.** Role of perceptions in the adoption of healthy lifestyle choices.

| Perception  | Overall                     |                                      | India               |                         | China                |                         | Japan                |                         | Italy               |                         |
|---|-----------------------------|--------------------------------------|---------------------|-------------------------|----------------------|-------------------------|----------------------|-------------------------|---------------------|-------------------------|
|   | OR <sup>a</sup><br>(95% CI) | Adjusted <sup>b</sup> OR<br>(95% CI) | OR<br>(95% CI)      | Adjusted OR<br>(95% CI) | OR<br>(95% CI)       | Adjusted OR<br>(95% CI) | OR<br>(95% CI)       | Adjusted OR<br>(95% CI) | OR<br>(95% CI)      | Adjusted OR<br>(95% CI) |
| <b>Health status (reference: low)</b>                                 |                             |                                      |                     |                         |                      |                         |                      |                         |                     |                         |
| High  | 3.67<br>(2.87-4.68)         | 3.42<br>(2.51-4.64)                  | 2.98<br>(2.07-4.28) | 2.62<br>(1.75-3.92)     | 6.02<br>(2.38-15.20) | 5.83<br>(2.30-4.79)     | 3.64<br>(1.59-8.37)  | 2.83<br>(1.18-6.77)     | 3.33<br>(2.01-5.51) | 6.22<br>(1.90-20.40)    |
| Medium  | 2.09<br>(1.72-2.54)         | 2.00<br>(1.59-2.50)                  | 1.76<br>(1.24-2.50) | 1.57<br>(1.07-2.31)     | 2.61<br>(1.85-3.69)  | 2.43<br>(1.72-3.45)     | 1.33<br>(0.72-2.45)  | 1.06<br>(0.54-2.08)     | 2.10<br>(1.42-3.12) | 2.46<br>(1.03-5.83)     |
| <b>Interpersonal relationships<sup>c</sup> (reference: decreased)</b> |                             |                                      |                     |                         |                      |                         |                      |                         |                     |                         |
| In-creased  | 2.21<br>(1.64-2.98)         | 2.42<br>(1.70-3.45)                  | 1.86<br>(1.03-3.37) | 2.16<br>(1.15-4.08)     | 2.01<br>(1.18-3.41)  | 1.77<br>(1.03-3.05)     | 4.43<br>(1.49-13.15) | 5.25<br>(1.46-8.92)     | 1.86<br>(1.07-3.22) | 1.93<br>(0.65-5.79)     |
| Not changed   | 1.25<br>(0.94-1.7)          | 1.18<br>(0.84-1.66)                  | 1.09<br>(0.60-1.97) | 1.18<br>(0.63-2.21)     | 1.03<br>(0.64-1.68)  | 0.99<br>(0.61-1.62)     | 1.87<br>(0.65-5.42)  | 1.88<br>(0.54-6.52)     | 1.59<br>(0.93-2.73) | 1.40<br>(0.50-3.96)     |
| <b>Fear response<sup>c</sup> (reference: poor)</b>                    |                             |                                      |                     |                         |                      |                         |                      |                         |                     |                         |
| Positive  | 2.43<br>(1.69-3.50)         | 2.50<br>(1.54-4.05)                  | 2.72<br>(1.38-5.36) | 2.41<br>(1.18-4.96)     | 2.38<br>(1.06-5.33)  | 2.18<br>(0.96-4.94)     | 1.84<br>(0.34-9.99)  | 4.85<br>(0.73-32.19)    | 1.62<br>(0.86-3.04) | 2.20<br>(0.41-11.71)    |
| Fair  | 1.36<br>(0.95-1.93)         | 1.33<br>(0.83-2.14)                  | 1.37<br>(0.71-2.65) | 1.32<br>(0.65-2.65)     | 1.46<br>(0.66-3.23)  | 1.32<br>(0.59-2.96)     | 0.93<br>(0.18-4.93)  | 1.97<br>(0.31-12.55)    | 1.34<br>(0.80-2.27) | 1.25<br>(0.27-5.80)     |

<sup>a</sup>OR: odds ratio.<sup>b</sup>Adjusted for sex, age, work status, and history of chronic illness.<sup>c</sup>Factor represented by a single item that was thought to best represent the underlying notion.

## Discussion

The aims of this short cross-national behavioral survey study were to generate rapid ideas regarding perspectives on health and lifestyle behavior and to provide initial insights into designing global but culturally tailored public health policies.

### Health Perceptions: Countrywise Status

A differential countrywise response was observed toward perceived health status across the survey participants; Indians had a better representation of high health status (41.4%) compared to respondents from other countries (China, 7.2%, Japan, 18.2%, and Italy, 22.5%). Despite the inconsistencies in health perceptions, there was a consistent influence of social support measured by perceptions of interpersonal relationships and fear of perceived health status. However, there were countrywise differences in the magnitude of the impact of perceptions on health status; perception of interpersonal relationships was most pronounced in the comparatively older Italian and Japanese respondents ( $\beta=.68$  and  $.60$ , respectively) and that of fear in the Chinese respondents ( $\beta=.71$ ). These findings favor the implementation of regularized virtual interpersonal interactions toward combating the adverse health impact of the pandemic, particularly in countries with a higher proportion of older people [34]. Controlling the fear response

through counseling would also aid the improvement of health outcomes in populations affected by pandemics. The findings of this survey related to the influence of gender on health perceptions (the health status score of female respondents was lower by 0.14 units compared to that of male respondents) are in line with the global trend of poorer health perception in women than in their male counterparts [35]. These real-time findings observed during the pandemic also relate with reports documented before the COVID-19 pandemic, with a generally higher prevalence of adverse mental health symptoms in women compared to men [36]. Overall, there seemed to be a differential influence of demographic variables on health perceptions across the global population during the pandemic.

The comparatively high scores of the perceived health status in Indian respondents could be underlined by an early phase of the pandemic with slower progression in India during the survey period [11]. The younger age of the Indian respondents (mean age 29.42 years, SD 12.29) seemed to further facilitate interpersonal relationships (54.6%) during the lockdown, which also explains their better health status ( $\beta=.38$ ) [34,37]. Younger age identity has been associated with well-being and better perceptions of health [38]. However, in this survey, an unexpectedly positive linear relationship was observed between increasing age and better perception of health status ( $\beta=.12$ ) in young Indian respondents. This finding can be attributed to the

compounding effect of the COVID-19 pandemic on already existing emotional distress among young adults (related to their examinations, uncertainties, social relationships, etc) [39].

Unfortunately, in line with previous reports [14,15], we could also observe a continued/posttraumatic impact of the pandemic in Chinese respondents, reflected in their comparatively low perception of health status (poor health status was reported by 57.2% of these respondents). We believe the poor health perceptions in the Chinese respondents is due to the underlying influence of fear perceptions ( $\beta=.71$ ). Further, since the country had successfully emerged from the first wave of the pandemic during the survey, and social norms had also almost returned to normal, with fewer imposed lockdowns, the moderate increase in interpersonal relationships (34.3%) may not be sufficient to facilitate health status.

The observed low status of perceived health in the Japanese respondents (low health status, 62.6%) is in accord with a health paradox in that country, which is a tendency to perceive health poorly despite the advanced economy [40,41]. Although this influence is not direct, an indirect influence of the comparatively old, middle-aged demographic profile of the Japanese respondents along with the mediatory impact of chronic diseases on health status ( $\beta=-.14$ ) could also underlie the lower health perceptions of the Japanese respondents [42]. The perception of poor sleep quality in the Japanese respondents also needs attention, as this finding is in line with reports of the suicidal tendencies in this country [43].

On a positive note, amid the aggravated pandemic at the time of the survey, the majority of the Italian respondents who were middle-aged perceived only partial fear of the pandemic (70.1% response), and they reported better health perceptions (health status score 8.43, SD 2.56) than Japanese respondents (health status score 6.81, SD 3.44) and Chinese respondents (health status score 7.09, SD 2.92). Approximately 55% of the responses for self-rated physical and mental health were in the moderate/fair tier, which is in accord with the reported tendency of Italian people toward intermediate categories of health perception [44]. The lack of negative influence of middle age and chronic illness on health perception can be attributed to the highly efficient medical care and adequate access to social support provided in Italy during the lockdown (improved interpersonal relationships were reported by 42.9% of Italian respondents).

