JMIR Formative Research

Impact Factor (2022): 2.2
Volume 5 (2021), Issue 7 ISSN 2561-326X Editor in Chief: Gunther Eysenbach, MD, MPH, FACMI

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Original Paper

Executive Function After Prenatal Alcohol Exposure in Children in a South African Population: Cross-sectional Study

Jacobus Gidion Louw[1,2,3*], MA; Alastair van Heerden[4,5*], PhD; Leana Olivier[1*], PhD; Tersius Lambrechts[2*], BA; Mandi Broodryk[1*], MA; Liska Bunge[1*], BA; Martlé Vosloo[1*], BA; Mark Tomlinson[3,6*], PhD

[1]Foundation for Alcohol Related Research, Cape Town, South Africa

[2]Department of Psychology, Stellenbosch University, Stellenbosch, South Africa

[3]Institute for Life Course Health Research, Department of Global Health, Faculty of Medicine and Health Sciences, Stellenbosch University, Cape Town, South Africa

[4]Centre for Community Based Research, Human Sciences Research Council, Pietermaritzburg, South Africa

[5]Developmental Pathways for Health Research Unit, Department of Paediatrics, Faculty of Health Science, University of the Witwatersrand/Medical Research Council, Johannesburg, South Africa

[6]School of Nursing and Midwifery, Queens University, Belfast, United Kingdom

[*]all authors contributed equally

Corresponding Author:
Jacobus Gidion Louw, MA
Foundation for Alcohol Related Research
42 Bloemhof Street
Bellville
Cape Town, 7535
South Africa
Phone: 27 216862646
Email: jl@farrsa.org.za

Abstract

Background: Alcohol is a teratogen; its consumption during pregnancy can lead to negative birth outcomes, collectively referred to as fetal alcohol spectrum disorders. Neurodevelopmental delays in higher-order cognitive functions that affect development of executive functions are a common feature. Studies on executive function in children have focused on children diagnosed with fetal alcohol spectrum disorder, and there is a lack of information on the impact on children not diagnosed with fetal alcohol spectrum disorder but who had been exposed to alcohol.

Objective: The aim of this study was to compare the development of executive function in children between 4 and 6 years of age with and without prenatal exposure to alcohol.

Methods: Children both exposed and not exposed to alcohol were recruited as part of a feasibility RCT evaluating a computer-based cognitive training program for improving executive function development. The study was conducted in a low–socioeconomic status community in South Africa with a high prevalence of fetal alcohol spectrum disorder. Neurodevelopment was assessed in participating children; NEPSY-II standardized scores for executive function domains were compared using a multivariate analysis of variance with group membership as the predictor variable.

Results: No significant differences in executive functions assessments (P=.39) were found between children in the alcohol-exposed group (n=76) and those in the nonexposed group (n=40). Both groups showed moderate to severe delays in domains. In all but one subtest, the average score for both groups was below the 25th percentile of expected norms.

Conclusions: We expected that alcohol exposure would have a measurable impact on executive function development. The lack of differences highlights the prevalence of developmental delays in low–socioeconomic status communities in South Africa and suggests that children are exposed to various threats to cognitive development.

International Registered Report Identifier (IRRID): RR2-10.2196/14489

(JMIR Form Res 2021;5(7):e20658) doi:10.2196/20658

KEYWORDS

fetal alcohol spectrum disorders; FASD; cognitive; executive function; experimental games; brain drug effects; child development; serious games; games; alcohol; training

Introduction

Prenatal Alcohol Exposure

Alcohol is a known teratogen when consumed during pregnancy and can lead to a number of negative outcomes including a characteristic pattern of dysmorphic facial features, growth retardation, deficient brain growth, and neurodevelopmental delays in the newborn child [1,2]. These outcomes vary in their presentation and severity and are grouped as fetal alcohol spectrum disorders. Diagnostic labels are assigned based on the number and pattern of associated characteristics of fetal alcohol spectrum disorder that are present. There are 4 diagnostic categories: fetal alcohol syndrome, partial fetal alcohol syndrome, alcohol-related neurodevelopmental disorder, and alcohol-related birth defects [1,3]. Apart from alcohol-related birth defects, neurodevelopmental delays are a common feature of all diagnoses [1].

The most common form of fetal alcohol spectrum disorder is alcohol-related neurodevelopmental disorder, for which physical features are not evident. As such, it is also the most difficult of the fetal alcohol spectrum disorders to diagnose [4]. The lack of observable physical features does not mean that the neurodevelopmental delays are less pronounced or serious than those in children with fetal alcohol syndrome. Affected individuals can have the full range of cognitive impairments associated with the other diagnoses [1,5,6]. It is important, therefore, to bear in mind that even if a person exposed to alcohol in utero does not meet fetal alcohol spectrum disorder criteria, there can still be negative developmental sequelae.

Fetal Alcohol Spectrum Disorder and Executive Function

Elementary and higher-order intellectual functions can be affected in individuals with fetal alcohol spectrum disorder, and dysfunction can be present regardless of whether the physical features of fetal alcohol spectrum disorder are present [7]. Some areas of particular concern include general intellectual ability [7-10], memory and learning [8,11,12], adaptive living skills [10], and executive functions [10,13,14].

Deficits in executive function are hallmarks of fetal alcohol spectrum disorder, with far-reaching consequences for affected individuals [7,8,13]. The term *executive functions* refers to a group of cognitive domains involved in guiding thoughts and goal-directed behavior [15]. The 3 main executive functions are inhibitory control, cognitive flexibility, and working memory [16,17], which are required for, among others, inhibiting inappropriate responses, task planning, and emotional regulation. These areas are also required for self-monitoring performance to identify and self-correct errors. Dysfunction in these areas is, therefore, associated with poor academic outcomes, behavioral problems, mental disorders, and difficulties in daily functioning [7,13,16,18].

Cognitive Training of Executive Function

Executive function in children is amenable to intervention [19-21]. There is considerable evidence that, when specific executive function processes are trained, improvements from training are also evident in similar domains [16,21,22], such as structurally similar cognitive training tasks, which is referred to as *near transfer* [23]. There is also limited evidence for far transfer, which is the transfer of improvements between structurally different tasks or fluid intelligence that depends on executive function [21,22]. Improvements are more pronounced in children with delays in executive function, which has been found in children with fetal alcohol spectrum disorder [16]. Because far transfer is not guaranteed, it is important to target the most significant areas of deficit for training through the intervention. A distinct profile of attention deficits may exist in children with fetal alcohol spectrum disorder, which could highlight where efforts need to be focused [24]. Studies in this field have focused on children who have already been diagnosed with fetal alcohol spectrum disorder [14,20,25]; however, a number of children affected by prenatal alcohol exposure may not meet the criteria for fetal alcohol spectrum disorder diagnosis and may be overlooked in epidemiological studies [26].

Study Aim and Hypothesis

If a diagnosis of fetal alcohol spectrum disorder is required for inclusion in studies on prenatal alcohol exposure's effect on executive function, the picture of alcohol's impact in utero will be incomplete. The aim of this paper was to compare executive function in children who had been exposed with those who had not been exposed to alcohol during prenatal development. Data for the analyses were obtained as part of a feasibility RCT of a computer-based cognitive training game. Assessments of executive function were conducted on children both exposed and nonexposed to alcohol. The primary hypothesis for this paper was that children in the alcohol-exposed group would perform poorer than those in the nonexposed group on standardized measures of executive function.

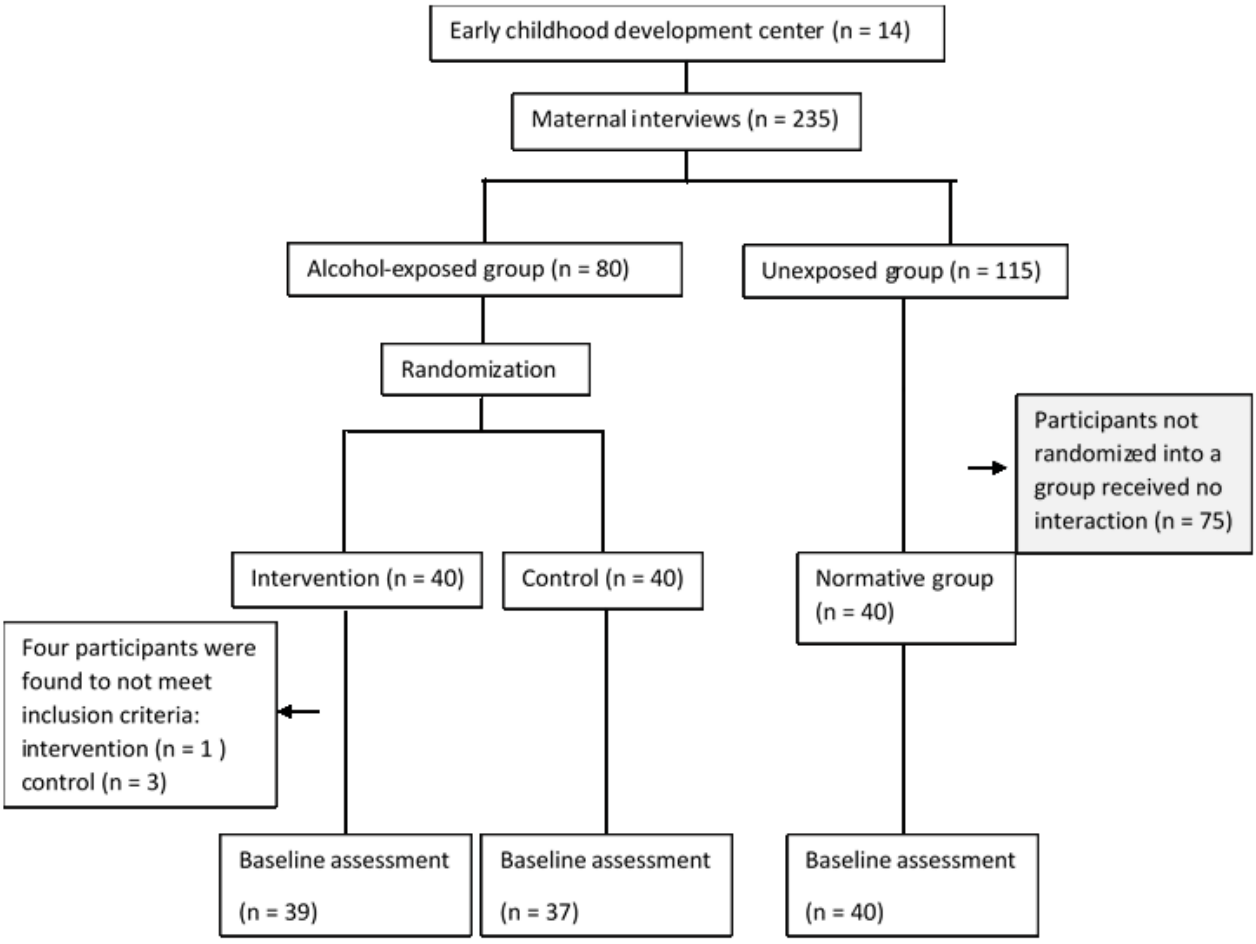
Methods

Design

This paper reports the findings of baseline assessments from a feasibility RCT of a computer-based cognitive training game (International Standard Randomized Controlled Trial Number; ISRTCN17244156). The trial protocol has been published [27]. Assessments were conducted at baseline before the start of the RCT intervention. The RCT comprised 3 arms. Children were recruited from local early childhood development (ECD) centers and assigned to groups based on in utero alcohol exposure, which was identified by interviewing children's biological mothers (Figure 1). Children exposed to alcohol were randomly assigned 1:1 to either the control or intervention group using block randomization. Once the intervention and control groups had been finalized, 40 unexposed children were individually selected for the third arm using random number tables [28] in

order to provide normative data. Baseline assessments were completed for all 3 groups. In line with the sample sizes of previous studies [12,29,30] on fetal alcohol spectrum disorder and cognitive function, a target of 120 participants was set.

Figure 1. CONSORT diagram.



Setting

Saldanha Bay municipality largely comprises Saldanha Bay, a harbor city with a population of 113,239 as of 2017 and main industries of agriculture, forestry, fishing, and manufacturing [31]. There is a high unemployment rate (17%) and significant income inequality (Gini coefficient 0.59 [31]). The prevalence of fetal alcohol spectrum disorder in the municipality is 64 per 1000 individuals [32].

Participants

Because we were interested in a population of children between the ages of 4 and 6 years, we approached an organization called Saldanha Bay ECD forum that serves ECD centers in low–socioeconomic status areas of the Saldanha Bay municipality. After giving an overview of the RCT, meetings were set up with the individual ECD center principals. At these meetings, the project was discussed in more depth, and the principals were asked if they would be willing to facilitate access to the parents of the children in their schools (ie, inform parents of the study and ask if they would like to participate).

We obtained the contact details of parents willing to allow their children to participate in the study, and community workers contacted these parents, obtained informed consent, and conducted interviews with biological mothers. The order in which parents from participating ECD centers were contacted was determined by randomly allocated numbers using Microsoft Excel. All consenting mothers identified by a particular ECD center were contacted for interviews before we moved on to mothers from another ECD. If, however, there were consenting mothers who were unavailable for interviews, we still moved on to a new ECD center. We followed up to see if they became available for interview at a later stage. New ECD centers were included until 80 participants exposed to alcohol had been identified, following which the 40 unexposed participants were selected.

Ethical Considerations

Ethics approval was obtained from the Health Research Ethics Committee at Stellenbosch University (N16/05/063). Data were deidentified after participants were allocated study IDs, and test administrators were blinded to alcohol exposure status during assessments.

Procedure

The structured interview used with the children's mothers has been used extensively in fetal alcohol spectrum disorder epidemiological studies in South Africa [32-34]. During the interview, a questionnaire was completed which included questions on sociodemographic information, pregnancy

behavior, and alcohol use during pregnancy. The interviews were conducted and questionnaires were completed by community workers trained in conducting this interview. Training was provided by one of the authors (JL) and included roleplay and recorded practice interviews. The interviews were conducted at the mothers' homes.

Children who were exposed to more than 3 standard drinks in 1 drinking session during pregnancy were defined as having had prenatal alcohol exposure.

Measures

Neurodevelopmental assessments of the children were conducted by trained psychometrists using NEPSY-II, a battery of individually administered tests that has been shown to reliably diagnose a range of childhood disorders [35]. Subtests can be selected based on the domains to be assessed [36]. NEPSY-II has been used in studies on fetal alcohol spectrum disorder and executive function [14,37] and has been extensively used globally, including in low- and middle-income countries [30]. Although no validation study for NEPSY-II has been conducted with data from South Africa, NEPSY-II has been successfully used in South African contexts [38,39]. We selected subtests that assessed attention and executive function; language; and memory and learning (Table 1).

Table 1. NEPSY-II domains and subtests.

Domain	Subtest
Attention and executive function	• Statue
Language	• Comprehension of instructions
Memory and learning	• Memory for designs content • Memory for designs spatial • Memory for designs • Narrative memory free and cued • Narrative memory and recognition contrasted • Sentence repetition

Data Analysis

Data were collected using REDCap [40] (Vanderbilt University) and analyzed using SPSS statistical software (version 25; IBM Corp). Since RCT group membership was not the variable of interest, to evaluate the impact of alcohol exposure, NEPSY-II scores for children in the alcohol group (RCT intervention and control groups) were compared to those from children in the nonexposed group. Before combining the RCT intervention and control groups, the demographic variables of the 3 groups were compared using 1-way analysis of variance and chi-square tests. The mean and median alcohol exposure for the alcohol-exposed group were also calculated. The mean and median scaled scores for subtests were calculated and compared to norms [35]. The scores were interpreted using the NEPSY II–suggested classification labels [41].