### Role of Perceptions in the Adoption of Lifestyle Choices: Countrywise Comparisons

Despite the imposed social isolation and home confinement and the prevailing fear during the COVID-19 pandemic, we observed a positive behavioral response toward lifestyle. Overall, 78.4% of the respondents adopted at least 2 healthy lifestyle choices during the COVID-19 pandemic. The majority of the respondents (67.6%) reported increased engagement in physical activity or exercise as opposed to the expected sedentary behavior due to home confinement. This favorable although unexpected outcome can be attributed to the timely release of the advisory recommendations made by various global and government agencies, including the WHO, on home-based or other easy - to - perform exercises under physical restrictions

[45,46]. One of the crucial affirmative responses observed in this survey was the overwhelming response toward substance use (94.1%), which is more justifiable by lack of availability [47] than motivational influence. Along similar lines, in a recent survey on the immediate response to COVID-19, a 3% reduction in smoking was reported in Italians, which was attributed to the fear of increased risk of respiratory distress or mortality [48]. To this end, we suggest the implementation of internet-based and cost-effective behavioral therapies, particularly cognitive behavioral therapy, which may aid the successful alleviation of maladaptive coping tendencies, thereby reducing the risk of future health catastrophes in the post-COVID-19 era [49,50].

Social connectedness is an important dimension that controls population health and healthy lifestyle behavior [51]. In this cross-national survey, perception of increased social support and capital, manifested through enhanced interactions among close friends and family members (measured as interpersonal relationships in the survey), seemed to fill the void of missing social connectedness and encouraged the adoption of healthy lifestyle choices (adjusted OR 2.42, 95% CI 1.70-3.45). The substantial representation of the adoption of healthy lifestyle choices in Chinese and Japanese respondents (~75%), irrespective of their overall poor health perceptions, could be related to reverse causality. In the Japanese respondents (who had an older, middle-aged demographic profile), their working status (OR 4.37, 95% CI 1.19-16.02) (Table S1, [Multimedia Appendix 1](#)) and interpersonal relationships (OR for the adoption of healthy lifestyle choices 5.25, 95% CI 1.46-18.92) also seemed to contribute significantly to the adoption of healthy lifestyle behavior.

The influence of interpersonal relationships on the adoption of healthy lifestyle choices was not consistent across different countries and was absent in the Italian respondents. However, this finding aligns with the previously reported relationship between a healthy lifestyle and self-perceived health in the European population [52]. Perception of good health was a prominent predictor of adoption of a healthy lifestyle (adjusted OR 6.22, 95% CI 1.90-20.40) in the middle-aged Italian respondents, with a 36.6% proportion of older individuals (>55 years). Even intermediate scores of health perceptions (health status) also significantly predicted the likelihood of the adoption of healthy lifestyle choices (OR 2.43, 95% CI 1.72-3.45) in the Chinese respondents compared to the respondents from other countries, explained by their demographic characteristic of younger age. These countrywise differential cultural influences of perceptions on health and health behaviors during pandemics indicate that endorsement of the same, such as family support and togetherness, should consider existing disparities, especially for western countries [13].

The findings of this report, particularly those regarding varied health perceptions and their differential influence on the likelihood of adopting healthy lifestyle choices, should be considered within the purview of the survey period with countrywise phase variations of the pandemic. Chinese respondents displayed the continued impact of the pandemic, as they had already witnessed one phase of the pandemic [2]. Younger Indian respondents scored better for their health- and behavior-related perceptions due to the stable and early phase

of the pandemic (as of April 22, there was a comparatively steady expansion of COVID-19 cases in India compared to other countries, with 18,985 confirmed cases [11]). However, the responses of Japanese and Italian respondents related to their older age; these countries were also witnessing rising waves of COVID-19 at the time of the survey [7,53]. Japan was under an extended state of national emergency, as the number of “untraceable” cases was soaring [7]. Italy was also under an extended period of lockdown and was one of the hardest-hit nations, with an apparent mortality rate of approximately 13% [53,54].

The observed predominantly female participation in the survey indicates a lack of stringent sampling but also highlights the active involvement of women, who are considered to be at high risk of socioeconomic vulnerability toward disease outbreaks such as the COVID-19 pandemic. The positive response for self-care in women is also a sign of improving gender equity toward health awareness. The observed overwhelmingly female participation level (75.2%) could not be ascribed to the gender representation of countries such as India and China [55] but could be ascribed to the high readiness of the female population to interactively use the internet, in particular to research health-related information and programs, as observed in recent reports [56-58].

The study is limited by the lack of inclusion of perceptions of preventive behaviors and did not compare the respondents' views on precautionary measures, such as the use of face masks [59]. In a recent cross-country comparison between Polish and Chinese respondents, higher use of face masks in Chinese respondents (Polish respondents, 35.0%; Chinese respondents, 96.8%;  $P < .001$ ) was found to be associated with better physical and mental impact of the COVID-19 pandemic [59]. Further, the observations of the adopted lifestyle choices presented here

are derived from a short lockdown period during the COVID-19 pandemic and are preliminary, influenced mostly by self-perception; demographic and cultural differences and realistic insight could only be obtained from a longer follow-up. Due to the self-reported nature of the observations, positive behavioral responses toward lifestyle are likely to be inflated.

Good perceived health was associated with improved interpersonal relationships. Older respondents were least likely to report a positive relationship change, as observed in the responses of Italian and Japanese survey participants. However, there was a strong influence of improved interpersonal relationships on perceived health as well as adoption of healthy lifestyle choices in Japanese respondents. These findings indicate the potential of regularized virtual interpersonal interactions to attenuate the adverse psychosocial impact of such pandemics.

In conclusion, the key finding of the survey is that the consistent positive influence of increased interpersonal relationships and good perceptions of health were found to have a significant influence on adopted lifestyle behaviors during the adverse time course of the COVID-19 pandemic. These favorable behavioral perceptions should be bolstered through enhanced health awareness, and regularized virtual interpersonal interactions, particularly in countries with an overall middle-aged or older population. Simultaneously, controlling the fear response through counseling would also help improve health outcomes in nations affected by pandemics. However, the observed human behavior has cultural influences, and it may not be globally generalizable.

### Data Availability Statement

The data that support the findings of this study are available on request from the corresponding author.

### Acknowledgments

The authors gratefully acknowledge the contributions of Dr Ravi Kulkarni and Dr Kousthubha for facilitating the data processing and providing technical support for preparing Google Forms, etc. There was no funding source for this study.

### Authors' Contributions

MNK conceptualized the survey, performed the literature search, collected data from public sources, and contributed to the manuscript writing. VM wrote the manuscript and performed the literature search and statistical analyses. NR conceptualized the study and revised the manuscript. HR reviewed the manuscript. MNK and VM finalized the manuscript. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

### Conflicts of Interest

None declared.

### Multimedia Appendix 1

Supplementary table.

[DOCX File, 20 KB - [formative\\_v5i6e23630\\_app1.docx](#)]

### References

1. Listings of WHO's response to COVID-19. World Health Organization. URL: <https://www.who.int/news-room/detail/29-06-2020-covidtimeline> [accessed 2021-05-10]



2. Srivastava N, Baxi P, Ratho R, Saxena S. Global trends in epidemiology of coronavirus disease 2019 (COVID-19). In: Saxena S, editor. *Coronavirus Disease 2019 (COVID-19). Medical Virology: From Pathogenesis to Disease Control*. Singapore: Springer; Apr 03, 2020.
3. Leane E, Samuel M, Oh H, Poulet E, Brunelin J. Suicidal behaviors and ideation during emerging viral disease outbreaks before the COVID-19 pandemic: a systematic rapid review. *Prev Med* 2020 Dec;141:106264 [FREE Full text] [doi: [10.1016/j.ypmed.2020.106264](https://doi.org/10.1016/j.ypmed.2020.106264)] [Medline: [33017599](https://pubmed.ncbi.nlm.nih.gov/33017599/)]
4. Yip PS, Cheung Y, Chau P, Law Y. The impact of epidemic outbreak: the case of severe acute respiratory syndrome (SARS) and suicide among older adults in Hong Kong. *Crisis* 2010 Mar;31(2):86-92. [doi: [10.1027/0227-5910/a000015](https://doi.org/10.1027/0227-5910/a000015)] [Medline: [20418214](https://pubmed.ncbi.nlm.nih.gov/20418214/)]
5. de Berker AO, Rutledge RB, Mathys C, Marshall L, Cross GF, Dolan RJ, et al. Computations of uncertainty mediate acute stress responses in humans. *Nat Commun* 2016 Mar 29;7(1):10996 [FREE Full text] [doi: [10.1038/ncomms10996](https://doi.org/10.1038/ncomms10996)] [Medline: [27020312](https://pubmed.ncbi.nlm.nih.gov/27020312/)]
6. Zheng W. Mental health and a novel coronavirus (2019-nCoV) in China. *J Affect Disord* 2020 May 15;269:201-202 [FREE Full text] [doi: [10.1016/j.jad.2020.03.041](https://doi.org/10.1016/j.jad.2020.03.041)] [Medline: [32339137](https://pubmed.ncbi.nlm.nih.gov/32339137/)]
7. Looi M. Covid-19: Japan prepares to extend state of emergency nationwide as "untraceable" cases soar. *BMJ* 2020 Apr 16;369:m1543. [doi: [10.1136/bmj.m1543](https://doi.org/10.1136/bmj.m1543)] [Medline: [32299811](https://pubmed.ncbi.nlm.nih.gov/32299811/)]
8. Chen J, Lu H, Melino G, Boccia S, Piacentini M, Ricciardi W, et al. COVID-19 infection: the China and Italy perspectives. *Cell Death Dis* 2020 Jun 08;11(6):438 [FREE Full text] [doi: [10.1038/s41419-020-2603-0](https://doi.org/10.1038/s41419-020-2603-0)] [Medline: [32513951](https://pubmed.ncbi.nlm.nih.gov/32513951/)]
9. Vaughan A. Italy in lockdown. *New Sci* 2020 Mar 14;245(3273):7 [FREE Full text] [doi: [10.1016/S0262-4079\(20\)30520-0](https://doi.org/10.1016/S0262-4079(20)30520-0)] [Medline: [32372775](https://pubmed.ncbi.nlm.nih.gov/32372775/)]
10. Signorelli C, Scognamiglio T, Odone A. COVID-19 in Italy: impact of containment measures and prevalence estimates of infection in the general population. *Acta Biomed* 2020 Apr 10;91(3-S):175-179 [FREE Full text] [doi: [10.23750/abm.v91i3-S.9511](https://doi.org/10.23750/abm.v91i3-S.9511)] [Medline: [32275287](https://pubmed.ncbi.nlm.nih.gov/32275287/)]
11. The Lancet. India under COVID-19 lockdown. *Lancet* 2020 Apr;395(10233):1315. [doi: [10.1016/s0140-6736\(20\)30938-7](https://doi.org/10.1016/s0140-6736(20)30938-7)]
12. Baumeister RF, Leary MR. The need to belong: desire for interpersonal attachments as a fundamental human motivation. *Psychol Bull* 1995 May;117(3):497-529. [Medline: [7777651](https://pubmed.ncbi.nlm.nih.gov/7777651/)]
13. Bavel JJV, Baicker K, Boggio PS, Capraro V, Cichocka A, Cikara M, et al. Using social and behavioural science to support COVID-19 pandemic response. *Nat Hum Behav* 2020 May;4(5):460-471. [doi: [10.1038/s41562-020-0884-z](https://doi.org/10.1038/s41562-020-0884-z)] [Medline: [32355299](https://pubmed.ncbi.nlm.nih.gov/32355299/)]
14. Wang C, Pan R, Wan X, Tan Y, Xu L, Ho CS, et al. Immediate psychological responses and associated factors during the initial stage of the 2019 coronavirus disease (COVID-19) epidemic among the general population in China. *Int J Environ Res Public Health* 2020 Mar 06;17(5):1729 [FREE Full text] [doi: [10.3390/ijerph17051729](https://doi.org/10.3390/ijerph17051729)] [Medline: [32155789](https://pubmed.ncbi.nlm.nih.gov/32155789/)]
15. Wang C, Pan R, Wan X, Tan Y, Xu L, McIntyre RS, et al. A longitudinal study on the mental health of general population during the COVID-19 epidemic in China. *Brain Behav Immun* 2020 Jul;87:40-48 [FREE Full text] [doi: [10.1016/j.bbi.2020.04.028](https://doi.org/10.1016/j.bbi.2020.04.028)] [Medline: [32298802](https://pubmed.ncbi.nlm.nih.gov/32298802/)]
16. Le HT, Lai AJX, Sun J, Hoang MT, Vu LG, Pham HQ, et al. Anxiety and depression among people under the nationwide partial lockdown in Vietnam. *Front Public Health* 2020 Oct 29;8:589359 [FREE Full text] [doi: [10.3389/fpubh.2020.589359](https://doi.org/10.3389/fpubh.2020.589359)] [Medline: [33194995](https://pubmed.ncbi.nlm.nih.gov/33194995/)]
17. Le XTT, Dang AK, Toweh J, Nguyen QN, Le HT, Do TTT, et al. Evaluating the psychological impacts related to COVID-19 of Vietnamese people under the first nationwide partial lockdown in Vietnam. *Front Psychiatry* 2020 Sep 2;11:824 [FREE Full text] [doi: [10.3389/fpsy.2020.00824](https://doi.org/10.3389/fpsy.2020.00824)] [Medline: [32982807](https://pubmed.ncbi.nlm.nih.gov/32982807/)]
18. Jeste DV, Lee EE, Cacioppo S. Battling the modern behavioral epidemic of loneliness: suggestions for research and interventions. *JAMA Psychiatry* 2020 Jun 01;77(6):553-554. [doi: [10.1001/jamapsychiatry.2020.0027](https://doi.org/10.1001/jamapsychiatry.2020.0027)] [Medline: [32129811](https://pubmed.ncbi.nlm.nih.gov/32129811/)]
19. Mattioli AV, Ballerini Puviani M, Nasi M, Farinetti A. COVID-19 pandemic: the effects of quarantine on cardiovascular risk. *Eur J Clin Nutr* 2020 Jun 05;74(6):852-855 [FREE Full text] [doi: [10.1038/s41430-020-0646-z](https://doi.org/10.1038/s41430-020-0646-z)] [Medline: [32371988](https://pubmed.ncbi.nlm.nih.gov/32371988/)]
20. Mukherjee S. Emerging infectious diseases: epidemiological perspective. *Indian J Dermatol* 2017;62(5):459-467 [FREE Full text] [doi: [10.4103/ijid.IJD\\_379\\_17](https://doi.org/10.4103/ijid.IJD_379_17)] [Medline: [28979007](https://pubmed.ncbi.nlm.nih.gov/28979007/)]
21. Lau JTF, Yang X, Tsui HY, Pang E, Wing YK. Positive mental health-related impacts of the SARS epidemic on the general public in Hong Kong and their associations with other negative impacts. *J Infect* 2006 Aug;53(2):114-124 [FREE Full text] [doi: [10.1016/j.jinf.2005.10.019](https://doi.org/10.1016/j.jinf.2005.10.019)] [Medline: [16343636](https://pubmed.ncbi.nlm.nih.gov/16343636/)]
22. Xiang Y, Yang Y, Li W, Zhang L, Zhang Q, Cheung T, et al. Timely mental health care for the 2019 novel coronavirus outbreak is urgently needed. *Lancet Psychiatry* 2020 Mar;7(3):228-229. [doi: [10.1016/s2215-0366\(20\)30046-8](https://doi.org/10.1016/s2215-0366(20)30046-8)]
23. Rajkumar RP. COVID-19 and mental health: a review of the existing literature. *Asian J Psychiatr* 2020 Aug;52:102066 [FREE Full text] [doi: [10.1016/j.ajp.2020.102066](https://doi.org/10.1016/j.ajp.2020.102066)] [Medline: [32302935](https://pubmed.ncbi.nlm.nih.gov/32302935/)]
24. Balanzá-Martínez V, Atienza-Carbonell B, Kapczinski F, De Boni RB. Lifestyle behaviours during the COVID-19 - time to connect. *Acta Psychiatr Scand* 2020 May;141(5):399-400 [FREE Full text] [doi: [10.1111/acps.13177](https://doi.org/10.1111/acps.13177)] [Medline: [32324252](https://pubmed.ncbi.nlm.nih.gov/32324252/)]
25. Tran BX, Ha GH, Nguyen LH, Vu GT, Hoang MT, Le HT, et al. Studies of novel coronavirus disease 19 (COVID-19) pandemic: a global analysis of literature. *Int J Environ Res Public Health* 2020 Jun 08;17(11):4095 [FREE Full text] [doi: [10.3390/ijerph17114095](https://doi.org/10.3390/ijerph17114095)] [Medline: [32521776](https://pubmed.ncbi.nlm.nih.gov/32521776/)]