To evaluate whether alcohol exposure predicted test performance, multivariate analysis of variance with group membership as the predictor variable was conducted to test the scaled scores of the 8 subtests. A Box *M* test for homogeneity of covariance was not significant (*P*=.59). The absence of multicollinearity was assumed for this analysis. Due to possible violation of some of the assumptions for multivariate analysis of variance, we used Pillai trace as the test statistic with a conservative level of α=.01.

Results

After engaging with the ECD forum, 27 ECD centers agreed to participate. To obtain 80 children with prenatal alcohol exposure, 235 interviews were completed in 14 ECD centers. Upon review of the assessment data, 4 children were excluded for being too young, and their data were excluded from analysis. The final sample (n=116) included 76 children in the alcohol-exposed group and 40 children in the nonexposed group (Figure 1).

There was a significant difference in age ($F_{2,113}$=6.90, *P*=.001, ω^2=.09) when comparing the 3 groups. A posthoc Tukey honestly significant difference test showed a significant difference (*P*=.001) between the RCT intervention and normative groups (mean difference 0.41) (Table 2). The intervention and control groups were combined as the alcohol-exposed group for subsequent analyses. The children in the alcohol-exposed group (n=76) had been, on average, exposed to 5.51 standard units of alcohol (SE 0.67) on at least 1 occasion during gestation (median 7.5 units).

Table 2. Characteristics of children and their mothers included in the randomized controlled trial.

Characteristic	Alcohol exposure (n=76)		No alcohol exposure (n=40)	*P* value
	RCT[a] intervention (n=39)	RCT control (n=37)		
Children				
Age (years), mean (SD)	4.72 (0.50)	4.83 (0.54)	5.14 (0.44)	.001
Gender, n				.92
Female	17	16	19	
Male	22	21	21	
Mother				
Age (years), mean (SD)	28.15 (5.32)	30.41 (5.85)	31.17 (6.18)	.08
Number of living children, mean (SD)	1.87 (0.95)	2.35 (1.27)	2.15 (1.21)	.19
Years of schooling, mean (SD)[b]	10.67 (1.69)	11.03 (1.78)	10.71 (2.07)	.66
Gravidity, mean (SD)	2.21 (1.10)	2.51 (1.40)	2.45(1.47)	.57
Monthly household income (ZAR)[c], mean (SD)[d]	4953.24 (4619.59)	4610.56 (3375.28)	5474.86 (6233.52)	.75
Pregnancy with participant planned, n (%)				.27
Yes	11 (28)	12 (32)	18 (45)	
No	28 (72)	25 (68)	22 (55)	
Received South African Social Security Agency grants, n (%)				.22
Yes	30 (76)	29 (78)	25 (62)	
No	9 (24)	8 (22)	15 (38)	
Currently employed[e], n (%)				.59
Yes	26 (68)	26 (70)	24 (60)	
No	12 (32)	11 (30)	16 (40)	

[a]RCT: randomized controlled trial.

[b]Missing data: n=1, n=4, and n=2 in the intervention, control, and no exposure groups, respectively.

[c]ZAR: South African Rand; an approximate exchange rate of ZAR 1 to US $0.07 is applicable at the time of publication.

[d]Missing data: n=3, n=4, and n=3 in the intervention, control, and no exposure groups, respectively.

[e]Missing data: n=2 and n=3 in the intervention and control groups, respectively.

There was no significant difference in monthly household income (mean difference ZAR 690.62, 95% CI −1259.95 to 2641.18, t_{108}=0.702, *P*=.48), South African Social Security Agency grant receipt (alcohol-exposed: 59/76, 78%; nonexposed: 25/40, 62%; χ_1^2=3.00, *P*=.08), or caregiver unemployment (alcohol-exposed: 24/76, 30%; nonexposed: 16/40, 40%; χ_1^2=1.01, *P*=.32) between the groups.

Alcohol-exposed (combined intervention and control groups) and nonexposed group mean scaled scores for all NEPSY-II subtests (except statue) fell into the borderline performance category (between the 11th and 25th percentiles) or lower. Children in the alcohol exposed group and the nonexposed group performed below the expected level (at or below the tenth percentile) for comprehension of instructions (means 4.97 and 5.37, respectively), narrative memory recall (means 5.10 and 5.14, respectively), and sentence repetition (means 6.24 and 5.46, respectively) subtests. Performance on the statue subtest was at the expected level for both the alcohol exposed (mean 10.68) and nonexposed (mean 10.26) groups.

Some participants were unable to successfully complete all subtests in the chosen battery (based on the NEPSY-II guidelines for discontinuation [35]). The multivariate analysis of variance included data from 107 children. The relationship between alcohol exposure and NEPSY-II subtest scores was not significant (*V*=0.081, $F_{8,98}$=1.073, *P*=.39). Posthoc univariate analyses on the subtest scores by group membership also revealed no significant differences (Table 3). The greatest variability in scores was found in the memory for designs (spatial) subtest (partial eta squared 0.033).

Table 3. Between-participant effects with alcohol exposure as the predictor variable.

Dependent variable	Type III sum of squares	*F* test (*df1*)	Partial eta squared	*P* value
Language				
Comprehension of instructions	3.753	0.560 (1)	0.005	.46
Memory and learning				
Memory for designs content	3.263	0.482 (1)	0.005	.49
Memory for designs spatial	20.849	3.566 (1)	0.033	.06
Memory for designs	6.172	2.076 (1)	0.019	.15
Narrative memory free and cued	0.049	0.008 (1)	0.000	.93
Narrative memory and recognition contrasted	4.636	0.427 (1)	0.004	.52
Sentence repetition	14.291	2.625 (1)	0.024	.11
Attention and executive function				
Statue	4.222	0.518 (1)	0.005	.47

Discussion

General

Performance on the NEPSY-II was poor, regardless of alcohol exposure. The data did not show any significant differences between the alcohol-exposed and nonexposed groups (*P*=.39).

Group Comparison

The differences in demographic characteristics of the mothers of children in the RCT intervention, RCT control, and nonexposed groups were not significant (age: *P*=.08; living children: *P*=.19; years of schooling: *P*=.66; gravidity: *P*=57), which decreases the possibility that there is a significant environmental variable other than alcohol exposure that can explain any observed differences. The difference in the age between the children in the RCT intervention group and the nonexposed group was significant, with a medium effect size of 0.09; the nonexposed group was an average of 5 months (mean difference 0.41 years) older than the intervention group. The impact of this is minimized by using the scaled scores from the NEPSY-II, therefore although significant, this difference was not concerning.

NEPSY-II Outcomes

The lack of difference between the alcohol-exposed and nonexposed groups was surprising given the strong associations that have been shown between alcohol use and deficits in executive function [10,42,43]. The average number of standard units of alcohol to which children were exposed exceeded the level defined as binge drinking (4 units of alcohol in 1 sitting [44]), and overall exposure to alcohol during pregnancy is based on a minimum estimate of exposure during pregnancy. The majority of women in the alcohol-exposed group used alcohol in a pattern associated with the highest risk of harm to pregnancy (average consumption was 5.51 units on one occasion).

NEPSY-II performance was similar for the exposed and nonexposed children. The finding of borderline scores on the NEPSY-II subtests for the entire group is unexpected and concerning. We hypothesized that the alcohol-exposed group would generally perform below expectation, and this was indeed the case. The nonexposed group, barring other causes of poor development, were expected to perform at age-appropriate levels. This did not prove to be the case, with no differences found between children in the alcohol-exposed group and nonexposed group.

It is possible that development of children in the alcohol-exposed group has not been impacted, with development occurring at the same rate as their peers. This does not imply that development of children in the alcohol-exposed groups will remain on par with that of their peers. It has been shown that the developmental trajectory of children with prenatal alcohol-exposure diverges from expected norms as they become older, which makes diagnosis and identification easier as time passes [45]. The young age of this cohort may therefore be a confounding factor.

As participants were recruited from underresourced and low–socioeconomic status areas, overall low performance may be linked to exposure to adverse childhood experiences. Adverse childhood experiences have a detrimental impact on cognitive development, social development, and mental health [46,47]. The impact on cognitive development overlaps with the impact on areas of development that we would expect from prenatal alcohol exposure [48]. It is important to note that, although adverse childhood experience measures frequently focus on abuse, neglect, parental separation, and exposure to criminality [49-51], this list is not exhaustive [49]. It is well established that poverty has a negative impact on cognitive assessments [52,53].

With 84 out of 116 (72%) households relying upon social grants, which amounts to only ZAR 410.00 (approximately US $27) each month per child for child support, these data indicate there are high levels of poverty and adversity. There is little that differentiates the alcohol exposed and unexposed groups, except for mothers' reported alcohol use. The Saldanha Bay municipal area also experiences problems with violence and crime [31], and because adversity can be defined as exposure to a combination of deprivation and threat [54], it is likely that a significant number of participants in both groups would fit the definition of having had exposure to childhood adversity.

It is also possible that NEPSY-II cannot detect differences between groups. It may be that the NEPSY-II is not sensitive enough to detect the difference in executive function between alcohol-exposed and nonexposed groups. There are, however, no other assessments used in research on executive function or fetal alcohol spectrum disorder that have more suitable norms or that are more culturally appropriate for a South African context. Measuring executive function in these age groups is complicated by the way in which executive function develops; different aspects of executive function develop at different times and at different rates. Attention control, for example, develops and matures before cognitive flexibility (which is related to working memory and inhibition). This development is consistent with spurts of growth and development in the frontal lobe [55]. Major developmental periods continue until approximately 13 years of age, but further improvements in executive function continue due to myelination of prefrontal connections into adolescence [55]. In the NEPSY-II, more subtests are available to test executive function from 6 years of age [35], and the combination of fewer subtests and the variable nature of executive function development can also mask potential developmental differences. This would, however, hold true for other available assessments as well.

We must also acknowledge that there may be children exposed to alcohol in the normative group. Although selection was based on a confirmation of prenatal alcohol exposure, some mothers may have been reluctant to admit drinking or they may have misreported the amount that they drank during pregnancy because alcohol use during pregnancy is heavily stigmatized [56].

Limitations

One of the study limitations is the lack of local norms for the NEPSY-II. The lack of local norms for neurodevelopmental assessments is an acknowledged problem in South Africa [38]. Language and culture bias may lead to a misrepresentation of actual cognitive abilities. These limitations were considered during the design phase of the study.

Another limitation is that we relied upon self-reporting of alcohol use. Underreporting of alcohol use was a concern due to possible reluctance on the part of the mother to admit to alcohol use. Mothers may also have found it difficult to recall alcohol use 5 years earlier. Some of the children in the nonexposed group may in fact have been exposed to alcohol. Inclusion due to alcohol use was based on recall of an average drinking session during pregnancy. Participants in the nonexposed group may, therefore, have been exposed to alcohol over a longer period of time but their reported alcohol use placed them in the nonexposed category because the level of exposure did not meet the threshold indicated in the fetal alcohol spectrum disorder diagnostic criteria [1].

Due to the size of the ECD centers, it was not possible to reach the total sample size in a single area or ECD center. Although the ECD centers were located in similar communities, there were still differences between centers that could have impacted on the performance of the children on the psychometric assessments. Some of these factors could include the number of children per ECD practitioner or the availability of toys and equipment for stimulation. It is well established that poverty has a negative impact on cognitive assessments [52,53].

Conclusions

We compared the performance of children exposed and not exposed to alcohol in utero on measures of executive function. We expected that alcohol exposure would have a measurable negative impact, but in our sample, there was none. This highlights that developmental delays are widely prevalent in resource poor and low–socioeconomic status communities in South Africa. As developmental delays form part of the diagnostic criteria of fetal alcohol spectrum disorder, this study also shows that caution should be used when interpreting normed scores. It is possible that a borderline or below average score may not necessarily support a diagnosis of fetal alcohol spectrum disorder as there are clearly other possible causes of poor development that must be excluded.

This paper also identified important avenues for further research. The lack of difference between alcohol-exposed and nonexposed groups needs to be further explored. Does this lack of difference remain as participants age? What is the prevalence of adverse childhood experiences and to what extent do adverse childhood experiences explain the lack of difference between the groups? Overall, this paper adds to the understanding that alcohol exposure in utero and its sequelae are only part of the possible developmental challenges faced by children in South African communities.

Acknowledgments

This study received funding from the Association for Alcohol Responsibility and Education (AWARE). We would also like to acknowledge the dedication of our community workers who conducted the interviews and the willingness of the participants and caregivers to participate in the study. We would also like to thank the Saldanha Bay ECD forum and the ECD centers in the Saldanha Bay municipality for their support.

Conflicts of Interest

JGL, LO, MB, LB, and MV are employed by the Foundation for Alcohol Related Research, which designed and developed the game used in the intervention. The other authors have no conflicts to declare.

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Abbreviations

ECD: early childhood development
RCT: randomized controlled trial
ZAR: South African Rand

Edited by G Eysenbach; submitted 26.05.20; peer-reviewed by N Khalili-Mahani; comments to author 04.07.20; revised version received 27.07.20; accepted 16.03.21; published 02.07.21.

Please cite as:
Louw JG, van Heerden A, Olivier L, Lambrechts T, Broodryk M, Bunge L, Vosloo M, Tomlinson M
Executive Function After Prenatal Alcohol Exposure in Children in a South African Population: Cross-sectional Study
JMIR Form Res 2021;5(7):e20658
URL: https://formative.jmir.org/2021/7/e20658
doi:10.2196/20658
PMID:34255647

Original Paper

A Web-Based Social Network Tool (GENIE) for Supporting Self-management Among High Users of the Health Care System: Feasibility and Usability Study

Ruta Valaitis[1], BScN, MSc, PhD; Laura Cleghorn[2], MA; Ivaylo Vassilev[3], PhD; Anne Rogers[3], SRN, PhD; Jenny Ploeg[1], BScN, MScN, PhD; Anita Kothari[4], PhD; Cathy Risdon[2], MD, DMan, CCFP, FCFP; James Gillett[5], PhD; Dale Guenter[2], MD, MPH, CCFP, FCFP; Lisa Dolovich[2], BScPhm, PharmD, MSc

[1]School of Nursing, McMaster University, Hamilton, ON, Canada

[2]Department of Family Medicine, McMaster University, Hamilton, ON, Canada

[3]School of Health Sciences, University of Southampton, Southampton, United Kingdom

[4]School of Health Studies, Western University, London, ON, Canada

[5]Health Aging and Society, McMaster University, Hamilton, ON, Canada

Corresponding Author:
Ruta Valaitis, BScN, MSc, PhD
School of Nursing
McMaster University
128 Main Street West
Hamilton, ON, L8S 4K1
Canada
Phone: 1 9055772022
Fax: 1 905 570 0667
Email: valaitis@mcmaster.ca

Abstract

Background: Primary care providers are well positioned to foster self-management through linking patients to community-based health and social services (HSSs). This study evaluated a web-based tool—GENIE (Generating Engagement in Network Involvement)—to support the self-management of adults. GENIE empowers patients to leverage their personal social networks and increase their access to HSSs. GENIE maps patients' personal social networks, elicits preferences, and filters local HSSs from a community service directory based on patient's interests. Trained volunteers (an extension of the primary care team) conducted home visits and conducted surveys related to life and health goals in the context of the Health TAPESTRY (Teams Advancing Patient Experience: Strengthening Quality) program, in which the GENIE tool was implemented. GENIE reports were uploaded to an electronic medical record for care planning by the team.

Objective: This study aims to explore patients', volunteers', and clinicians' perceptions of the feasibility, usability, and perceived outcomes of GENIE—a tool for community-dwelling adults who are high users of the health care system.