26. Loy BD, Cameron MH, O'Connor PJ. Perceived fatigue and energy are independent unipolar states: supporting evidence. *Med Hypotheses* 2018 Apr;113:46-51 [FREE Full text] [doi: [10.1016/j.mehy.2018.02.014](https://doi.org/10.1016/j.mehy.2018.02.014)] [Medline: [29523293](https://pubmed.ncbi.nlm.nih.gov/29523293/)]
27. Lerdal A. A concept analysis of energy. its meaning in the lives of three individuals with chronic illness. *Scand J Caring Sci* 1998;12(1):3-10. [doi: [10.1080/02839319850163075](https://doi.org/10.1080/02839319850163075)] [Medline: [9601440](https://pubmed.ncbi.nlm.nih.gov/9601440/)]
28. Bowling A. Just one question: if one question works, why ask several? *J Epidemiol Community Health* 2005 May 01;59(5):342-345 [FREE Full text] [doi: [10.1136/jech.2004.021204](https://doi.org/10.1136/jech.2004.021204)] [Medline: [15831678](https://pubmed.ncbi.nlm.nih.gov/15831678/)]
29. Chandola T, Jenkinson C. Validating self-rated health in different ethnic groups. *Ethn Health* 2000 May;5(2):151-159. [doi: [10.1080/713667451](https://doi.org/10.1080/713667451)] [Medline: [10984833](https://pubmed.ncbi.nlm.nih.gov/10984833/)]
30. Cislighi B, Cislighi C. Self-rated health as a valid indicator for health-equity analyses: evidence from the Italian health interview survey. *BMC Public Health* 2019 May 09;19(1):533 [FREE Full text] [doi: [10.1186/s12889-019-6839-5](https://doi.org/10.1186/s12889-019-6839-5)] [Medline: [31072306](https://pubmed.ncbi.nlm.nih.gov/31072306/)]
31. Cullati S, Mukhopadhyay S, Sieber S, Chakraborty A, Burton-Jeangros C. Is the single self-rated health item reliable in India? A construct validity study. *BMJ Glob Health* 2018 Nov 09;3(6):e000856 [FREE Full text] [doi: [10.1136/bmjgh-2018-000856](https://doi.org/10.1136/bmjgh-2018-000856)] [Medline: [30483411](https://pubmed.ncbi.nlm.nih.gov/30483411/)]
32. Bačak V, Ólafsdóttir S. Gender and validity of self-rated health in nineteen European countries. *Scand J Public Health* 2017 Aug;45(6):647-653. [doi: [10.1177/1403494817717405](https://doi.org/10.1177/1403494817717405)] [Medline: [28673121](https://pubmed.ncbi.nlm.nih.gov/28673121/)]
33. Park JH, Lee KS. Self-rated health and its determinants in Japan and South Korea. *Public Health* 2013 Sep;127(9):834-843. [doi: [10.1016/j.puhe.2012.12.012](https://doi.org/10.1016/j.puhe.2012.12.012)] [Medline: [23790805](https://pubmed.ncbi.nlm.nih.gov/23790805/)]
34. Goodwin R, Hou WK, Sun S, Ben-Ezra M. Quarantine, distress and interpersonal relationships during COVID-19. *Gen Psychiatr* 2020;33(6):e100385 [FREE Full text] [doi: [10.1136/gpsych-2020-100385](https://doi.org/10.1136/gpsych-2020-100385)] [Medline: [33163857](https://pubmed.ncbi.nlm.nih.gov/33163857/)]
35. Boerma T, Hosseinpoor AR, Verdes E, Chatterji S. A global assessment of the gender gap in self-reported health with survey data from 59 countries. *BMC Public Health* 2016 Jul 30;16(1):675 [FREE Full text] [doi: [10.1186/s12889-016-3352-y](https://doi.org/10.1186/s12889-016-3352-y)] [Medline: [27475755](https://pubmed.ncbi.nlm.nih.gov/27475755/)]
36. Lim GY, Tam WW, Lu Y, Ho CS, Zhang MW, Ho RC. Prevalence of depression in the community from 30 countries between 1994 and 2014. *Sci Rep* 2018 Feb 12;8(1):2861 [FREE Full text] [doi: [10.1038/s41598-018-21243-x](https://doi.org/10.1038/s41598-018-21243-x)] [Medline: [29434331](https://pubmed.ncbi.nlm.nih.gov/29434331/)]
37. Kalish Y, Luria G, Toker S, Westman M. Till stress do us part: on the interplay between perceived stress and communication network dynamics. *J Appl Psychol* 2015 Nov;100(6):1737-1751. [doi: [10.1037/apl0000023](https://doi.org/10.1037/apl0000023)] [Medline: [25867166](https://pubmed.ncbi.nlm.nih.gov/25867166/)]
38. Benyamini Y, Burns E. Views on aging: older adults' self-perceptions of age and of health. *Eur J Ageing* 2020 Dec;17(4):477-487. [doi: [10.1007/s10433-019-00528-8](https://doi.org/10.1007/s10433-019-00528-8)] [Medline: [33381001](https://pubmed.ncbi.nlm.nih.gov/33381001/)]
39. Shanahan L, Steinhoff A, Bechtiger L, Murray AL, Nivette A, Hepp U, et al. Emotional distress in young adults during the COVID-19 pandemic: evidence of risk and resilience from a longitudinal cohort study. *Psychol. Med* 2020 Jun 23:1-10. [doi: [10.1017/s003329172000241x](https://doi.org/10.1017/s003329172000241x)]
40. Kim M, Khang YH. Why do Japan and South Korea record very low levels of perceived health despite having very high life expectancies? *Yonsei Med J* 2019 Oct;60(10):998-1003 [FREE Full text] [doi: [10.3349/ymj.2019.60.10.998](https://doi.org/10.3349/ymj.2019.60.10.998)] [Medline: [31538436](https://pubmed.ncbi.nlm.nih.gov/31538436/)]
41. Shigemura J, Ursano RJ, Morganstein JC, Kurosawa M, Benedek DM. Public responses to the novel 2019 coronavirus (2019-nCoV) in Japan: mental health consequences and target populations. *Psychiatry Clin Neurosci* 2020 Apr;74(4):281-282 [FREE Full text] [doi: [10.1111/pcn.12988](https://doi.org/10.1111/pcn.12988)] [Medline: [32034840](https://pubmed.ncbi.nlm.nih.gov/32034840/)]
42. Park J, Lee K. Self-rated health and its determinants in Japan and South Korea. *Public Health* 2013 Sep;127(9):834-843. [doi: [10.1016/j.puhe.2012.12.012](https://doi.org/10.1016/j.puhe.2012.12.012)] [Medline: [23790805](https://pubmed.ncbi.nlm.nih.gov/23790805/)]
43. Radford MH. Transcultural issues in mood and anxiety disorders: a focus on Japan. *CNS Spectr* 2004 Jun 07;9(6 Suppl 4):6-13. [doi: [10.1017/s1092852900025451](https://doi.org/10.1017/s1092852900025451)] [Medline: [15181380](https://pubmed.ncbi.nlm.nih.gov/15181380/)]
44. Hardy MA, Acciai F, Reyes AM. How health conditions translate into self-ratings: a comparative study of older adults across Europe. *J Health Soc Behav* 2014 Sep 19;55(3):320-341 [FREE Full text] [doi: [10.1177/0022146514541446](https://doi.org/10.1177/0022146514541446)] [Medline: [25138200](https://pubmed.ncbi.nlm.nih.gov/25138200/)]
45. Dwyer MJ, Pasini M, De Dominicis S, Righi E. Physical activity: benefits and challenges during the COVID-19 pandemic. *Scand J Med Sci Sports* 2020 Jul 16;30(7):1291-1294 [FREE Full text] [doi: [10.1111/sms.13710](https://doi.org/10.1111/sms.13710)] [Medline: [32542719](https://pubmed.ncbi.nlm.nih.gov/32542719/)]
46. Mattioli AV, Ballerini Puviani M, Nasi M, Farinetti A. COVID-19 pandemic: the effects of quarantine on cardiovascular risk. *Eur J Clin Nutr* 2020 Jun 05;74(6):852-855 [FREE Full text] [doi: [10.1038/s41430-020-0646-z](https://doi.org/10.1038/s41430-020-0646-z)] [Medline: [32371988](https://pubmed.ncbi.nlm.nih.gov/32371988/)]
47. Gupta R, Hussain A, Misra A. Diabetes and COVID-19: evidence, current status and unanswered research questions. *Eur J Clin Nutr* 2020 Jun 13;74(6):864-870 [FREE Full text] [doi: [10.1038/s41430-020-0652-1](https://doi.org/10.1038/s41430-020-0652-1)] [Medline: [32404898](https://pubmed.ncbi.nlm.nih.gov/32404898/)]
48. Di Renzo L, Gualtieri P, Pivari F, Soldati L, Attinà A, Cinelli G, et al. Eating habits and lifestyle changes during COVID-19 lockdown: an Italian survey. *J Transl Med* 2020 Jun 08;18(1):229 [FREE Full text] [doi: [10.1186/s12967-020-02399-5](https://doi.org/10.1186/s12967-020-02399-5)] [Medline: [32513197](https://pubmed.ncbi.nlm.nih.gov/32513197/)]
49. Ho CS, Chee CY, Ho RC. Mental health strategies to combat the psychological impact of coronavirus disease 2019 (COVID-19) beyond paranoia and panic. *Ann Acad Med Singap* 2020 Mar 31;49(3):155-160. [doi: [10.47102/annals-acadmedsg.202043](https://doi.org/10.47102/annals-acadmedsg.202043)]

50. Zhang MW, Ho RC. Moodle: The cost effective solution for internet cognitive behavioral therapy (I-CBT) interventions. *THC* 2017 Feb 21;25(1):163-165. [doi: [10.3233/thc-161261](https://doi.org/10.3233/thc-161261)]
51. Martino J, Pegg J, Frates EP. The connection prescription: using the power of social interactions and the deep desire for connectedness to empower health and wellness. *Am J Lifestyle Med* 2017 Oct 07;11(6):466-475 [FREE Full text] [doi: [10.1177/1559827615608788](https://doi.org/10.1177/1559827615608788)] [Medline: [30202372](https://pubmed.ncbi.nlm.nih.gov/30202372/)]
52. de Groot LCPMG, Verheijden M, de Henauw S, Schroll M, van Staveren WA, SENECA Investigators. Lifestyle, nutritional status, health, and mortality in elderly people across Europe: a review of the longitudinal results of the SENECA study. *J Gerontol A Biol Sci Med Sci* 2004 Dec;59(12):1277-1284. [doi: [10.1093/gerona/59.12.1277](https://doi.org/10.1093/gerona/59.12.1277)] [Medline: [15699526](https://pubmed.ncbi.nlm.nih.gov/15699526/)]
53. Torri E, Sbrogiò LG, Rosa ED, Cinquetti S, Francia F, Ferro A. Italian public health response to the COVID-19 pandemic: case report from the field, insights and challenges for the department of prevention. *Int J Environ Res Public Health* 2020 May 22;17(10):3666 [FREE Full text] [doi: [10.3390/ijerph17103666](https://doi.org/10.3390/ijerph17103666)] [Medline: [32456072](https://pubmed.ncbi.nlm.nih.gov/32456072/)]
54. Ceylan Z. Estimation of COVID-19 prevalence in Italy, Spain, and France. *Sci Total Environ* 2020 Aug 10;729:138817 [FREE Full text] [doi: [10.1016/j.scitotenv.2020.138817](https://doi.org/10.1016/j.scitotenv.2020.138817)] [Medline: [32360907](https://pubmed.ncbi.nlm.nih.gov/32360907/)]
55. Chao F, Gerland P, Cook AR, Alkema L. Systematic assessment of the sex ratio at birth for all countries and estimation of national imbalances and regional reference levels. *Proc Natl Acad Sci U S A* 2019 May 07;116(19):9303-9311 [FREE Full text] [doi: [10.1073/pnas.1812593116](https://doi.org/10.1073/pnas.1812593116)] [Medline: [30988199](https://pubmed.ncbi.nlm.nih.gov/30988199/)]
56. Bali S, Dhatt R, Lal A, Jama A, Van Daalen K, Sridhar D, Gender and COVID-19 Working Group, Women in Global Health, and Gender and COVID-19 Working Group. Off the back burner: diverse and gender-inclusive decision-making for COVID-19 response and recovery. *BMJ Glob Health* 2020 May 07;5(5):e002595 [FREE Full text] [doi: [10.1136/bmjgh-2020-002595](https://doi.org/10.1136/bmjgh-2020-002595)] [Medline: [32385047](https://pubmed.ncbi.nlm.nih.gov/32385047/)]
57. Wenham C, Smith J, Morgan R. COVID-19: the gendered impacts of the outbreak. *The Lancet* 2020 Mar;395(10227):846-848. [doi: [10.1016/s0140-6736\(20\)30526-2](https://doi.org/10.1016/s0140-6736(20)30526-2)]
58. Perrotta D, Grow A, Rampazzo F, Cimentada J, Del FE, Gil-Clavel S, et al. Behaviors and attitudes in response to the COVID-19 pandemic: insights from a cross-national Facebook survey. *medRxiv*. Preprint posted online on July 15, 2020. [FREE Full text] [doi: [10.1101/2020.05.09.20096388](https://doi.org/10.1101/2020.05.09.20096388)]
59. Wang C, Chudzicka-Czupala A, Grabowski D, Pan R, Adamus K, Wan X, et al. The association between physical and mental health and face mask use during the COVID-19 pandemic: a comparison of two countries with different views and practices. *Front Psychiatry* 2020 Sep 9;11:569981 [FREE Full text] [doi: [10.3389/fpsy.2020.569981](https://doi.org/10.3389/fpsy.2020.569981)] [Medline: [33033485](https://pubmed.ncbi.nlm.nih.gov/33033485/)]

## Abbreviations

**SARS:** severe acute respiratory syndrome

**SVYASA:** Swami Vivekananda Yoga Anusandhana Samsthana

**WHO:** World Health Organization

*Edited by G Eysenbach; submitted 18.08.20; peer-reviewed by P Mathur, R Ho, A Videira-Silva; comments to author 26.10.20; revised version received 03.12.20; accepted 11.04.21; published 01.06.21.*

*Please cite as:*

Manjunath NK, Majumdar V, Rozzi A, Huiro W, Mishra A, Kimura K, Nagarathna R, Nagendra HR  
Health Perceptions and Adopted Lifestyle Behaviors During the COVID-19 Pandemic: Cross-National Survey  
*JMIR Form Res* 2021;5(6):e23630

URL: <https://formative.jmir.org/2021/6/e23630>

doi: [10.2196/23630](https://doi.org/10.2196/23630)

PMID: [33900928](https://pubmed.ncbi.nlm.nih.gov/33900928/)

©Nandi Krishnamurthy Manjunath, Vijaya Majumdar, Antonietta Rozzi, Wang Huiro, Avinash Mishra, Keishin Kimura, Raghuram Nagarathna, Hongasandra Ramarao Nagendra. Originally published in *JMIR Formative Research* (<https://formative.jmir.org/>), 01.06.2021. This is an open-access article distributed under the terms of the Creative Commons Attribution License (<https://creativecommons.org/licenses/by/4.0/>), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in *JMIR Formative Research*, is properly cited. The complete bibliographic information, a link to the original publication on <https://formative.jmir.org/>, as well as this copyright and license information must be included.

## Short Paper

# Acceptability of Research and Health Care Visits During the COVID-19 Pandemic: Cross-sectional Survey Study

Kathryn M Ross<sup>1,2</sup>, MPH, PhD; Young-Rock Hong<sup>3</sup>, PhD, MPH; Rebecca A Krukowski<sup>4</sup>, PhD; Darci R Miller<sup>3</sup>, MPH; Dominick J Lemas<sup>3</sup>, PhD; Michelle I Cardel<sup>2,3</sup>, PhD

<sup>1</sup>Department of Clinical and Health Psychology, College of Public Health and Health Professions, University of Florida, Gainesville, FL, United States

<sup>2</sup>Center for Integrative Cardiovascular and Metabolic Diseases, University of Florida, Gainesville, FL, United States

<sup>3</sup>Department of Health Outcomes and Biomedical Informatics, College of Medicine, University of Florida, Gainesville, FL, United States

<sup>4</sup>Department of Preventive Medicine, College of Medicine, University of Tennessee Health Science Center, Memphis, TN, United States

**Corresponding Author:**

Kathryn M Ross, MPH, PhD

Department of Clinical and Health Psychology

College of Public Health and Health Professions

University of Florida

PO Box 10065

Gainesville, FL, 32610

United States

Phone: 1 3522948433

Email: [kmross@phhp.ufl.edu](mailto:kmross@phhp.ufl.edu)

## Abstract

**Background:** The COVID-19 pandemic has had a widespread impact on attendance in biomedical research and health care visits.

**Objective:** This study aimed to identify when and how American adults might feel comfortable about resuming in-person research and health care visits.

**Methods:** Cross-sectional questionnaire data were collected from 135 adults (age: median 48 years; women: n=113, 83.7%; White participants: n=92, 68.2%) who were engaged in health-related research.