Methods: This study involved 2 primary care clinician focus groups and 1 clinician interview (n=15), 1 volunteer focus group (n=3), patient telephone interviews (n=8), field observations that captured goal-action sequences to complete GENIE, and GENIE utilization statistics. The patients were enrolled in a primary care program—Health TAPESTRY—and Ontario's Health Links Program, which coordinates care for the highest users of the health care system. NVivo 11 (QSR International) was used to support qualitative data analyses related to feasibility and perceived outcomes, and descriptive statistics were used for quantitative data.

Results: Most participants reported positive overall perceptions of GENIE. However, feasibility testing showed that participants had a partial understanding of the tool; volunteer facilitation was critical to support the implementation of GENIE; clinicians perceived their navigation ability as superior to that of GENIE supported by volunteers; and tool completion took 39 minutes, which made the home visit too long for some. Usability challenges included difficulties completing some sections of the tool related to medical terminology and unclear instructions, limitations in the quality and quantity of HSSs results, and minor technological challenges. Almost all patients identified a community program or activity of interest. Half of the patients (4/8,

50%) followed up on HSSs and added new members to their network, whereas 1 participant lost a member. Clinicians' strengthened their understanding of patients' personal social networks and needs, and patients felt less social isolation.

Conclusions: This study demonstrated the potential of GENIE, when supported by volunteers, to expand patients' social networks and link them to relevant HSSs. Volunteers require training to implement GENIE for self-management support, which may help overcome the time limitations faced by primary care clinicians. Refining the filtering capability of GENIE to address adults' needs may improve primary care providers' confidence in using such tools.

(JMIR Form Res 2021;5(7):e25285) doi:10.2196/25285

KEYWORDS

web-based tool; usability; feasibility; self-management; social network; primary care; health and social services; linkages; high systems users; volunteers

Introduction

Background

It has been reported that globally, 1 in 3 adults have multiple chronic conditions (MCCs) [1]. There was an increase from 45.7% in 1988 to 59.6% in 2018 with regard to adults in the United States with 2 or more MCCs, and the weighted prevalence of 2 or more MCCs was higher in those aged ≥65 years [2]. Fostering self-management support for health conditions is particularly important, given the rising numbers and projected rise in complex multimorbidity. Self-management support builds problem-solving skills to enhance self-efficacy to carry out behaviors toward a desired goal and can support positive health outcomes, reduce the burden of long-term conditions for the patient and the health system, and decrease health system costs [3,4]. A qualitative systematic review identified challenges that patients experienced with self-management, including dealing with physical and emotional symptoms; living with pain, depression, and fatigue; and having a lack of understanding of self-management strategies related to conflicting information from providers [5]. Kang et al [6] found that quality of life scores were higher among patients with good versus low self-management strategy scores regardless of the number of comorbidities.

Improving access to health and social services (HSSs) to address self-management can be supported through information, referrals, facilitation, and system navigation by primary care providers [7-9]. Results from a longitudinal study of 300 randomly selected patients with diabetes or chronic heart disease found that connecting people to social support resources, including a variety of people and groups, supported self-management and physical and mental health [10]. Patients with multiple and complex health and social conditions are likely to derive the maximum benefit from linkages to HSSs [11].

In recent years, researchers have established that social networks can influence positive health behaviors and practices, and this is also true in populations that are managing long-term conditions [12-15]. Social connectedness has been shown to be particularly beneficial for vulnerable groups, such as those living in poverty and with chronic illnesses [16]. Reeves et al [10] established associations between connections with and the use of local networks, resulting in improved physical and mental well-being and better coping with their conditions. Personal and social networks and relationships in community settings can act as a conduit for accessing resources and provide support for managing long-term conditions, which can complement what is provided by formal service provision.

The implementation of a self-management support intervention in 31 primary care settings in England had poor uptake because of a perceived lack of relevance and fit to accessible sources of support and because primary care health care professionals did not prioritize self-management support [17]. Primary care providers in Canada have been tasked with fostering self-management through support and coaching, referral management, and linking to relevant community-based resources and services [4,18,19]. However, like their UK peers, they have struggled with limited time for coaching; a lack of knowledge of what community-based HSSs are available and how they can address health and social needs; and a lack of time to keep up with changing community services, including concerns about their quality [20,21]. Despite these challenges, it is argued that there is a need for primary care providers to implement effective self-management support interventions that incorporate connections to community resources for those living with long-term conditions [22] and, particularly, for those who are known to be isolated, requiring more encouragement to make connections [23-25].

The aim of the GENIE (Generating Engagement in Network Involvement) tool was to encourage the expansion of a patient's social networks to reduce the negative health impacts of long-term conditions and to reduce the concomitant social effects, such as social isolation and loneliness [23]. GENIE is a web-based tool that aims to support self-management by leveraging adults' engagement with their personal social network to facilitate the uptake of relevant community-based activities and HSSs. Studies have shown that when GENIE was delivered by trained facilitators to adults with chronic health and social conditions in the community settings, there was an increase in the diversity of participants' networks and greater engagement with community activities [26,27]. Given these positive results and the challenges faced by primary care providers in implementing self-management strategies [17], research is needed to understand the feasibility, usability, and perceived impacts of implementing GENIE within the primary context, with the use of trained facilitators as an extension of the primary care team. This knowledge will be useful to inform future implementation of the GENIE tool in primary care and can serve

as a basis for the development of outcome measures to be used in future controlled studies.

Research Questions

This study examined the feasibility, usability, and perceived patient outcomes of the implementation of GENIE with adults enrolled in Ontario's Health Links Program. This program alerts health providers to individuals with high rates of health service utilization to target care and thereby reduce health care costs [28]. The research questions were as follows:

1. What is the usability and feasibility of implementing GENIE, facilitated by lay volunteers and primary care providers, with 55- to 69-year-old adults enrolled in the Health Links Program?
2. What are patients', providers', and volunteers' perceptions of the impact of the use of GENIE?

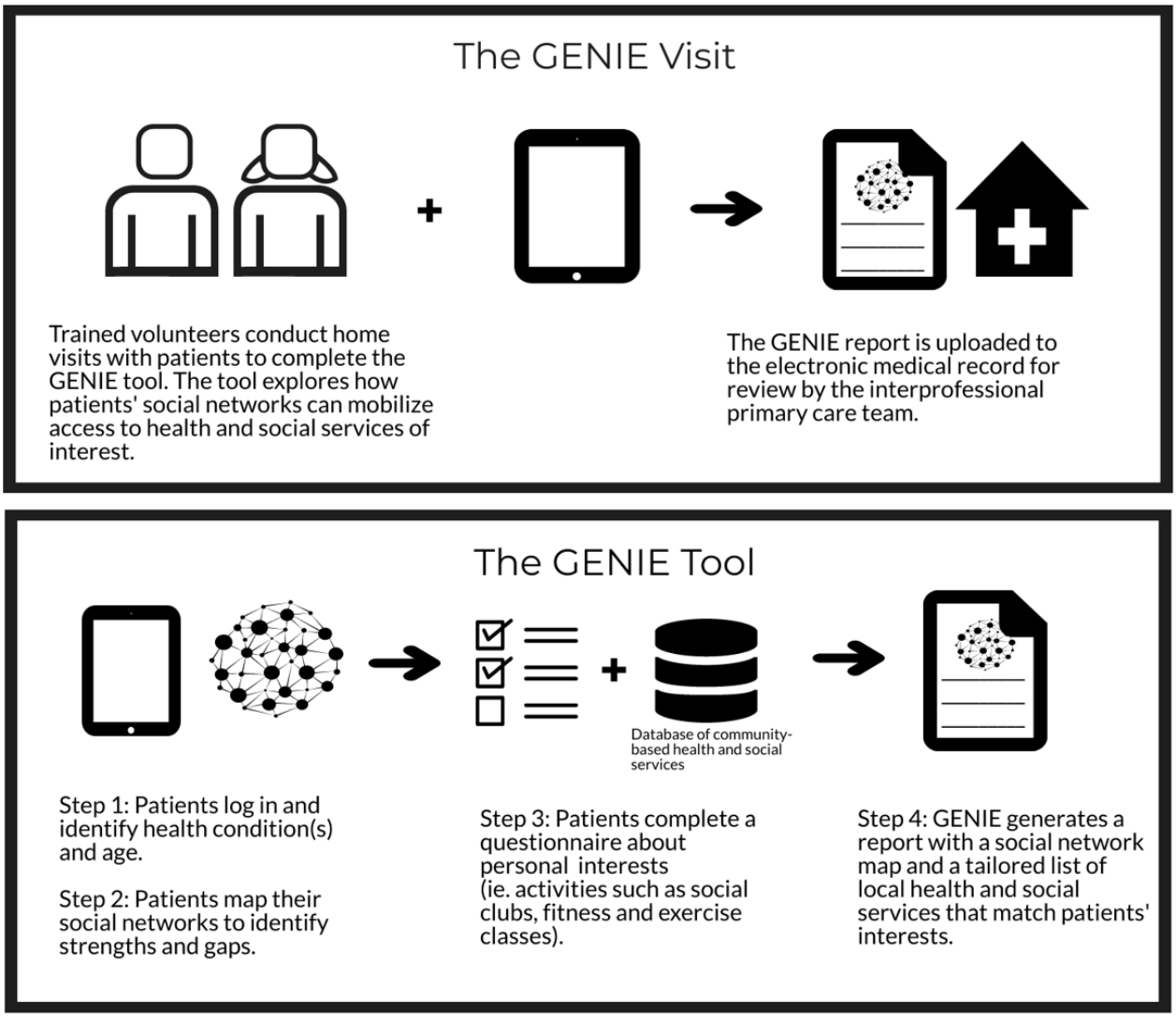
Methods

Social Network Tool (GENIE)

Overview

GENIE is a web-based tool designed by a team of researchers from the United Kingdom [29]. GENIE has been previously implemented by trained lay or health care workers in various contexts in the United Kingdom and Europe to link patients to community-based HSSs to support them in reaching their life and health goals [22,24,26]. The GENIE tool has 3 core functions: (1) mapping a patient's personal social network to better understand a patient's support network and identify possible network members who can assist them; (2) selecting topics of interest that relate to patients' interests under the categories of activities, health, learning, support, independent living, volunteering, and pets; and (3) geolocating local community programs, services, and resources related to the selected categories (Figure 1).

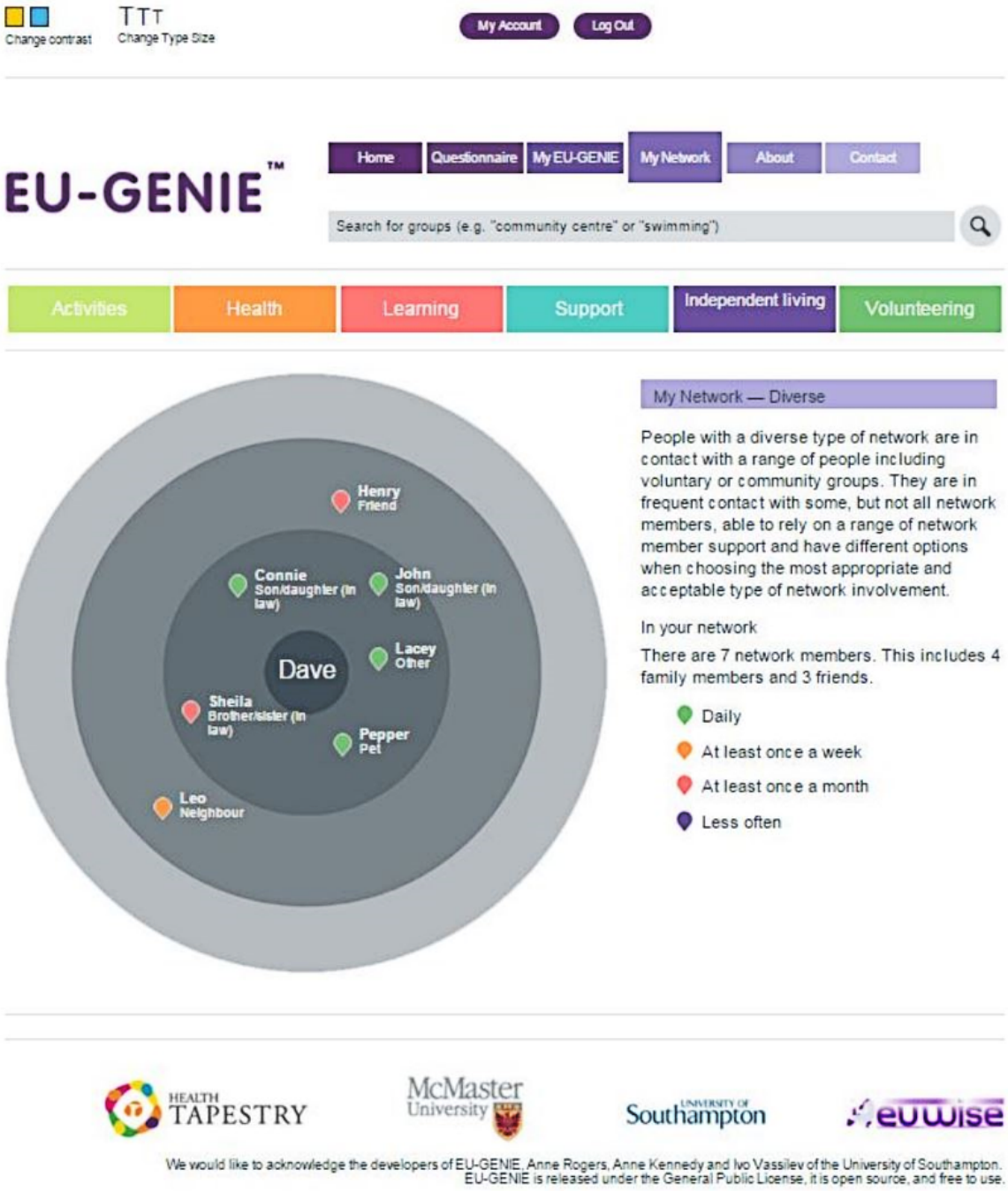
Figure 1. Depiction of the GENIE visit and tool. GENIE: Generating Engagement in Network Involvement.



The GENIE tool consists of 4 steps. First, patients enter an email address (or get help to obtain an email address) to log in and enable them to save their results, select from a list of common health conditions (eg, heart problems, stroke, diabetes, arthritis, and cancer), and enter their age and postal code.

Second, the patients generate a personal network map that lists individuals, groups, or organizations (eg, son or daughter-in-law, friend, and social club) that the patients consider important to them in relation to being healthy and living at home. Network members who are deemed to be most important to them are placed closest to the center of the circle, where the patients are placed, with others moving out into the outer circles. Each member is categorized by type (eg, family, friend, neighbor, group, or organization), which determines the typology of that patient's network. Network typologies can consist of mostly friends and family members; mostly professionals; or a diverse mix of professionals, organizations, friends, and family (eg, *My Network–Diverse*; Figure 2). Diverse networks are the most robust social networks in the GENIE typology containing family, friends, and *weak tie* relationships, whereas *very isolated* and *friend and family supported* networks have fewer members and less diversity of relationships. Research has shown that people with long-term health conditions and diverse networks are associated with enhanced self-management skills [30]. Patients also indicate the frequency at which they meet with each network member. This information can help identify network members who may be more available to support a patient's HSS use.

Figure 2. Example of network mapping and categories of interest in GENIE (Generating Engagement in Network Involvement).



Third, patients answer 12 questions about their interests organized under the following categories: (1) activities, (2) health, (3) learning, (4) support, (5) independent living, (6) volunteering, and (7) pets. Some questions have subquestions, for example, if a patient is interested in *activities*, they are

prompted with subquestions to refine the topic (ie, reading and writing, drama and music, arts and crafts, or social clubs).

Fourth, once the patients complete the questionnaire, they move to a web page listing links to relevant community-based HSSs organized under the relevant categories. For example, if a patient indicates that they are interested in physical activity, they can find HSSs listed under the *health* tab related to this subactivity (Figure 3). HSSs are geomapped for selection based on the patient's preferred distance from their postal code (1 km, 2 km, 5 km, 10 km, or 50 km). Relevant HSSs, including a brief description of their programs or services, are populated from the region's community information database.

Patients review their results and mark their *favorites* (Figure 3), which can be saved, downloaded, and printed in a short report for easy access (Figure 4) [13]. Facilitators were to encourage patients to consider their social networks to help in overcoming barriers to access the desired HSSs.

Figure 3. Example of a user's favorited list of links geomapped for the health category. GENIE: Generating Engagement in Network Involvement.

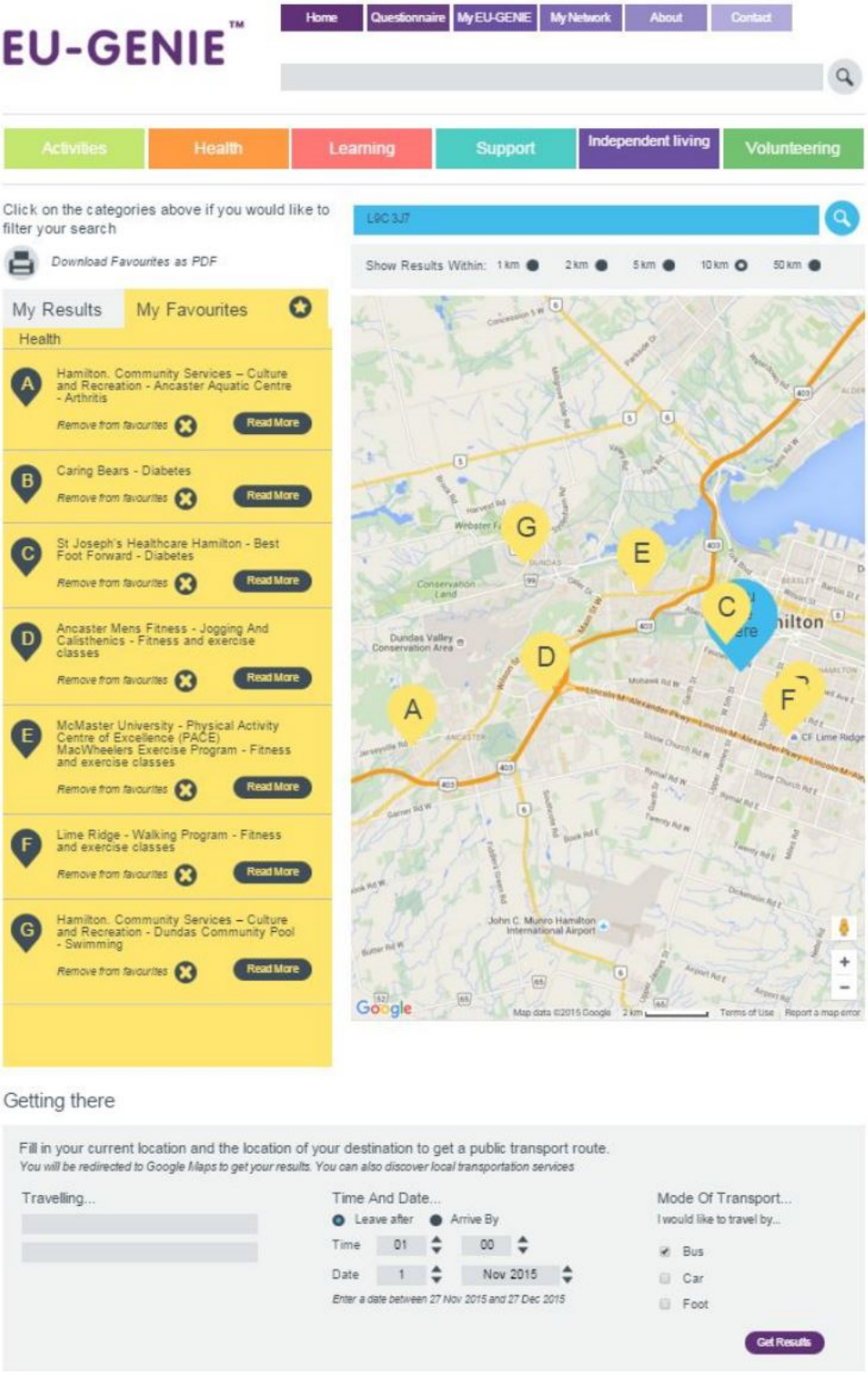
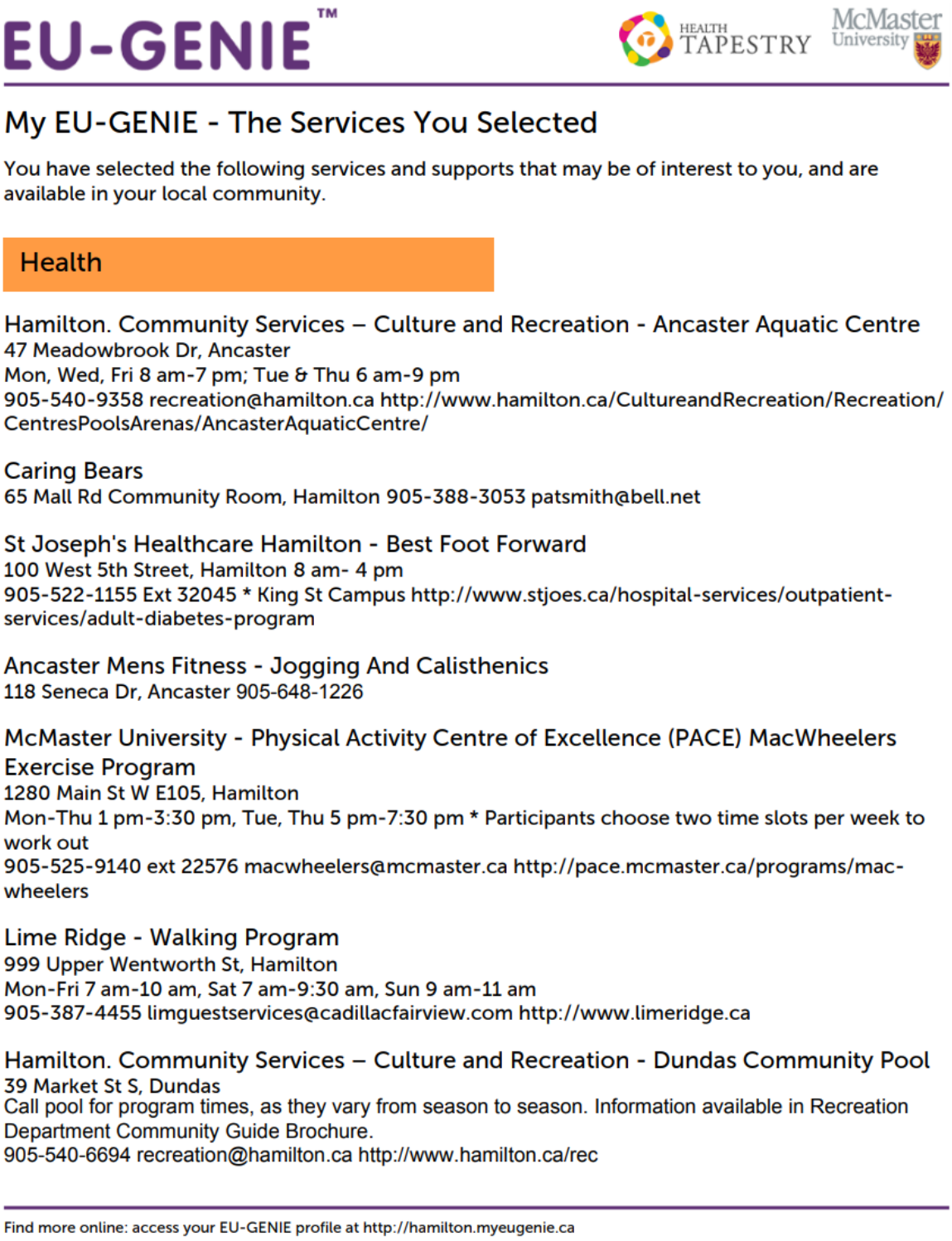


Figure 4. An example of a printed report of favorites for users to follow up. GENIE: Generating Engagement in Network Involvement.


EU-GENIE™

HEALTH TAPESTRY McMaster University

My EU-GENIE - The Services You Selected

You have selected the following services and supports that may be of interest to you, and are available in your local community.

Health

Hamilton. Community Services – Culture and Recreation - Ancaster Aquatic Centre
47 Meadowbrook Dr, Ancaster
Mon, Wed, Fri 8 am-7 pm; Tue & Thu 6 am-9 pm
905-540-9358 recreation@hamilton.ca http://www.hamilton.ca/CultureandRecreation/Recreation/CentresPoolsArenas/AncasterAquaticCentre/

Caring Bears
65 Mall Rd Community Room, Hamilton 905-388-3053 patsmith@bell.net

St Joseph's Healthcare Hamilton - Best Foot Forward
100 West 5th Street, Hamilton 8 am- 4 pm
905-522-1155 Ext 32045 * King St Campus http://www.stjoes.ca/hospital-services/outpatient-services/adult-diabetes-program

Ancaster Mens Fitness - Jogging And Calisthenics
118 Seneca Dr, Ancaster 905-648-1226

McMaster University - Physical Activity Centre of Excellence (PACE) MacWheelers Exercise Program
1280 Main St W E105, Hamilton
Mon-Thu 1 pm-3:30 pm, Tue, Thu 5 pm-7:30 pm * Participants choose two time slots per week to work out
905-525-9140 ext 22576 macwheelers@mcmaster.ca http://pace.mcmaster.ca/programs/mac-wheelers

Lime Ridge - Walking Program
999 Upper Wentworth St, Hamilton
Mon-Fri 7 am-10 am, Sat 7 am-9:30 am, Sun 9 am-11 am
905-387-4455 limguestservices@cadillacfairview.com http://www.limeridge.ca

Hamilton. Community Services – Culture and Recreation - Dundas Community Pool
39 Market St S, Dundas
Call pool for program times, as they vary from season to season. Information available in Recreation Department Community Guide Brochure.
905-540-6694 recreation@hamilton.ca http://www.hamilton.ca/rec

Find more online: access your EU-GENIE profile at http://hamilton.myeugenie.ca

Adaptation of GENIE for Use in Canada

GENIE was adapted for use in Hamilton, Canada. The UK open-source tool required minor word modifications in the questionnaire to address the linguistic differences between Canadian and British audiences (eg, changing the word *befriending* to *friendly visiting*). A second significant adaptation was linking GENIE to a back-end database of community-based HSSs. In the United Kingdom, community information services with databases, such as those in Canada, do not exist. The Hamilton database was maintained by the Region's Community Information Service—Information Hamilton. Most programs and services included in the database are run by not-for-profit organizations or government organizations. For-profit services were included if there were no not-for-profit agencies available that offered the same or similar service (eg, home oxygen providers). All database entries were tagged with keywords using the AIRS/211 LA Taxonomy of Human Services which

is the industry standard for the Alliance of Information and Referral Systems (AIRS) [31]. To link the database to GENIE, keywords related to all topics of interest listed in the GENIE questionnaire were identified. For example, if a patient had an interest in walking or outdoor activities, programs and services were tagged with the AIRS categories of walking programs, walking tours, and nature centers or walks. This enabled GENIE to filter information from the database to match the selected areas of interest. Information Hamilton staff pulled together a complete list of all database items with selected search terms for our review for relevance to this adult population and to mark services for exclusion, such as youth programs or programs outside of the city. The database was updated daily by Information Hamilton's staff, who regularly reach out and work with local service organizations to keep the database up to date.

Implementation of GENIE

GENIE facilitators were volunteers who attended a half-day training session to learn about the application of the GENIE tool during home visits. They visited with patients in 2 instances (the GENIE visit in Figure 1). At baseline, they would sign up patients and log on to GENIE, identify their social networks, and help patients to explore links to community support. The volunteers were trained to facilitate the use of the GENIE tool to engage in a discussion with the patients about their social networks, to discuss the access and use of community-based services, and to identify any additional services that they would like to access through the preparation of the GENIE report. The reports were sent to the patients' electronic medical records for review by the primary care huddle team (a component of the Health TAPESTRY [Teams Advancing Patient Experience: Strengthening Quality] program) for planning and care coordination. The team told patients about any critical information regarding their plan of care and consulted with the relevant family physician in the clinic when needed. The report was printed and left with the patient after the home visit. After 3 months, the volunteer would return to the patient's home, log on to GENIE, repeat the social network mapping, and revisit the GENIE report to determine if the patient had explored any HSSs. The volunteer role was intentionally limited to the role of a nonmedical volunteer facilitator. If any health care–based issues or concerns arose, patients would be encouraged to connect with their primary care provider [32].

Setting and Sample

The study was conducted between August 2017 and March 2018 at 2 sites of a family health team (composed of 2 interprofessional primary care team clinics) that serves 30,000 patients in Hamilton, Canada. It targeted patients who were enrolled in Ontario's Health Links Program [28]. Modeled after accountable care organizations in the United States, England, Australia, and New Zealand, the Health Links Program was launched in 2012 in Ontario, Canada, to improve care coordination for patients with complex needs who are the highest users of the health care system. The program connects them to primary care providers and engages them in their health care via active care planning [28]. These patients are considered high-cost, high-need users of the health care system—the top 5% of the population who use two-thirds of the health care spending [33]. GENIE was implemented with a small sample of Health Links patients within the context of the Health TAPESTRY program. Health TAPESTRY provided a unique structure for GENIE's implementation within a primary care setting, as the program includes the use of trained volunteers as an extension of the primary care team, who visit patients in their homes. Health TAPESTRY is a multicomponent primary care intervention that centers on supporting older adults' life and health goals [34,35]. The Health TAPESTRY program components include (1) trained volunteers visiting in pairs to collect health information using web-based surveys related to health risks and life goals [36], (2) care coordination by an interprofessional primary care team, (3) the use of technology to share health information between volunteers and primary care providers, and (4) support for system navigation [37]. Trained community volunteers implemented the GENIE tool, in addition to the Health TAPESTRY surveys. GENIE results and survey data were compiled into a web-based report that was transmitted to the interprofessional primary care team to support the formulation of a patient care plan.

Ethics approval was received for this study from the Hamilton Integrated Research Ethics Board Project number 13-366. All participants provided written informed consent before data collection.

Data Collection

GENIE was field tested for feasibility and usability with a small group of volunteers and patients who were also receiving the Health TAPESTRY program. Data collection methods included (1) use statistics, (2) field observation in the community with patients and volunteers, (3) field observation notes taken during primary care team meetings, (4) focus groups with clinicians and volunteers, and (5) patient interviews. A summary of the data collected is provided in Table 1, and the focus group guides are provided in Multimedia Appendix 1.

Field observations focused on the usability captured via researcher observations during home visits with volunteers and patients at baseline. Field usability testing [38,39] was conducted via observation to assess the cognitive processes of users performing task completion of the GENIE tool, as trained volunteers facilitated the use of the web tool in a home visit. LC and RV observed volunteer and participant dyads to identify potential usability problems, with particular attention to goal-action sequences and interactions between volunteers and participants, dimensions of competencies (skills and knowledge required to complete the tool), barriers to the productive use of the tool, time to complete the tool, and ease of use for participants and volunteers [39]. Field observation notes captured procedures for each step or task to complete the tool (Multimedia Appendix 2). Tasks included setting up, completing the introductory and demographic page, completing network mapping and the questionnaire, discussing and tailoring the results, and printing the final results and the *my network* page that included the social network map. It also included comments and questions raised by the participants and volunteers as they worked through the task. Field notes were recorded by LC at interprofessional team meetings, in which patient GENIE reports were reviewed and discussed.