**Results:** More than half of the respondents (65/122, 53.3%) felt that the COVID-19 pandemic positively affected their desire to participate in research. Although 73.6% (95/129) of respondents also indicated a willingness to attend in-person health care visits while Centers for Disease Control and Prevention (CDC) guidelines are implemented, 85.8% (109/127) indicated a willingness to attend in-person, outdoor visits, and 92.2% (118/128) reported a willingness to attend drive-through visits (with CDC guidelines implemented during both visit types). Videoconferencing was the most preferred format for intervention visits; however, adults over the age of 65 years preferred this format less than younger adults ( $P=.001$ ).

**Conclusions:** Researchers and clinicians should continue to provide opportunities for continuing the conduction of remote-based interventions while enforcing CDC guidelines during in-person visits.

(JMIR Form Res 2021;5(6):e27185) doi:[10.2196/27185](https://doi.org/10.2196/27185)

**KEYWORDS**

COVID-19; health care access; telehealth; research recruitment; telemedicine; belief; access; willingness; cross-sectional; survey

## Introduction

Lockdown and stay-at-home orders that were enacted to contain the spread of COVID-19 [1] have disrupted biomedical research and health care [2,3]. There has been a rapid increase in the adoption of telehealth methods that provide remote care delivery [4,5], which has offset some of the impacts of the COVID-19 pandemic [6]; however, it remains important to understand how

to resume the provision of research and clinical care in a manner that individuals feel is safe. Identifying these factors could provide insights into feasible and acceptable approaches to conducting research and health care visits both during the ongoing pandemic surge and, importantly, during future postpandemic recovery [7]. Thus, this study investigated the acceptability of in-person and remote research and health care visits during the COVID-19 pandemic in order to characterize



when and how American adults would feel comfortable about resuming research and health care–related clinic visits.

## Methods

This study was a cross-sectional analysis of US adults who were enrolled in biomedical research studies. An email describing this study and a link for participating in the web-based survey was sent to 250 adults who had previously completed a survey that assessed COVID-19 impacts on research participation and mental health outcomes [8], and additional participants were recruited through professional networks. Networks included colleagues of study investigators who were conducting behavioral intervention trials across the United States. They were informed via email and social media (Facebook and Twitter) to share the study information and survey link with participants who were enrolled in their studies. Potential respondents who clicked the survey link were provided with a description of this study and were asked to provide informed consent before completing the survey. Consent was obtained and data were collected via REDCap (Research Electronic Data Capture; Vanderbilt University) [9] between September 17 and October 17, 2020.

The 87-item questionnaire, which was developed by the study team, was used to collect sociodemographic information (ie, age, gender, race and ethnicity, educational attainment, and household income), query respondents about the number of underlying health conditions that were suspected to increase COVID-19 severity [10], and ask other questions about physical and mental health and research participation. This study used data collected from 10 items that focused on engagement with research and the willingness to attend research and health care visits (Multimedia Appendix 1). The University of Florida Institutional Review Board provided ethical approval for this study.

Descriptive statistics were computed to describe research participation and health care engagement. In total, 3 items for querying respondents about their beliefs regarding participating in research and whether the COVID-19 pandemic has positively or negatively affected their desire to participate in research were scored on 5-point, Likert-style scales (Multimedia Appendix 1). For analysis purposes, responses to each item were converted into binary indicators; “Not at all” was categorized as “No,” and the responses “A little bit,” “Moderately,” “Quite a bit,” and “Extremely” were categorized as “Yes.” Furthermore, 4 items for querying respondents about their willingness to attend various types of health care visits were scored on a 3-point scale. Similarly, binary variables were used to indicate whether a respondent would feel comfortable with each health care visit type (ie, in-person visits, outdoor visits, and drive-through clinic visits). Chi-square and Fisher exact tests were used for bivariate analyses involving participants’ age, gender, and race. Analyses were conducted by using SAS (Statistical Analysis System) version 9.4 (SAS Institute), and statistical significance was assessed based on a 2-sided *P* value of <.05. Study findings were reported by using the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines.

## Results

Responses were collected from 135 adults participating in biomedical research. Table 1 provides the full sample’s characteristics (see Multimedia Appendix 2 for a correlation table between these variables). The median age of respondents was 48 years, and the sample was predominately female (113/135, 83.7%) and Non-Hispanic White (92/135, 68.2%). Moreover, the sample was highly educated (at least a college degree: 103/135, 76.3%), had generally high incomes (respondents reporting a household income of ≥US \$75,000 per year: 77/135, 57.1%), and was well-insured (respondents reporting having private or public health insurance: 127/135, 94.1%).



**Table 1.** Sample characteristics.

| Characteristic                                | Value      |
|---|------------|
| Age (years), median (IQR)                     | 48 (38-57) |
| <b>Age group (years), n (%)</b>               |            |
| 18-39   | 40 (29.6)  |
| 40-54   | 50 (37)    |
| 55-64   | 28 (20.7)  |
| ≥65   | 17 (12.6)  |
| <b>Gender, n (%)</b>                          |            |
| Women   | 113 (83.7) |
| Men   | 22 (16.3)  |
| <b>Race and ethnicity, n (%)</b>              |            |
| Non-Hispanic White                            | 92 (68.2)  |
| Non-Hispanic Black                            | 11 (8.1)   |
| Hispanic                                      | 7 (5.2)    |
| Asian   | 2 (1.5)    |
| Other or multiple races                       | 23 (17)    |
| <b>Education, n (%)</b>                       |            |
| High school or less                           | 6 (4.4)    |
| Some college                                  | 26 (19.3)  |
| College graduate                              | 31 (23)    |
| Some graduate or professional                 | 13 (9.6)   |
| Graduate or professional degree               | 59 (43.7)  |
| <b>Household income (US \$), n (%)</b>        |            |
| <25,000                                       | 19 (14.1)  |
| 25,000-49,999                                 | 23 (17)    |
| 50,000-74,999                                 | 16 (11.9)  |
| 75,000-99,999                                 | 21 (15.6)  |
| ≥100,000                                      | 56 (41.5)  |
| <b>Health insurance, n (%)</b>                |            |
| Private                                       | 92 (68.2)  |
| Public  | 35 (25.9)  |
| Uninsured                                     | 8 (5.9)    |
| <b>Number of underlying conditions, n (%)</b> |            |
| 0   | 98 (72.6)  |
| 1   | 29 (21.5)  |
| ≥2  | 8 (5.9)    |

Table 2 presents participants' beliefs and willingness to attend research and health care-related clinic visits. Respondents were more likely to indicate that the COVID-19 pandemic positively (vs negatively) impacted their desire to participate in research (65/122, 53.3% vs 49/122, 40.2%;  $P=.04$ ). Moreover, a majority of respondents (77/120, 64.2%) indicated that they did not believe that such participation put them at greater risk of

contracting COVID-19. The most preferred methods of engaging in behavioral interventions included videoconferencing (60.7%) and in-person sessions (53.3%). Regarding future research participation, respondents were most interested in engaging in clinical (108/135, 80%) and public health research (85/135, 63%) and were least interested in vaccine development research (59/135, 43.7%).

**Table 2.** Research participants' preferences for engaging in research and clinical care during the COVID-19 pandemic.

| Questions and responses  | Value, n (%) <sup>a</sup> |
|--|---------------------------|
| <b>Research participation</b>  |                           |
| <b>Do you believe that participating in research puts you more at risk for COVID-19?</b>   |                           |
| No (not at all)  | 77 (64.2)                 |
| Yes (a little bit to extremely)  | 43 (35.8)                 |
| <b>Has COVID-19 positively affected your desire to participate in research?</b>  |                           |
| No (not at all)  | 57 (46.7)                 |
| Yes (a little bit to extremely)  | 65 (53.3)                 |
| <b>Has COVID-19 negatively affected your desire to participate in research?</b>  |                           |
| No (not at all)  | 73 (59.8)                 |
| Yes (a little bit to extremely)  | 49 (40.2)                 |
| <b>What type of research would you be interested in participating in at a future time? (multiple responses allowed)</b>                                    |                           |
| Public health (eg, hand washing to prevent flu)  | 85 (63)                   |
| Emergency preparedness (eg, preparing for a natural disaster)  | 68 (50.4)                 |
| Vaccine development (eg, COVID-19 vaccine development)   | 59 (43.7)                 |
| Clinical research (eg, studies that help you improve your own health)  | 108 (80)                  |
| <b>Clinic visit</b>  |                           |
| <b>Attending in-person clinic visits during the COVID-19 pandemic while adhering to social distancing, sanitation, and mask-wearing protocols</b>          |                           |
| Not comfortable  | 34 (26.4)                 |
| Somewhat or very comfortable   | 95 (73.6)                 |
| <b>Attending in-person, outdoor clinic visits during the COVID-19 pandemic while adhering to social distancing, sanitation, and mask-wearing protocols</b> |                           |
| Not comfortable  | 18 (14.2)                 |
| Somewhat or very comfortable   | 109 (85.8)                |
| <b>Attending drive-through clinic visits during the COVID-19 pandemic with masks</b>   |                           |
| Not comfortable  | 10 (7.8)                  |
| Somewhat or very comfortable   | 118 (92.2)                |
| <b>Attending drive-through clinic visits during the COVID-19 pandemic without masks</b>  |                           |
| Not comfortable  | 76 (59.8)                 |
| Somewhat or very comfortable   | 51 (40.2)                 |
| <b>At what point would you be willing to go back to in-person clinic visits? (multiple responses allowed)</b>  |                           |
| When there is a COVID-19 vaccine   | 41 (30.4)                 |
| When there is a medication for effectively treating COVID-19   | 30 (22.2)                 |
| When cases have decreased in my area for 2 weeks or more   | 23 (17)                   |
| When hospitals have the capacity to treat cases  | 10 (7.4)                  |
| I already feel comfortable attending an in-person clinic visit   | 71 (52.6)                 |
| I don't think I will feel comfortable going to an in-person visit until there are no cases of COVID-19 in the United States                                | 8 (5.9)                   |
| <b>What is your preferred way of engaging in treatment if enrolled in behavioral intervention? (multiple responses allowed)</b>                            |                           |
| In person  | 72 (53.3)                 |
| Phone  | 49 (36.3)                 |
| Videoconferencing platforms (eg, Zoom and Google Hangouts)   | 82 (60.7)                 |
| Other platforms (eg, Slack, WeChat, and GroupMe)   | 33 (24.4)                 |