Table 1. Data collection by participant type.

Participant type	Usability	Feasibility	Perceived outcomes
Patients	• Use statistics (baseline; 3 months) • Field observation during patient home visits by a pair of volunteers (time 1)	• Use statistics (time to complete the GENIE[a] tool) • Interviews (3 months)	• Interviews (3 months)
Volunteers	• Field observation during patient home visits by a pair of volunteers	• N/A[b]	• Focus group (3 months)
Primary care providers	• Monthly huddle (care coordination team meeting) notes • Focus group (3 months)	• Monthly huddle notes • Focus group (3 months)	• Focus group (3 months)

[a]GENIE: Generating Engagement in Network Involvement.

[b]N/A: not applicable.

RV and LC conducted focus groups with volunteers and clinicians from 2 teams immediately following their huddle team meetings, which helped to gain participation in the research. Semistructured interviews were conducted by LC with study participants to explore the feasibility of GENIE using an interview guide that applied concepts from the Normalization Process Theory (NPT) [40] and perceived impacts. The NPT has been used for the feasibility study of a web-based program in primary care [41]. All focus groups and interviews with providers took place 6 months after the first use of GENIE by patients. The interview and focus group guide were tailored for each participant group (patients, volunteers, and the primary care huddle team) to explore the feasibility, usability, and perceived impacts of GENIE (refer to Multimedia Appendix 1 for the full guides).

The participants were recruited via convenience sampling. Lists of Health Links patients were distributed to their physicians from the 2 clinics that participated in the Health TAPESTRY program. A total of 25 Health Links Program patients were invited to participate in the study via a letter from their primary care physician. Physicians selected these patients based on age (55-69 years), enrollment in Health Links, and a clinical assessment indicating that they could benefit from improved care coordination offered by the GENIE and Health TAPESTRY. The target number of participants was 10, with diverse demographic characteristics (gender and age), which was deemed sufficient for usability testing [42,43]. A research coordinator received signed consent forms from 11 potential participants who were contacted by telephone to schedule the first of 2 home visits. One participant could not be contacted, another participant died before the first planned visit, and a third patient participated in the first home visit but withdrew from the study because of mental health distress. A total of 8 participants completed the study. All clinicians involved in the Health TAPESTRY program were invited to participate in the focus groups, which included questions about the GENIE tool. All *huddle* clinicians (a selected small interdisciplinary core team who met regularly to plan patient care) participated in a focus group held at each of the 2 sites (n=16). The remaining clinicians who worked in the clinic and were members of the huddle team were also invited to participate in one-on-one interviews. Of all the clinicians, 17% (7/41) agreed to participate. All clinic managers and volunteer coordinators agreed to participate in the interviews (n=3). Three volunteers who were trained to facilitate the GENIE tool participated in the focus group.

Participants

We recruited 5 male and 3 female patients (4 patients from each clinic) with an average age of 63 years (SD 4.6; range 57-69 years). Half of the patients (4/8, 50%) had no computer access and had never used computers, whereas the other half (4/8, 50%) had used computers regularly. A total of 6 patients were married, 1 was divorced, and 1 had unknown marital status. Participants had a mean of 3.9 (SD 1.8) chronic diseases, ranging from 2 to 8 chronic diseases, including depression (n=6), anxiety (n=5), diabetes (n=5), cancer (n=4), arthritis (n=4), chronic obstructive pulmonary disease (n=2), heart disease (n=2), and pancreatitis (n=1).

Of the 3 volunteers, 1 was a male university student and 2 were retired females. The primary care team participants were members of the interprofessional teams at 2 clinics. One team had 7 members and included a dietitian, an occupational therapist, a physiotherapist, a pharmacist, a system navigator, 2 physicians, and a registered practical nurse. The second team had 9 members and consisted of an occupational therapist, a physiotherapist, a pharmacist, a system navigator, a physician, a psychologist, a registered practical nurse, and 2 nurse practitioners.

Analysis

Qualitative data (interview, focus group, huddle notes, and field observation notes) were uploaded and organized using NVivo (QSR International) software, version 10 [44]. Two authors (LC and RV) reviewed all the data sources. Field observation notes were coded in NVivo according to their organizing criteria using a qualitative descriptive approach (Multimedia Appendix 2) by LC, and they were reviewed by RV. LC coded the interview and focus groups by inductively organizing the coding using the interview guide that was guided by NPT [40]. RV reviewed all the coding, and the research team reviewed the final coding structure with themes to increase rigor in the results.

Participants' network maps were categorized using criteria developed by the GENIE founders and coauthors AR and IV, to identify the network typologies (based on the size of the network and type of network members). All authors reviewed

and discussed the preliminary and final findings and interpretations.

Results

Areas of Interest and Services Chosen for Potential Follow-up in GENIE

All patients completed a network map and a questionnaire that asked about a person's interests in various types of activities. Table 2 shows the categories and areas of interest chosen by participants. Patients were most interested in getting more physically fit (8/8, 100%), managing their weight (6/8, 75%), and learning about their health condition (6/8, 75%). All other topics garnered some interest, except knowing more about supports for a pet. Participants chose a range of 4-9 topics of interest, with an average of 6.

Patients favorited programs or services from the HSS database for potential follow-up that were related to the following: social clubs (5/8, 62%), home support (2/8, 25%), swimming (2/8, 25%), drama and music (1/8, 13%), and fitness and exercise (1/8, 13%). A total of 4 patients followed up with their favorited community services, including community or seniors' social clubs (n=3) and an aquafit class (n=1). One patient was disinterested in the community services. Patients could also find relevant HSSs to address the health conditions of interest. Patients selected diabetes (1/8, 13%), cancer (1/8, 13%), and other health conditions (1/8, 13%) but did not follow up on any of the relevant HSSs.

Table 2. Patient responses to GENIE (Generating Engagement in Network Involvement) survey questions related to topics of interest.

Categories and GENIE survey questions and subquestions	Patients with an interest in the category, n (%)
Activities	
I am interested in doing creative things (subquestions include reading and writing, drama and music, and arts and crafts).	5 (63)
I would like to know more about social activities (social clubs).	4 (50)
Health	
I would like to learn more about my health (draws from a checklist of health problems including heart problems, diabetes, arthritis, kidney problems, cancer, anxiety, depression, hypertension, and other).	6 (75)
I would like to manage my weight better (subquestions include weight management and nutrition).	6 (75)
I would like to get more physically fit (subquestions include fitness and exercise classes, walking or outdoor activities, and swimming).	8 (100)
Learning	
I would like to know more about looking after someone (caregiving).	4 (50)
I would like to learn new skills or take a course.	2 (25)
Support	
I would like to see people more often (subquestions include friendly visiting, counselling, and caregiver support).	4 (50)
Independent living	
I would like to know more about things that will help me remain independent (subquestions include transportation services and financial and benefits advice).	5 (63)
Volunteering	
I would like to help other people (subquestion includes volunteering opportunities).	4 (50)
New addition	
I would like to know more about supports for my pets.	0 (0)

Feasibility and Usability

Overview

Most patients and volunteers shared positive perceptions of the tool overall, such as the perception that the tool was easy to follow and understand. In addition, most patients noted that they would recommend it to others. However, several feasibility and usability issues were identified, as listed in Textbox 1 and described later. Quotations from participants are indicated by the participant type and ID number, such as patient 1, volunteer 3, and clinician 5. As we did not always capture the clinician's names in the huddle meeting notes, participant IDs are missing for some quotes.

Textbox 1. Feasibility and usability themes.

Feasibility: interview and focus group data, primary care provider huddle notes, and use statistics

- Partial understanding of the purpose of GENIE (Generating Engagement in Network Involvement)
- Need for facilitation to complete GENIE
- Clinician's navigation ability superior to GENIE supported by volunteers
- Time to complete GENIE

Usability: field observation notes

- GENIE inputs
  - Challenges in completing sections of the tool related to terminology used and lack of clarity in instructions
    - Chronic disease terms not understood
    - Unclear questions in the questionnaire
    - Unclear instructions related to who to add to the network and labeling their relationship
- GENIE and database outputs
  - Limitations in the quality and quantity of health and social service results
    - Quality of data insufficient in relation to community resources to match a health and social services to a patient
    - Quantity of data creates information overload
  - Technological challenges
    - Email setup concerns
    - Challenges printing results

Feasibility

Partial Understanding of the Purpose of GENIE

Generally, clinicians, volunteers, and many patients had a partial understanding of the purpose of GENIE. Most understood that it was meant to assess if patients were connected to the community; to determine their social support, including family, friends, and community-based resources during times of stress; and to find community resources to support them that match the patient's goals and assist them with self-management. Patient 3 explained the following: "it's more or less so [...] who you can contact to help you with different things to achieve your goals." Furthermore, a provider explained:

> *My understanding was to sort of trial this tool to help people find individualized supports for them, so individualized, as in based on their needs and hopefully in their local neighbourhood, supports that they identify that they need to accomplish the goals that they outlined for themselves.* [Clinician 2]

Some confusion was also evident. It was noted in an observation during patient 1's home visit that volunteers needed to be clearer about the purpose of GENIE when explaining it to the patient. In addition, clinical teams required the research coordinator to explain how to interpret the maps and network typologies. Most importantly, there was a gap in understanding the link between the social network component of GENIE and the use of the network to help mobilize the uptake of HSSs.

Need for Facilitation to Complete GENIE

The need to have someone to facilitate the patient's completion of GENIE was identified through many observational field notes. This was related to the lack of access to computers or the internet by some patients, as noted above. In addition, volunteers or the research coordinator needed to explain the purpose of the tool, including the network map and survey questions; read out the descriptions of the topics of interest; facilitate moving around in the network map; or support tailoring the selection of services for follow-up. Working through GENIE required assistance from the facilitator in all cases.

Clinician's Navigation Ability Superior to GENIE Supported by Volunteers

This theme was raised by clinicians who believed that they were better able to tailor the service to their patients than what the volunteers could offer with GENIE. Clinician 4 noted the following: "The software is good, but it's not as good as a person who actually knows what's going on there." Clinicians explained that they could better match patients to services, given their knowledge of their patients and services. Clinician 2 explained:

> *...sometimes that layer of information and that layer of referral is based on a depth of understanding of community services, a depth of understanding of the patient, and a depth of understanding of how they form relationships. And, you know, you are never going to copy that from a database.*

The relevance of some selected HSSs was questioned by their clinicians. One clinician explained that going with the most convenient service based on location was not the best approach to select a service and that other criteria may be more important. On the other hand, another clinician questioned why a service was chosen by the patient that was out of the local area of the patient's home. Furthermore, clinicians perceived that paper-based resources listing community services in the clinic, such as flyers, booklets, and posters, would be more popular for patients.

Time to Complete GENIE

GENIE was completed along with other screening surveys in the Health TAPESTRY program, adding time to the home visit. This created a challenge to completing GENIE, which took an average of 31.9 minutes (range 20-42). This time was in addition to the average of 57 minutes (SD 22) that the volunteers spent to complete the home visit. Volunteers also raised the challenge that, at times, completing GENIE broke the flow of the visit and took much longer than the numerous but short Health TAPESTRY surveys. Volunteer 2 noted:

> *...it delays things, they might lose interest while all this is still going on. It stops the flow of the visit.*

This was noted as being less of a problem in completing the social network map than in completing the questionnaire.

Usability

GENIE Inputs—Challenges in Completing Sections of the Tool Related to Terminology Used and Lack of Clarity in Instructions

Two main usability challenges were apparent in completed GENIE. These included (1) the use of unclear terminology and (2) confusion related to the instructions about who was to be added to the network map and how to label them. The first screen on logging in asked patients to check their chronic health conditions from a list of common conditions. On the basis of observations, it was noted that one patient and some volunteers were confused about certain chronic disease terms, including hypertension and chronic obstructive pulmonary disease, requiring simplification of these terms. Observation notes also indicated that one question in the questionnaire, "I would like help caring for other people" was misunderstood by one patient. One volunteer and patient also misunderstood the category of *finances and benefits*, as this item fell under the category in the questionnaire related to remaining independent.

Although network mapping was reported by most volunteers to be generally easy to use and visually helpful, clarification regarding the criteria used to determine who gets added to the network map and how to label the relationship was needed. Everyone struggled with the criteria needed to put someone into the network circles. The guiding question asks, "Who are the people close to you who help you with a long-term condition?" Some questioned whether this meant the people who could help or those who were most important to the patient but did not necessarily help. Clinician 6 commented:

> *And that could be geographically or that could be emotionally or support-wise. And I wonder if that were clarified a bit that might also help to find the purpose of the tool.*

Furthermore, volunteers were unsure about how to label some network members, such as roommates, social groups, and nurse practitioners.

GENIE and Database Outputs: Limitations in the Quality and Quantity of HSS Results

Usability challenges, noted in field observations and clinician and volunteer focus groups, were identified. Some programs or services appeared to be missing or outdated regarding the quality of the community's HSS database. A huddle note indicated that a clinician asked, "Why didn't YMCA cancer support programs come up?" Further, patient 1 asked, "Why the Burlington Seniors Centre on New Street does not show up?" Another limitation was the lack of details for some services, such as costs to participate, which raised concerns about the limits of matching a patient's interests based solely on traveling distance. A note from both team meetings indicated that clinicians objected to having *just a list* of services in the output and explained that what needs to happen is *matching the patient to the service*, in other words, better tailoring of the service to the patient's needs and context.

The sheer quantity of results of HSSs produced by the GENIE report, particularly if there were many interests selected, was noted to be overwhelming by many volunteers and clinicians. Clinician 3 noted:

> *Sometimes providing the information is overload for patients and it doesn't really go anywhere. Many people will come with, you know, I was given four pamphlets about stuff and I don't know what to do with this and I don't know how to connect with them or I don't – which one am I supposed to choose for myself.*

Furthermore, volunteer 1 explained:

> *When you give someone a huge list which often came up as this massive list, like, I can feel [the patients] getting discouraged. I would get discouraged.*

Despite this challenge, the clinic teams appreciated the list of potential resources as a useful starting point. The paper-based list was also appreciated by some patients:

> *Sometimes it's nice to have something on paper.* [Patient 3]

Technical Challenges

Some patients had no email address or had to use a family member's email address to create an account and log on to GENIE. They were worried that sharing an email address would open them up to spam and unwanted follow-up emails. The researcher assured them in the visit that their email would not be shared with anyone and that there would be no follow-up email. The researcher could also create a new email address to enable them only to use the GENIE tool.

Several participants also had technical challenges in printing reports because of the occasional problem of generating the PDF for the report, which was a function in the tool. In addition,

some general challenges associated with the printer included connecting the printer to the tablet because the researcher needed to use Wi-Fi or a hotspot to print from a portable printer that did not work in a few instances. Patients preferred to have a printed copy of the report.

Evaluation Impacts

Clinicians perceived that GENIE strengthened their understanding of their patients' social networks through social network maps, and in one case, it moved the team to work with a patient who was identified as being socially isolated. Furthermore, clinician 5 described:

> *There was one that we looked at just recently where caregiver strain was a major issue for the person and yet all their ties were people that they care for, and that highlighted, I think, the real dilemma in that situation.*

In a few cases, the use of GENIE sparked patient action, including reviewing more GENIE results after the visit and actively connecting more with family. For example, patient 8 noted:

> *It's sort of a graphic that shows you how little you might have [been] involved with the people that are close to you. Maybe it's sort of like almost visual cues that maybe I haven't been as close as possible to my family. And I think that also sparked me to be more active phoning them.*

Participants from all groups identified several potential impacts of using GENIE. There was a perception that GENIE provided the opportunity to reduce isolation by encouraging and enabling patients to become more involved in their community and establish connections. For example, volunteer 3 noted that GENIE could potentially help patients "be more involved in community and connections with other people rather than just be isolated in their homes, perhaps as an encouragement to develop or maintain those connections." Patient 8 explained how it could help clinicians gain a better understanding of the patient's needs:

> *I think it does help people identify what they need. And then for the doctors or practitioners or whoever is there that it's just one more thing that, [...] sometimes you don't have time to talk about everything when you go to your family doctor. So, I think it's a good thing because support is really important to your well-being. And you had quite a few different things; [...] it was your medical plus the activities or social life.*

There were limited changes in network size, frequency, or makeup over time. Of 8 patients, 4 had network membership gains at time 2 (3 months later), with new members added to their network as they joined clubs or classes. However, 1 patient experienced a network loss of 1 member. Patients did not note any changes in the frequency of contact with their network members or groups in the 3 months' time frame (daily, monthly, weekly, or less). Finally, 25% (2/8) of patients showed no change in their network size or composition. Individual's network typologies indicated that 50% (4/8) of patients had *very isolated* networks and 50% (4/8) of patients had *friend and family supported* networks at time 1. None of the patients had diverse networks at any time point.

Factors Influencing Community Services Follow-up

Several barriers to the use of community services were identified. The most common barrier reported by patients and a volunteer was the distance to travel to the service or program. Patient 4 explained "I drive but I do not go downtown, and I do not like to drive downtown, and I do not like to rely on people for that." Transportation issues were also noted, indicating that proximity is an important factor influencing service use. A few patients also mentioned that they did not want to leave home because of feeling unwell from chronic headaches or fear of getting confused owing to an acquired brain injury.

Motivation was identified by the clinic teams as a barrier for patients to access community-based services. On the basis of an observation, a patient identified key areas of concern as weight gain, information about his health, walking and outdoor activities, and caregiver support; although he seemed interested in these areas, he was not interested in attending any services or programs. Volunteers spoke about the potential of GENIE to influence motivation:

> *It creates awareness for people of what is available out there. And if they are motivated to do it, you know, that just might be the final push, if you will, to go out and do that.* [Volunteer 1]

Other barriers that were raised in a few instances were mobility issues, eligibility challenges (may not be eligible for transportation support because the patient can walk), and a lack of services in the area of interest.

Discussion

Principal Findings

This study showed that GENIE—a web-based social network tool—was generally feasible and usable for patients, volunteers, and the primary care team, although a number of feasibility and usability challenges were identified. A key feasibility challenge was the gap in understanding the purpose of GENIE by clinicians, patients, and volunteers. NPT points out that sense-making work, that is, having a clear understanding of the purpose of the novel intervention, is important to support its normalization or uptake in practice [40]. In this study, volunteers indicated that the social network maps were useful to help patients reflect on their personal support, and providers found it valuable to better understand their patients' social contexts. However, there was a lack of understanding of how mobilizing the patient's social network could help patients to access their community HSSs of interest identified through GENIE. Research has shown that social support can influence chronic disease self-management [45,46]. In a GENIE study involving older adults with diabetes, facilitators used GENIE as "a positive disruption to self-management by prompting reconsideration of network members and how they impact on self-management as well as an avenue to connect to new activities and sources of support" [47]. Given the partial understanding of the purpose of GENIE, this study highlights the need to improve GENIE

training to ensure that users have a clear understanding of its purpose and how the components are meant to work together.

Another key feasibility challenge was that primary care providers reported relying more on their personal knowledge of HSSs than on GENIE results. In addition, NPT suggests that individually and collectively, participants need to see the value, benefit, and importance of the innovation for it to be taken up in practice [40]. Our results indicated that clinicians had a somewhat limited belief in the benefits of GENIE. They explained that their long-standing knowledge of their patients increased their ability to suggest suitable HSSs compared with GENIE search results. Other research has shown that physicians rely on their health care team's knowledge of HSSs [20], use out-of-date resources to identify programs and services, and the HSS search strategies that are used are limited. Ploeg et al [48] also found making referrals to HSSs challenging. It has been shown that physicians understand the importance of social care needs; however, they do not have sufficient time to address them, necessitating assistance from others to fill this gap [49]. Physicians have relied on the interprofessional team to make community linkages for their patients [20], adding pressure on the team to be up to date on HSSs. This is a particular challenge in primary care practices that do not have interprofessional team support. Even when interprofessional teams are present, it takes time to identify the patient's needs, match them to relevant services, and assist them in making the necessary connections. Additional time is required to consider patients' personal social networks and mobilize them to assist in HSSs uptake.

It was not surprising that the time needed to complete GENIE was a feasibility challenge, given that it was used within the Health TAPESTRY program, which was time-intensive on its own. This is the first instance to our knowledge that GENIE was implemented in the context of another program—Health TAPESTRY. As such, it was not possible to determine the feasibility issues of GENIE, independent of the context of Health TAPESTRY. However, the Health TAPESTRY program provided the necessary infrastructure for GENIE to be implemented in a novel way by volunteers visiting patients at home within a primary care context, thereby adding new knowledge to the field.

Usability results showed that better GENIE filtering of HSS results was needed (eg, costs of services and eligibility criteria). Patients found the number of HSS results from GENIE overwhelming, particularly when the patient indicated interest in multiple activities. This generated numerous pages of results. Given this usability challenge, it is not surprising that facilitation was needed to support the use of GENIE to help prioritize the selections. Consistent with previous studies, there was an awareness of the need to focus on a narrower set of options. The key role of conversations with the facilitator was to understand acceptable options for new activities and training facilitators to understand and develop their role in helping the patient negotiate a focus on a small number of options acceptable to them [26,50]. Furthermore, improved facilitator training was needed to guide the participant to place themselves "at the centre of the circle and encourage them to think about why and how some people and resources might be more or less important to them" [50] to help HSSs uptake.

The accuracy and completeness of the database of community services that was feeding GENIE's output and GENIE's filtering capability also had some usability challenges. For example, a patient may have indicated an interest in a swimming program; however, the listing would not indicate its relevance to seniors. Future research is needed to better identify what patients want from an HSS database to help them further refine their results and identify relevant HSSs to meet their needs. Although it has been argued that there is a need for comprehensive and centralized community information systems [51], keeping information and referral database content up to date is challenging [52]. Community information and referral service databases in the United States and Canada tend to be managed by libraries or other community service agencies offering formal and structured community information services. Community capacity to maintain these databases requires consistent government funding. The research team worked closely with the regional community organization to notify them about missing or irrelevant information, which helped keep their databases up to date. Creating an ongoing feedback loop between primary care providers, volunteers, and community agencies who manage community service information databases could be a useful strategy to help increase their accuracy and increase the relevance of the data shared. Another potential solution would be to allow primary care providers to leave comments on HSS databases based on their knowledge and feedback from their patients on the HSS.

Usability results showed a need for modifications to the tool and more volunteer training to clarify the use of terms and phrases. For example, the use of the phrase *someone close to you* was a point of confusion between the volunteer and the patient in their interaction to map a patient's personal network. A second important usability finding was that a few patients had difficulties understanding medical terms for chronic conditions. This indicates a need to strengthen health literacy for some adults with chronic conditions particularly, as it has been shown to influence the appropriate use of health services [53]. Future research is needed to better address the gap between the use of professional terminology and the public's understanding when used in eHealth tools [54].

A systematic review by Stellefson et al [55] found that multidisciplinary teams (eg, diabetes care managers, nurses, primary care physicians, pharmacists, and social workers) can support patients' use of the web 2.0 interventions to assist in the management of chronic diseases. This review supported the need for facilitation in the use of digital tools for self-management among older adults, which may be particularly important for those who are managing multiple chronic health and social conditions and are high users of the health care system. Furthermore, studies have shown that community members prefer to receive information informally through everyday conversations rather than via databases and that having skilled people in the community helps to translate information for them [56]. Finally, obtaining information from web sources can be challenging for adults with sensory losses, language issues, or poor health literacy, requiring facilitation by others [51]. This study supported that trained volunteers were a valuable extension of the primary care setting that could support

the use of GENIE by high users of the health system. However, improvements are needed to (1) the GENIE app and the HSSs database, (2) provide a stronger orientation of the benefits of GENIE to clinicians, and (3) deliver more comprehensive training for volunteers. NPT speaks of the importance of allocating the division of labor around skill sets to support operationalizing the innovation [40]. Ideally, volunteer training would expand the volunteer role from that of a basic facilitator to include skills in motivational interviewing and increasing their knowledge about HSSs. The primary care team would need to endorse this enhanced volunteer role. Overall, more research is needed to explore how to better engage primary care in mobilizing HSSs support for these vulnerable adults.

With regard to outcomes, the patient uptake of services that were identified by GENIE was variable. Half of the patients (4/8, 50%) attended a new club or social group as a result of the intervention, pointing to the need and interest in social connection. A 2017 systematic literature review of social prescribing in primary care indicated positive impacts, including the use of recommended community links among others [57]. However, their results should be considered with caution, as the included studies were shown to have a high risk of bias. This feasibility study involved high users of the health care system and therefore likely presented participants with significant barriers to HSS uptake. More research is needed to explore which populations can benefit the most from such interventions and whether the addition of social prescribing by primary care providers combined with the use of GENIE supported by volunteers as an extension of the team would result in the better uptake of HSSs. Finally, 2 perceived outcomes of GENIE were identified in our study that can inform outcomes in future research with GENIE—the reduction of social isolation and the increased awareness of patients' needs, interests, and social context among their primary care providers.

Finally, the most common topics of interest selected by patients were health related: weight management, physical activity, and health management. These topics mirrored those of the top 6 life and health goals identified by older adults in another study conducted in Ontario [32]. Furthermore, GENIE studies conducted in the United Kingdom also showed that most activities chosen in other related GENIE studies also tended to be health related [26,27]. This provides support that the topics in the GENIE tool are relevant to an adult population. However, it should be noted that patients were not offered the opportunity to nominate other topics of interest.

Strengths and Limitations

This study involved 8 patients who were high users of the health care system, a population that is not frequently studied. A strength of this study is that data were collected from multiple sources (observation, interviews, focus groups, and GENIE use statistics) and from the perspectives of patients, providers, and volunteers to assess the feasibility, usability, and perceived impacts of GENIE. There were challenges in recruiting and retaining patients, and as such, the study is limited by its small sample size. However, the size is adequate for usability testing [42]. Data were collected between 2017 and 2018. Although technology rapidly changes, GENIE's main functions remain relevant in addressing current challenges in primary care. In addition, the use of volunteers in primary care is a more recent innovation that continues to be tested [58], and we believe that this study is relevant today. Moreover, the implementation of GENIE occurred in the context of the Health TAPESTRY program. In this regard, the transferability of the study findings is low. Despite this, the study has contributed new knowledge about the feasibility and usability of using GENIE in a primary care context that involves trained volunteers as a unique extension of the team. Finally, as with most complex interventions, more research is needed to isolate and identify factors influencing the success and failure of its implementation and outcomes.

Conclusions

GENIE provides an opportunity for patients to identify a program or activity that could help expand their social network and to identify social support that can be leveraged to increase social participation. More volunteer training and experience were required to enhance the implementation of GENIE to its full potential. Over time, volunteers may develop more familiarity with the landscape of HSSs and play a more important role in navigating patients through the system. With well-trained and experienced volunteers, more active follow-up (by phone or in-person), and perhaps actual accompaniment to attend a new program or service, more success might be possible in matching patients to programs and services. However, some clinicians perceive that there can be a mismatch in the right services for patients through GENIE. Volunteers, or perhaps peer approaches, may be a viable solution to support social prescribing and the uptake of services for populations living with complex health and social conditions needing self-management support. This study informs potential measures of research outcomes and points to GENIE's potential. More research is needed to investigate the impact of one-on-one facilitation in primary care by volunteers and digital tools, preferably using comparative designs [56] that consider cost.

Acknowledgments

The authors acknowledge support from the following McMaster undergraduate nursing students: Olana Lovell for assisting with conducting interviews and focus groups and Eric Park and Natalie Chan for assisting with data analysis. The authors would like to thank the patients, volunteers, and clinicians who participated in this study, Pauline Kajiura and Simon LeBrun from Information Hamilton for their constant support, and the developers of the GENIE tool—Anne Rogers, Anne Kennedy, and Ivo Vassilev of the University of Southampton. The authors gratefully acknowledge the funding support from Health Canada (grant 6817-06-2013/5570001) and the Government of Ontario (grant 06547 for INSPIRE-PHC [Innovations Strengthening Primary

Health Care Through Research-Primary Health Care]; Ministry of Health and Long-Term Care), the additional financial support from the Labarge Optimal Aging Initiative, and the financial and in-kind support from the McMaster Family Health Organization and the McMaster University Department of Family Medicine.

Authors' Contributions

All authors were involved in the conceptualization of the study. RV and LC collected and analyzed the data and wrote the initial manuscript drafts. All authors were involved in the interpretation of results, provided feedback on drafts, and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Interview guides for GENIE (Generating Engagement in Network Involvement).
[DOCX File , 28 KB - formative_v5i7e25285_app1.docx]

Multimedia Appendix 2
GENIE (Generating Engagement in Network Involvement) observation field notes.
[DOCX File , 16 KB - formative_v5i7e25285_app2.docx]

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Abbreviations

AIRS: Alliance of Information and Referral Systems
GENIE: Generating Engagement in Network Involvement
HSS: health and social service
INSPIRE-PHC: Innovations Strengthening Primary Health Care Through Research-Primary Health Care
MCC: multiple chronic condition
NPT: Normalization Process Theory
TAPESTRY: Teams Advancing Patient Experience: Strengthening Quality

Edited by G Eysenbach; submitted 28.10.20; peer-reviewed by G Boyle, V Stara, L Desveaux, P Cook; comments to author 08.01.21; revised version received 01.04.21; accepted 31.05.21; published 12.07.21.

Please cite as:
Valaitis R, Cleghorn L, Vassilev I, Rogers A, Ploeg J, Kothari A, Risdon C, Gillett J, Guenter D, Dolovich L
A Web-Based Social Network Tool (GENIE) for Supporting Self-management Among High Users of the Health Care System: Feasibility and Usability Study
JMIR Form Res 2021;5(7):e25285
URL: https://formative.jmir.org/2021/7/e25285
doi:10.2196/25285
PMID:34255654

Original Paper

Designing Asynchronous Remote Support for Behavioral Activation in Teenagers With Depression: Formative Study

Arpita Bhattacharya[1*], PhD; Ria Nagar[2,3*], BA; Jessica Jenness[3*], PhD; Sean A Munson[4*], PhD; Julie A Kientz[4*], PhD

[1]Department of Informatics, University of California, Irvine, Irvine, CA, United States

[2]Psychological Science, University of Glasgow, Glasgow, United Kingdom

[3]Department of Psychiatry and Behavioral Sciences, University of Washington, Seattle, WA, United States

[4]Human Centered Design and Engineering, University of Washington, Seattle, WA, United States

[*]all authors contributed equally

Corresponding Author:
Arpita Bhattacharya, PhD
Department of Informatics
University of California, Irvine
6210 Donald Bren Hall
Irvine, CA, 92697
United States
Phone: 1 (949) 824 2901
Email: arpitab@uci.edu

Abstract

Background: Many teenagers in the United States experience challenges with symptoms of depression, and they lack adequate resources for accessing in-person mental health care. Involving teens and clinicians in designing technologies that use evidence-based practices that reduce barriers to accessing mental health care is crucial. Interventions based on behavioral activation (BA) help teens understand the relationship between mood and activity, help them practice goal-directed behaviors to improve mood, and may be particularly well-suited to delivery via internet-based platforms.

Objective: This study aims to understand the needs and challenges that teens and mental health clinicians face in depression management and involve them in the design process of a remote intervention that uses asynchronous remote communities. Our goal is to understand the benefits and challenges of adapting BA to an internet-based platform that supports the asynchronous remote community approach as a delivery tool for teen depression management.