<sup>a</sup>Sample size is not equal across questions due to missing responses.

Almost three-quarters of respondents (95/129, 73.6%) felt comfortable with attending in-person, indoor clinic visits, and over 85% felt comfortable with attending outdoor (109/127, 85.8%) and drive-through (118/128, 92.2%) clinic visits while adhering to Centers for Disease Control and Prevention (CDC) guidelines (social distancing, sanitation, and mask wearing; Table 2). Although respondents indicated the highest level of comfort with attending drive-through visits while wearing a mask (118/128, 92.2%), fewer respondents were comfortable with attending drive-through visits without masks (51/127, 40.2%). Over half of the respondents (71/135, 52.6%) reported a willingness to attend in-person clinic visits at the time the survey was conducted; one-third (41/135, 30.4%) reported a willingness to attend in-person clinic visits when there is a COVID-19 vaccine, and over 20% (30/135) reported a willingness to attend in-person clinic visits when there is a medication for effectively treating COVID-19. Fewer participants reported considering local or national case counts (23/135, 17% and 8/135, 5.9%, respectively) or hospital capacity for treating COVID-19 cases (10/135, 7.4%) when determining their willingness to attend in-person clinic visits.

There were no significant differences between men and women or between White participants and people of color in terms of responses for any survey items (all *P* values were  $>.05$ ); however, younger adults (aged 18-64 years) were significantly more likely to report feeling comfortable with videoconferencing platforms than adults over the age of 65 (78/118, 66.1% vs 4/17, 23.5%;  $P=.001$ ).

## Discussion

Research participants felt that engaging in biomedical research studies did not increase their personal risk of contracting COVID-19 and were interested in future research activities. Interestingly, over half of respondents indicated that the COVID-19 pandemic positively impacted their desire to participate in research (65/122, 53.3%), and fewer indicated that the COVID-19 pandemic had a negative impact (49/122, 40.2%). Although we do not have additional data to explain this finding, it is possible that the greater news coverage of biomedical research during the pandemic has increased individuals' appreciation for this scientific process [11] and increased individuals' interest in participating in research. It also may be possible that some individuals (especially younger adults and those with high incomes [12,13]) have experienced increased scheduling flexibility due to the pandemic (eg, due to cancelled travel and events and restrictions on many leisure-time activities [14]) and thus may have more free time to participate in research.

With the ongoing pandemic, most respondents reported a willingness to attend in-person, health care-related clinic visits while adhering to CDC guidelines (95/129, 73.6%); however, even more were comfortable with outdoor (109/127, 85.8%) and drive-through (118/128, 92.2%) formats. Our results also

suggested that the availability of vaccines and effective COVID-19 treatments may improve individuals' willingness to resume attending in-person clinic visits. Overall, videoconferencing was the most preferred format. Videoconferencing offers greater flexibility in scheduling compared to in-person visits, and this format can also retain the visual cues (eg, eye contact and body language) that are lost in phone-based delivery formats [15]. The increased use of smartphones and other mobile devices [16] coupled with advances in mobile internet speeds have made videoconferencing an accessible delivery format for a large proportion of the population, although access to unlimited data packages and poor coverage (eg, in rural areas) still remain substantial barriers for many people [17]. Considerations should also be made regarding the technology literacy of target populations (eg, our results demonstrated that adults over the age of 65 preferred this format less than younger adults).

Taken together with other findings that support the role of telehealth approaches in health care delivery [15], our results suggest that researchers and clinicians should provide opportunities for continuing the conduction of remote-based intervention after the pandemic. As research and health care centers move beyond stopgap telehealth approaches, such opportunities will require the development of sustainable, secure telehealth systems that can link to existing medical record networks, provide access to affiliate providers, and provide critical data security and patient privacy [7].

The limitations to this study included the use of a convenience sample of biomedical research participants that consisted predominately of highly educated White women with health insurance. Although this sample is generally reflective of research populations within the nutrition and obesity intervention fields [18,19], this limited our results' generalizability to other populations. The fact that respondents were already participating in biomedical research may have also resulted in bias, as personal experiences with web-based or in-person research may affect the perceived acceptability of these formats and promote a greater willingness to participate in future research studies. Further, due to the descriptive nature of the analysis, additional studies (including those with larger and more generalizable samples) are necessary to replicate our results and to explore other facilitators and barriers to attending health-related research and clinic visits. Finally, there were no approved vaccines for COVID-19 at the time when the questionnaire was distributed; however, several vaccines have since received approval in the United States [20,21], with distribution starting in early December 2020 [22]. Thus, future studies should assess whether the actual (vs hypothetical) availability of these vaccines affects individuals' willingness to attend research and clinic appointments (especially given the unexpectedly high prevalence of vaccine hesitancy during the initial vaccine rollouts [23]). Despite these limitations, the results from this study provide timely evidence for informing practitioners and researchers about how to reopen and resume research and clinic operations.

## Acknowledgments

There was no funding source to support the work conducted herein. KMR is supported by the National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) under award R01DK119244 and the National Institutes of Health, National Heart, Lung, and Blood Institute (NHLBI) under award R03HL154272. RAK is supported by the NIDDK under award numbers R01DK104872 and R01DK107747. DJL is supported by the NIDDK under award K01DK115632. MIC is supported by the NHLBI under award K01HL141535 and the National Center for Advancing Translational Sciences under award ULTR001427.

## Authors' Contributions

All authors contributed to the study design, development of the questionnaire, drafting of the manuscript, and review of the final manuscript. YRH conducted the data analyses.

## Conflicts of Interest

None declared.

### Multimedia Appendix 1

Survey questions used in this study.

[DOCX File, 28 KB - [formative\\_v5i6e27185\\_app1.docx](#)]

### Multimedia Appendix 2

Correlation matrix between the sample's characteristics.

[DOCX File, 19 KB - [formative\\_v5i6e27185\\_app2.docx](#)]

## References

- Chatterjee A, Gerdes MW, Martinez SG. Statistical explorations and univariate timeseries analysis on COVID-19 datasets to understand the trend of disease spreading and death. *Sensors (Basel)* 2020 May 29;20(11):3089 [FREE Full text] [doi: [10.3390/s20113089](#)] [Medline: [32486055](#)]
- Ziedan E, Simon KI, Wing C. Effects of state COVID-19 closure policy on Non-COVID-19 health care utilization. National Bureau of Economic Research. 2020 Jul. URL: [https://www.nber.org/system/files/working\\_papers/w27621/w27621.pdf](https://www.nber.org/system/files/working_papers/w27621/w27621.pdf) [accessed 2021-05-06]
- Asaad M, Habibullah NK, Butler CE. The impact of COVID-19 on clinical trials. *Ann Surg* 2020 Sep 01;272(3):e222-e223 [FREE Full text] [doi: [10.1097/SLA.0000000000004113](#)] [Medline: [32541234](#)]
- Augenstein J. Opportunities to expand telehealth use amid the coronavirus pandemic. *Health Affairs Blog*. 2020 Mar 16. URL: <https://www.healthaffairs.org/doi/10.1377/hblog20200315.319008/full/> [accessed 2021-02-18]
- Galewitz P. Telemedicine surges, fueled by coronavirus fears and shift in payment rules. *Kaiser Health News*. 2020 Mar 27. URL: <https://khn.org/news/telemedicine-surges-fueled-by-coronavirus-fears-and-shift-in-payment-rules/> [accessed 2021-02-18]
- Baum A, Kaboli PJ, Schwartz MD. Reduced in-person and increased telehealth outpatient visits during the COVID-19 pandemic. *Ann Intern Med* 2021 Jan;174(1):129-131 [FREE Full text] [doi: [10.7326/M20-3026](#)] [Medline: [32776780](#)]
- Wosik J, Fudim M, Cameron B, Gellad ZF, Cho A, Phinney D, et al. Telehealth transformation: COVID-19 and the rise of virtual care. *J Am Med Inform Assoc* 2020 Jun 01;27(6):957-962 [FREE Full text] [doi: [10.1093/jamia/ocaa067](#)] [Medline: [32311034](#)]
- Cardel MI, Manasse S, Krukowski RA, Ross K, Shakour R, Miller DR, et al. COVID-19 impacts mental health outcomes and ability/desire to participate in research among current research participants. *Obesity (Silver Spring)* 2020 Dec;28(12):2272-2281 [FREE Full text] [doi: [10.1002/oby.23016](#)] [Medline: [32845582](#)]
- Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform* 2009 Apr;42(2):377-381 [FREE Full text] [doi: [10.1016/j.jbi.2008.08.010](#)] [Medline: [18929686](#)]
- Richardson S, Hirsch JS, Narasimhan M, Crawford JM, McGinn T, Davidson KW, the Northwell COVID-19 Research Consortium, et al. Presenting characteristics, comorbidities, and outcomes among 5700 patients hospitalized with COVID-19 in the New York City area. *JAMA* 2020 May 26;323(20):2052-2059 [FREE Full text] [doi: [10.1001/jama.2020.6775](#)] [Medline: [32320003](#)]
- State of Science Index Survey. 3M. URL: [https://www.3m.com/3M/en\\_US/state-of-science-index-survey/](https://www.3m.com/3M/en_US/state-of-science-index-survey/) [accessed 2021-02-18]
- Belot M, Choi S, Tripodi E, van den Broek-Altenburg E, Jamison JC, Papageorge NW. Unequal consequences of COVID-19 across age and income: Representative evidence from six countries. *IZA Institute of Labor Economics*. 2020 Jun. URL: <http://ftp.iza.org/dp13366.pdf> [accessed 2021-05-26]

13. Papageorge NW, Zahn MV, Belot M, van den Broek-Altenburg E, Choi S, Jamison JC, et al. Socio-demographic factors associated with self-protecting behavior during the Covid-19 pandemic. *J Popul Econ* 2021 Jan 14;1-48 [FREE Full text] [doi: [10.1007/s00148-020-00818-x](https://doi.org/10.1007/s00148-020-00818-x)] [Medline: [33462529](https://pubmed.ncbi.nlm.nih.gov/33462529/)]
14. Stodolska M. #QuarantineChallenge2k20: Leisure in the time of the pandemic. *Leis Sci* 2020 Jun 24;43(1-2):232-239 [FREE Full text] [doi: [10.1080/01490400.2020.1774007](https://doi.org/10.1080/01490400.2020.1774007)]
15. Isautier JM, Copp T, Ayre J, Cvejic E, Meyerowitz-Katz G, Batcup C, et al. People's experiences and satisfaction with telehealth during the COVID-19 pandemic in Australia: Cross-sectional survey study. *J Med Internet Res* 2020 Dec 10;22(12):e24531 [FREE Full text] [doi: [10.2196/24531](https://doi.org/10.2196/24531)] [Medline: [33156806](https://pubmed.ncbi.nlm.nih.gov/33156806/)]
16. Mobile fact sheet. Pew Research Center. URL: <https://www.pewresearch.org/internet/fact-sheet/mobile/> [accessed 2021-02-18]
17. Perrin A. Digital gap between rural and nonrural America persists. Pew Research Center. 2019 May 31. URL: <https://www.pewresearch.org/fact-tank/2019/05/31/digital-gap-between-rural-and-nonrural-america-persists/> [accessed 2021-02-18]
18. Pagoto SL, Schneider KL, Oleski JL, Luciani JM, Bodenlos JS, Whited MC. Male inclusion in randomized controlled trials of lifestyle weight loss interventions. *Obesity (Silver Spring)* 2012 Jun;20(6):1234-1239 [FREE Full text] [doi: [10.1038/oby.2011.140](https://doi.org/10.1038/oby.2011.140)] [Medline: [21633403](https://pubmed.ncbi.nlm.nih.gov/21633403/)]
19. Haughton CF, Silfee VJ, Wang ML, Lopez-Cepero AC, Estabrook DP, Frisard C, et al. Racial/ethnic representation in lifestyle weight loss intervention studies in the United States: A systematic review. *Prev Med Rep* 2018 Feb 02;9:131-137 [FREE Full text] [doi: [10.1016/j.pmedr.2018.01.012](https://doi.org/10.1016/j.pmedr.2018.01.012)] [Medline: [29616185](https://pubmed.ncbi.nlm.nih.gov/29616185/)]
20. Tanne JH. Covid-19: FDA panel votes to approve Pfizer BioNTech vaccine. *BMJ* 2020 Dec 11;371:m4799. [doi: [10.1136/bmj.m4799](https://doi.org/10.1136/bmj.m4799)] [Medline: [33310748](https://pubmed.ncbi.nlm.nih.gov/33310748/)]
21. Tanne JH. Covid-19: FDA authorizes Moderna vaccine as US starts vaccinating health workers. *BMJ* 2020 Dec 21;371:m4924 [FREE Full text] [doi: [10.1136/bmj.m4924](https://doi.org/10.1136/bmj.m4924)]
22. Tanne JH. Covid-19: Pfizer-BioNTech vaccine is rolled out in US. *BMJ* 2020 Dec 14;371:m4836. [doi: [10.1136/bmj.m4836](https://doi.org/10.1136/bmj.m4836)] [Medline: [33318040](https://pubmed.ncbi.nlm.nih.gov/33318040/)]
23. Coustasse A, Kimble C, Maxik K. COVID-19 and Vaccine Hesitancy: A Challenge the United States Must Overcome. *J Ambul Care Manage* 2021;44(1):71-75. [doi: [10.1097/JAC.0000000000000360](https://doi.org/10.1097/JAC.0000000000000360)] [Medline: [33165121](https://pubmed.ncbi.nlm.nih.gov/33165121/)]

## Abbreviations

**CDC:** Centers for Disease Control and Prevention

**NHLBI:** National Heart, Lung, and Blood Institute

**NIDDK:** National Institute of Diabetes and Digestive and Kidney Diseases

**REDCap:** Research Electronic Data Capture

**SAS:** Statistical Analysis System

**STROBE:** Strengthening the Reporting of Observational Studies in Epidemiology

*Edited by G Eysenbach; submitted 14.01.21; peer-reviewed by R Daryabeygi, A Chatterjee, S Mahalingaiah; comments to author 09.02.21; revised version received 23.02.21; accepted 22.04.21; published 02.06.21.*

*Please cite as:*

Ross KM, Hong YR, Krukowski RA, Miller DR, Lemas DJ, Cardel MI

Acceptability of Research and Health Care Visits During the COVID-19 Pandemic: Cross-sectional Survey Study

*JMIR Form Res* 2021;5(6):e27185

URL: <https://formative.jmir.org/2021/6/e27185>

doi: [10.2196/27185](https://doi.org/10.2196/27185)

PMID: [34033577](https://pubmed.ncbi.nlm.nih.gov/34033577/)

©Kathryn M Ross, Young-Rock Hong, Rebecca A Krukowski, Darci R Miller, Dominick J Lemas, Michelle I Cardel. Originally published in *JMIR Formative Research* (<https://formative.jmir.org>), 02.06.2021. This is an open-access article distributed under the terms of the Creative Commons Attribution License (<https://creativecommons.org/licenses/by/4.0/>), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in *JMIR Formative Research*, is properly cited. The complete bibliographic information, a link to the original publication on <https://formative.jmir.org>, as well as this copyright and license information must be included.



---

Publisher:  
JMIR Publications  
130 Queens Quay East.  
Toronto, ON, M5A 3Y5  
Phone: (+1) 416-583-2040  
Email: [support@jmir.org](mailto:support@jmir.org)

---

<https://www.jmirpublications.com/>