Methods: We enrolled mental health clinicians (n=10) and teens (n=8) in separate, private, internet-based groups on Slack (Slack Technologies Inc). They participated in 20-minute design activities for 10 weeks and were then invited to interviews about their experiences in the study.

Results: Both teen and clinician participants wanted internet-based support for BA as a supplement to in-person therapy. Although participants perceived the asynchronous format as conducive to supporting accessible care, teens and clinicians raised concerns about safety, privacy, and the moderating of the internet-based group. Design decisions that address these concerns need to be balanced with the potential benefits of learning coping skills, increasing access to mental health care, and promoting asynchronous human connection to support teens.

Conclusions: We discuss considerations for balancing tensions in privacy and safety while designing and selecting internet-based platforms to support remote care and integrating evidence-based support when designing digital technologies for the treatment of teens with depression.

(JMIR Form Res 2021;5(7):e20969) doi:10.2196/20969

KEYWORDS

teens; mental health; behavioral activation; asynchronous remote communities

Introduction

Background

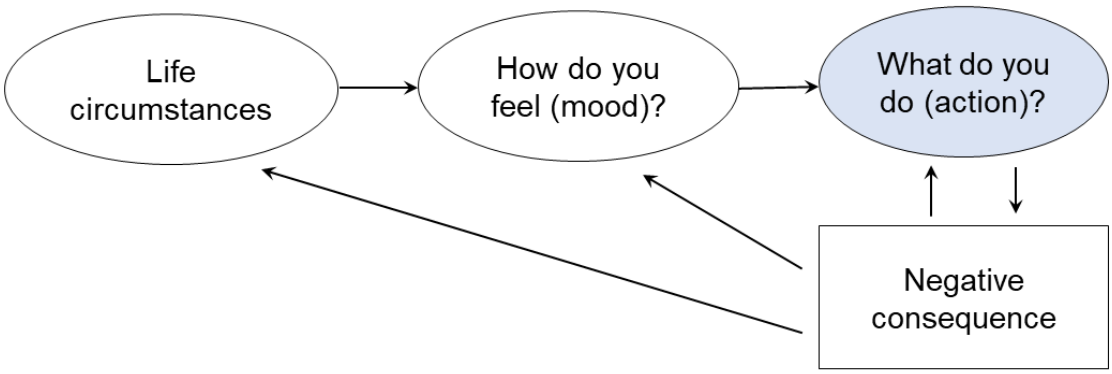
Approximately 3.2 million teenagers are diagnosed with depression each year [1]. Depression in teens is a serious and debilitating disorder associated with lifelong negative outcomes, including increased risk of recurrence into adulthood, social difficulties, physical illness, and suicidality [1-5]. More than 60% of adolescents with depression do not receive in-person mental health care, and among those who do, treatment engagement is low [1,6]. Evidence-based psychosocial interventions (EBPIs) for individuals with depression typically require frequent interactions between patients and mental health providers throughout time, which can be a barrier for patients and costly to administer in person [1].

Technology-based tools may provide an opportunity to improve the usability and engagement of EBPIs, particularly among teens where daily technology use is nearly ubiquitous [7]. Asynchronous remote communities (ARCs) are technology-mediated groups that use private internet-based platforms to deliver weekly tasks to participants in a format that is lightweight, accessible, usable, and low burden [8]. ARCs capitalize on the reach of technology while also providing support, social interactions, and motivation to engage in care. In this study, we seek to engage teens and mental health clinicians in the design process to understand how to use an ARC platform to support an EBPI for depression.

Overview of Behavioral Activation Therapy

Behavioral activation (BA) is an EBPI for individuals with depression [9-11] and lends itself to a wide range of implementation and training methods [12,13]. BA is based on a functional analytic model of depression that highlights the transactional associations among environmental stress, behavior, and mood (Figure 1) [10]. Specifically, BA approaches the treatment of depression through two primary targets: (1) increasing the experience of positive reinforcement (rewarding experiences) to help improve mood and (2) decreasing avoidance of reinforcing activities that may negatively reinforce depression symptoms. To address these treatment targets, BA emphasizes practicing goal-directed rather than mood-directed behavior. For example, if a teen is rejected by a friend and subsequently experiences a low mood, a mood-directed behavior would be to isolate from all peers to avoid further rejection. Isolation from a broader group of peers would likely lead to negative consequences, such as worsening friendships and a lack of social contact. These negative consequences feedback in the teen's environmental stress, low mood, and avoidant behaviors, ultimately resulting in a negative cycle of depression. Alternatively, goal-directed behavior refers to setting and following small steps toward a goal (instead of a mood) that aligns with the teen's core values and is likely to positively influence their mood. For example, despite the mood-directed inclination to avoid potential rejection, the teen may set a goal to see a movie with a friend and follow small steps toward this goal, such as calling the friend, setting a time and date, and selecting a movie to watch. Although BA holds promise as an effective treatment for depression [11,14], there is an opportunity to improve the usability of and engagement with BA via internet-based technologies, particularly among teens who are highly engaged with social and mobile technologies [7,15,16].

Figure 1. Behavioral activation model of depression among teens.



Designing for Teen Mental Health

Technology can be creatively designed to engage teens in EPBIs for emotional and mental health management. Researchers have used different modalities of engagement for preteens and teens, such as engaging parents and children with strategies for social and emotional skill learning through digital storytelling and dialogic inquiry [17] and designing a toy that provides real-time biofeedback to mitigate negative emotional responses [18]. Researchers have also designed a social robot (Ecological Momentary Assessment Robot) [19] with teens to assess their stress and support emotive and embodied interactions. In a pilot randomized controlled trial of a website delivering BA modules on planning activities to improve mood, Davidson et al [12] found that 96.2% of teen participants who had depression symptoms completed the module. They suggested tracking activities and moods and sending reminders using mobile technology to improve engagement [12]. Rohani et al [20] designed an app called MORIBUS based on BA for activity planning and rating and visualizing mood patterns for adults with depression. In their feasibility study, participants found personal visual insights into the relationship between their mood and activity most useful with an overall compliance rate of 71%. Researchers identified opportunities to support the need for

flexibility in logging activities instead of only in-the-moment logging, as participants had individual usage patterns. For example, some participants logged their activities at the end of the day when they had privacy, versus a few who logged it as they completed the activity. Flexibility in how and when individuals engage with internet-based mental health tools can be supported by an asynchronous format of logging and participating in activities.

The Need for an ARC Method

When working with teens, researchers have encountered challenges in using common design methods (eg, curt or not fully formed responses, power imbalance, and access constraints), suggesting a need for new and innovative ways to involve them in design [21]. ARCs are private internet-based groups in which researchers can deliver periodic research tasks to participants and gather information about their perceptions in a format that is lightweight, accessible, usable, and low burden. Researchers have used the ARC method to engage adults living with chronic and stigmatized illnesses and people who face challenges with access to care [8,22,23]. Asynchronous methods have also been used in conjunction with internet-based social networking tools to engage with youth in intervention research [24,25]. For example, researchers enrolled 79 young adults in private Facebook groups to deliver cognitive behavioral therapy interventions for smoking cessation for 90 days [25]. SharpTalk was an internet-based, moderated peer support discussion forum designed for youths aged 16-25 years who engage in self-harm [24]. For teens, ARCs on social networking platforms offer more convenient and lightweight access than visiting offline research sites, as teens may encounter barriers to in-person appointments, such as the need for transportation and parental support. ARCs also support engaging with and following teens' activities throughout time and teens who are geographically distributed. Our previous work highlighted ARCs as a promising approach for engaging teens in EBPIs for mental health that leverages technology's reach while understanding teens' challenges with mental health, needs for support and social interactions, and motivations [26]. In this study, we sought to expand the use of ARCs to understand the benefits and challenges of adapting BA to an internet-based platform that supports intervention delivery and engagement tools for teen depression management.

Study Overview

In this study, we aim to use and adapt the ARC method to involve teenagers and clinicians in the design process of adapting BA interventions. We built our group guidelines and protocols for moderating the group and handling internet-based disclosures of adverse events based on ethical considerations on balancing teens' safety, preference to remain anonymous, and potential distress by Sharkey et al [24] (Multimedia Appendices 1-3).

The following research aims guided the design of our internet-based activities, interviews, and analysis:

- Aim 1 (A1): using the ARC to understand perceptions, needs, and challenges of clinicians and teens in designing technologies for the treatment of teen depression
- Aim 2 (A2): understanding what clinicians and teenagers envision from the design and delivery of BA for the treatment of teen depression using internet-based technology platforms that support an ARC approach

To address these aims, we aim to use the ARC method with clinicians and teens in two separate, private, internet-based groups and post 20-minute–long design activities each week for 10 weeks. Each activity prompted clinicians and teens to provide feedback on adapting the BA to Slack (Slack Technologies Inc) and design implementation ideas. We seek to discover their needs, design constraints, and facilitators of and barriers to adapting BA for asynchronous delivery and analyzed their experiences with the ARC. This empirical work provides design recommendations for researchers and practitioners working with internet-based technologies to use EBPIs for teen depression management. On the basis of our analysis, both clinicians and teens highlighted (1) the need for technology to be a supplement to therapy and not a replacement, preserving the in-person interaction that therapy usually provides and (2) the importance of balancing human connection on the web while considering both privacy and safety.

Methods

Overview

We conducted two separate ARC studies on Slack with 10 mental health clinicians (C1-C10, including therapists, primary care, and school counselors), who worked with depressed teens, and 8 teen participants (T1-T8) aged between 15 and 19 years who experienced mild-to-moderate symptoms of depression. We aimed to understand clinicians' and teens' current perceptions, strategies, challenges, and technology use in managing depression (A1) and their design ideas for adapting BA to internet-based platforms that support an ARC approach to intervention (A2). We created separate groups for teens and clinicians to prevent power dynamics between teens and clinicians from influencing each other's answers, creating separate spaces where each group could prioritize their own needs and preferences; thus, each group could communicate comfortably. We started the teen groups 3 weeks after the clinician group so that we could make changes to the activities based on clinicians' feedback and use the teens' time efficiently. Clinicians were recruited through snowball sampling of a network of researchers. To recruit teens, we contacted participants from an earlier study [26] who agreed to be recontacted, posted flyers in clinician participants' clinics with their permission, and used snowball sampling. The study was approved by the Human Subjects Division of the University of Washington.

Participants

In total, 10 clinician participants started the study, with 8 completing all internet-based activities. All clinicians (n=10) were from urban or suburban areas in Seattle and Kent, Washington (Table 1), and 8 had previous experience using BA with teens. We started the study with 8 teenage participants, and 4 teenagers dropped out by week 9. All teen participants identified as female (Table 2) and were from rural, suburban, and urban regions across the United States. A clinician dropped

out in week 4 (because of a family emergency) and another dropped out in week 7 (because of difficulties with using the Slack platform; Table 3). The client base and setting of the clinicians included teens and preteens with depression (11-18 years), including school counseling, community clinics, pediatrics, primary care, immigrants, and refugees. The client base and setting of the clinicians included teens and preteens with depression (11-18 years), including school counseling, community clinics, pediatrics, primary care, immigrants, and refugees.

Table 1. Summary of demographic details of clinician participants (n=10).

Demographics	Values
Age (years), mean (range)	39 (31-50)
Gender, n (%)	
Women	7 (70)
Men	3 (30)
Nonbinary	0 (0)
Education level, n (%)	
Graduate education	7 (70)
Professional degree	3 (30)
Race or ethnicity, n (%)	
White	8 (80)
Asian	1 (10)
Hispanic	1 (10)
Household income (US $), n (%)	
50,000-75,000	4 (40)
100,000-150,000	2 (20)
150,000-200,000	1 (10)
≥200,000	3 (30)
Region, n (%)	
Urban	8 (80)
Suburban	2 (20)
Washington	10 (100)
Experience with evidence-based practice, n (%)	
Cognitive behavioral therapy	8 (80)
Behavioral activation	8 (80)
Mindfulness-based approaches	6 (60)
Dialectical behavior therapy	4 (40)
Interpersonal psychotherapy	3 (30)
Acceptance and commitment therapy	2 (20)
Other	3 (30)

Table 2. Summary of demographic details of teen participants in study 2 (n=8).

Demographics	Values
Age (years), mean (range)	17.5 (15-19)
Gender, n (%)	
Women	8 (100)
Men	0 (0)
Nonbinary	0 (0)
Education level, n (%)	
College education with degree	1 (13)
Some college education but no degree	2 (25)
High school	2 (25)
Less than high school	3 (38)
Race or ethnicity, n (%)	
White	5 (63)
Asian	1 (13)
More than one race	1 (13)
Did not disclose	1 (13)
Household income (US $), n (%)	
35,000-49,000	1 (13)
75,000-100,000	1 (13)
150,000-199,000	1 (13)
≥200,000	2 (25)
Did not disclose	3 (38)
Region level, n (%)	
Rural	1 (13)
Suburban	2 (25)
Urban	5 (63)
Washington	5 (63)
Philadelphia	1 (13)
Iowa	1 (13)
New York	1 (13)
Therapy experience, n (%)	
Received treatment for depression in the past	6 (75)
In treatment during the study	5 (63)

Table 3. Summary of activities on the private Slack group.

Week	Design activity	Purpose and activities	Clinician completion rate (n=10), n (%)	Teen completion rate (n=8), n (%)
1	Introductions	• Learning how to use features of Slack • Getting to know other participants	10 (100)	7 (88)
2	Technology to manage mood	• Sharing current strategies and technologies that participants have found helpful for their clients (clinicians) and themselves (teens and clinicians)	10 (100)	7 (88)
3	Internet-based mental health support, part 1	• Learning about more features of Slack such as polls with example poll • Ideating on benefits and challenges of using the internet-based platform of Slack	10 (100)	7 (88)
4	Internet-based mental health support, part 2	• Voting polls on preferred features of Slack for internet-based support with mood • Voting polls for the format of the internet-based support (eg, group vs individual) and the length of internet-based support	9 (90)	8 (100)
5	Adapting BA[a] to the web	• Psychoeducational video explaining BA • Prototype: obtain feedback on a summary of BA activities for 6-week format (Multimedia Appendix 4)	9 (90)	7 (88)
6	BA Model and activity monitoring	• Explaining BA model with a video and concepts through slides (Figure 2) and ask participants to give examples from their lives by uploading hand-drawings (Figure 3) • Prototype: mock-up of mood and activity monitoring in survey format	8 (80)	6 (75)

7	Upward and downward spiraling of mood; introducing SMART[b] goals	• Providing feedback on upward and downward spiraling of mood and planning SMART goals
		• Prototypes:
		  • Survey format for reflecting on upward and downward spirals in mood and action (Figure 4)
		  • Survey format for individually planning a SMART goal, mini-steps, and setting reminders
			8 (80)	6 (75)

8	SMART goal planning	• Providing feedback on technological adaptations of planning a SMART goal, mini-steps, and setting reminders
		• Prototypes:
		  • Mock-up of chatbot format
		  • Direct messaging format in which participants pair up with a peer and a researcher moderator. Participants were asked to share SMART goals and provide feedback on each other's goals
			7 (70)	6 (75)

9	Overcoming barriers	• Providing feedback on overcoming barriers to mini-steps and SMART goals.
		• Prototypes:
		  • Survey format
		  • Chatbot format with prompts to overcome barriers (Figure 5)
		• Direct messaging format by pairing up with a peer from week 8, following up, and sharing barriers
			7 (70)	4 (50)

10	Teaching components	• Identifying how to deliver teaching components of BA in internet-based formats such as videos and chatbots	7 (70)	4 (50)
11-12	Exit interviews and surveys	• Providing feedback on the method and follow-up questions on depression management	9 (90)	5 (63)

[a]BA: behavioral activation.

[b]SMART: specific, measurable, appealing, realistic, and timebound.

Figure 2. Example of a slide (PDF) of instructions presented to teens to explain the Downward and Upward Spiral Worksheet for behavioral activation.

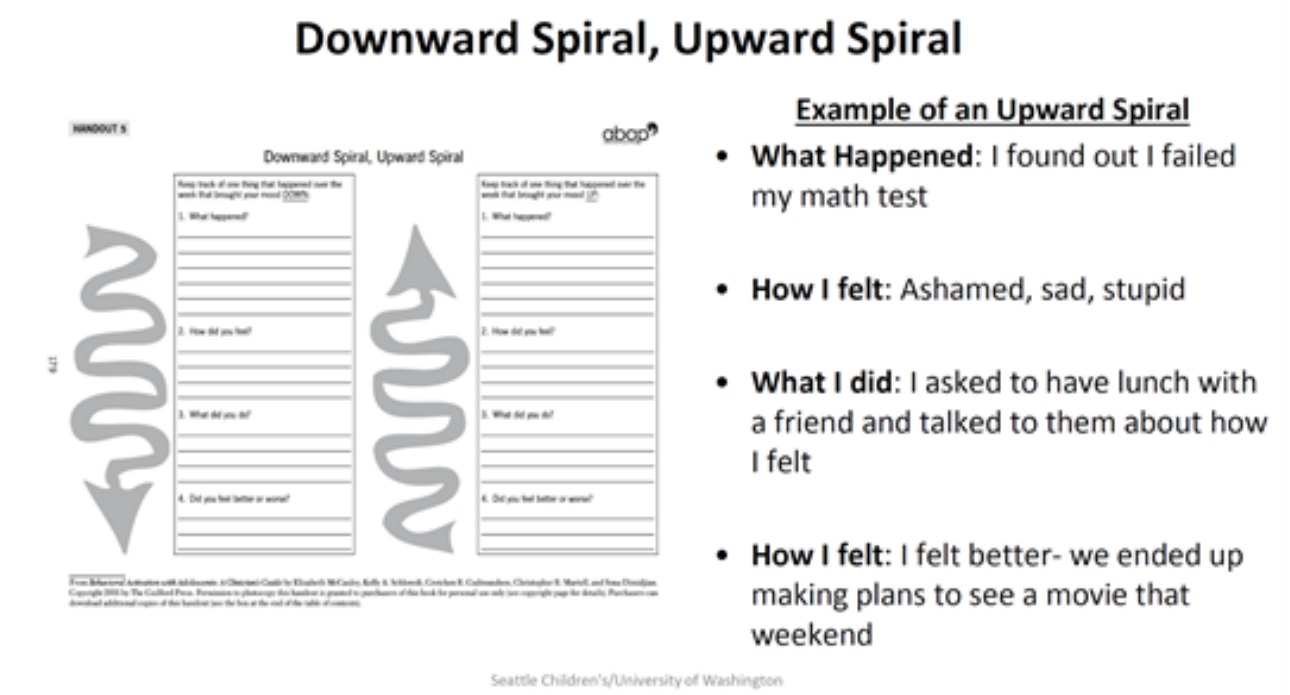


Figure 3. "How behavioral activation (BA) works for me?" Hand-drawn picture from a teen participant explaining how BA would apply to their life circumstances. BA: behavioral activation.

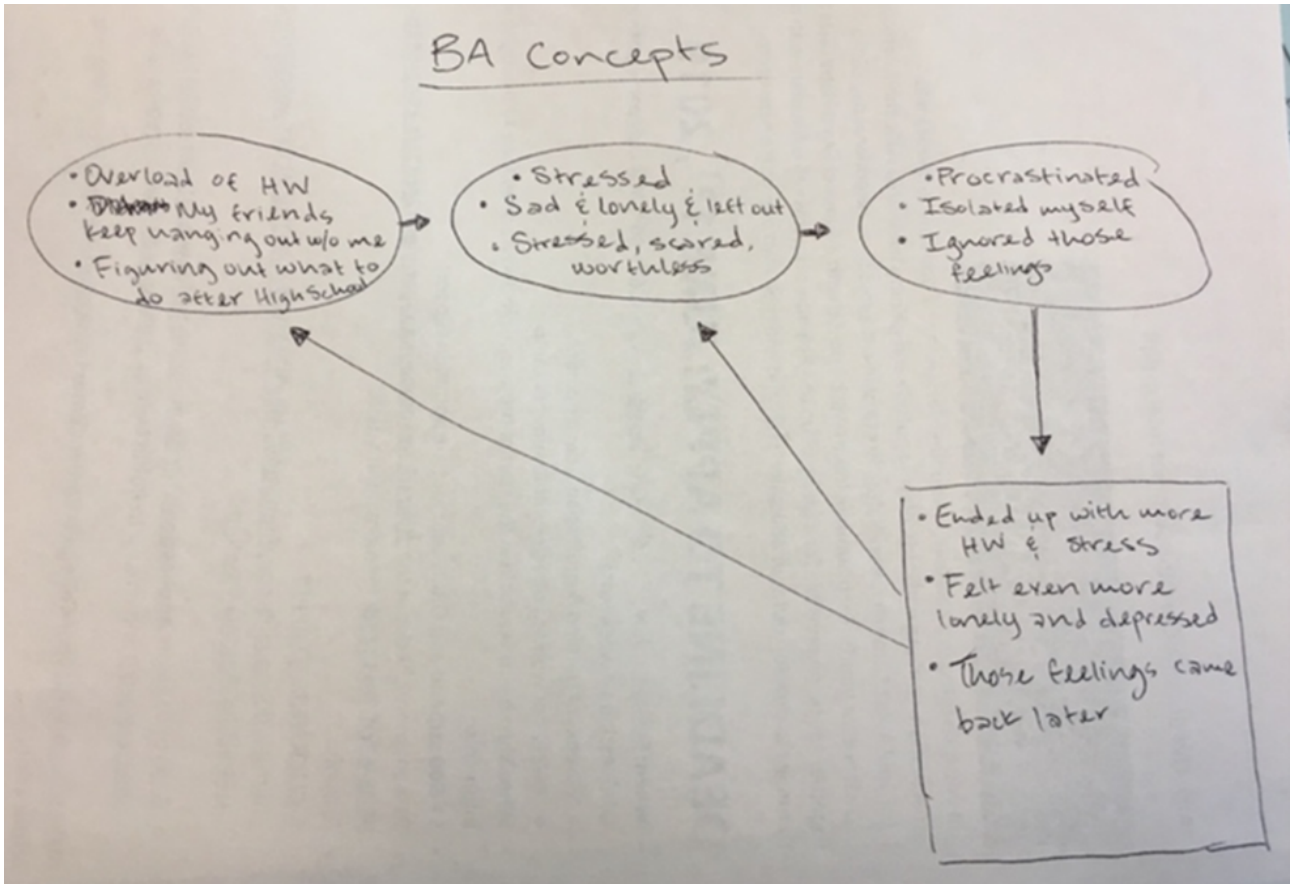


Figure 4. Mock-up for the internet survey–based adaptation of the downward spiral module in behavioral activation.

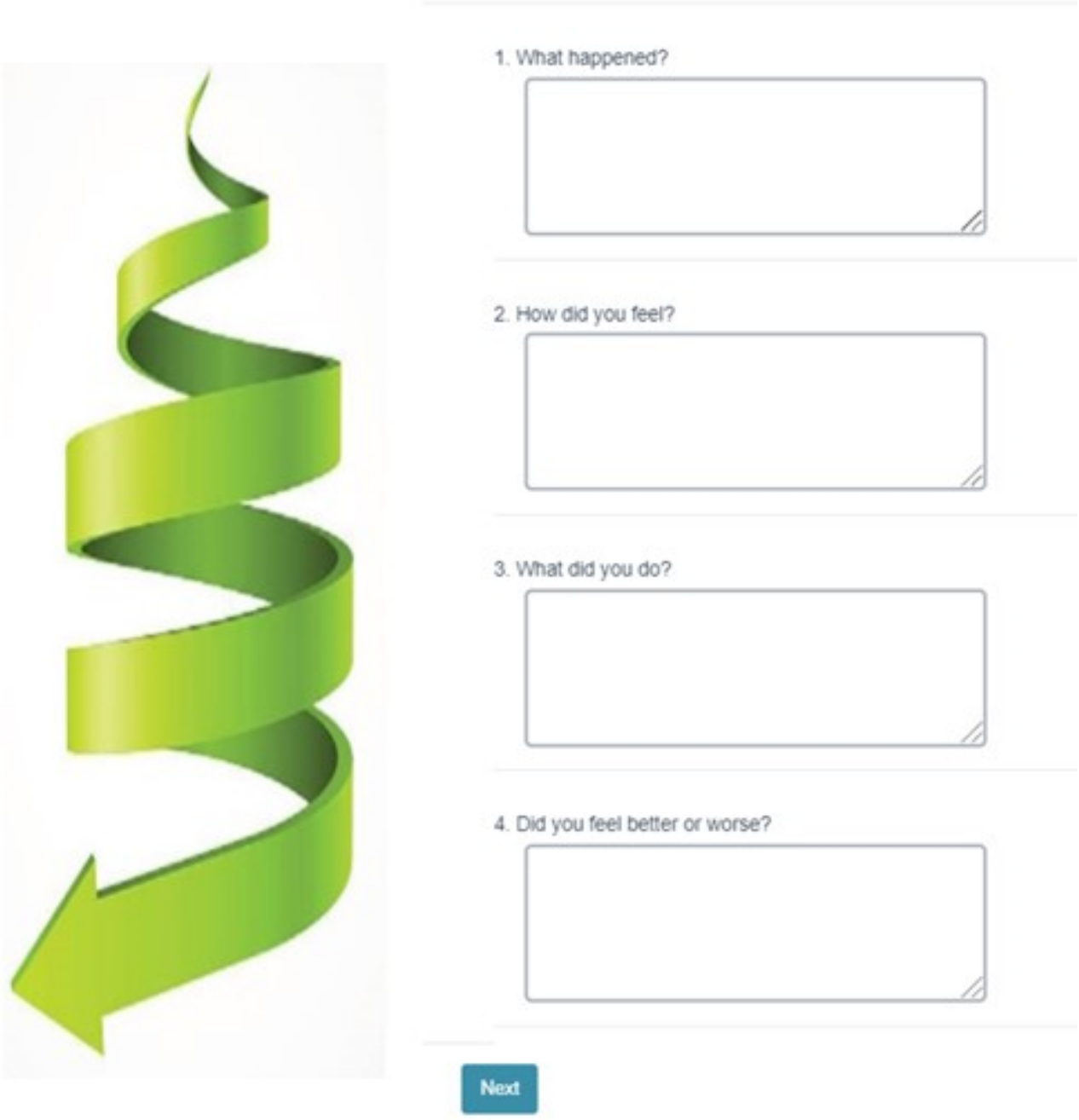


Figure 5. Teen and clinician preferences for features of internet-based support. The figure contains the first author's name as an example to protect participants' privacy.

Survey Measures

At the beginning of the study, teens completed the Patient Health Questionnaire-8 (PHQ-8) adolescent scale [27]. Although some teens did not identify with having experienced clinical levels of depression (n=1), all teen participants had mood ratings on the PHQ-8 in the 5 (mild depression) to 14 (moderate depression) range (mean 8.87, SD 3.14). In the poststudy surveys, we asked all teen and clinician participants to complete the acceptability, intervention appropriateness, and feasibility of intervention measures [28] and user burden scale [29] surveys to determine participant approval of and burden using BA delivered on an internet-based platform.

Internet-Based Group Activities

We conducted 10 weekly activities in the clinician group followed by 10 weekly activities in the teen groups (Table 3; Multimedia Appendix 4), each designed to take 20 minutes to complete. The groups were moderated, and all clinicians and

teen participants selected a pseudonym to use as their username on Slack to protect their privacy.

Poststudy Interviews

To learn about clinician and teen participants' experiences with depression treatment, the ARC method, and further explore ideas for implementing BA via an ARC platform, we conducted 30- to 40-minute exit interviews with 9 clinicians and 5 teens and surveys with participants between June and August 2019. All interviews were audio-recorded and transcribed professionally. The study protocol is provided in Multimedia Appendix 5.

Design of Prototypes of BA Activities

We created low-fidelity prototypes to show how some BA activities might be adapted to an interactive, asynchronous remote platform and showed them to our clinician and teen participants to obtain feedback. Prototypes included low-fidelity paper-based or survey-based mock-ups and screenshots, and the research team could easily incorporate feedback and iterate on the design before investing resources into building the tool (eg, Figures 2-5). For each module in weeks 6 to 10, we posted worksheets from the BA handbook [1] for take-home activities and low-fidelity prototypes of the technological adaptations of these take-home worksheets (Table 3). On the basis of feedback from clinicians, we presented each BA module to the teen groups by using examples on 2-3 slides (Figure 2) to briefly introduce and explain each activity along with the technology mock-ups of the survey or chatbots. All participants were asked to try and review adaptations in the form of surveys, voting polls, group and direct messages on Slack; upload photographs; and critique chatbot mock-ups. We asked participants to provide feedback on the content and format of these activities and their engagement and experiences with these activities.

In week 9, we posted a module to overcome barriers to SMART (specific, measurable, appealing, realistic, and timebound) goals that they planned in week 8. In the first part of this activity, participants were given examples of barriers and suggestions to overcome these barriers. These mock-ups also included survey prompts, a chatbot mock-up, and direct messaging with peers (Figure 4). In week 10, we presented mock-ups of possible teaching formats when delivering modules of BA. These remote teaching formats included animated videos to explain BA modules, teen peers explaining based on their lived experiences, and an interactive format using a chatbot where the respondent can use dialog and voting polls.

Analysis

We calculated the average scores of the PHQ-8 [27] and each question of the acceptability, intervention appropriateness, and feasibility of intervention measures [28] for the clinician group and teen groups, respectively. For the user burden scale [29], we computed the average scores of teens and clinician groups separately across each of the 6 constructs: physical, mental and emotional, time and social, financial, difficulty of use, and privacy. By "making and analyzing thematic connections" [30], 2 researchers inductively analyzed the qualitative data each week from the clinician and teen groups and the interview transcripts by developing codes. Both coders first independently coded a subset of the data corresponding to the same weeks and discussed codes together to prepare a codebook (Multimedia Appendix 6). Coders then separately coded all the data based on the codebook, reviewed the codes together, discussed and resolved any discrepancies in coding, and wrote memos. We discussed the results with the entire team and used our research aims to guide an affinity diagramming process [31], through which our final two themes emerged.

Ethical Considerations

Important considerations for using ARC with minors include maintaining privacy and confidentiality, ethical handling of adverse event disclosures on the web (such as suicidality, abuse, or harassment), and the possibility of distress for others in a group setting. We obtained the emergency contact information of an adult from all teen participants and informed the teens that this person would be contacted if they disclosed medical emergencies or concerns of harm to self or another. With the consent forms, we asked the participants to review group guidelines and pinned them on the Slack group. We explicitly stated on the consent form, group guidelines (Multimedia Appendix 1), and the first day of activities that we were not professional counselors but were willing to listen to grievances and provide them with 24-7 helpline numbers such as Teen Link and the National Suicide Prevention helplines to reach out to professionals. We had protocols for internet-based disclosures of adverse events (Multimedia Appendix 2) and child abuse (Multimedia Appendix 3) in place for the research team. Teens were informed that they could expect a response within 1 business day if they contacted the moderator with questions or concerns. Both the clinician and teen groups were monitored by a moderator who could contact a licensed psychologist with doctoral-level training in child clinical psychology (Jessica Jenness, PhD) if any safety or emergency concerns arose. Moderators read all the posts, monitored for safety concerns and emotional distress, and reached via email or Slack private message in case of concern. No immediate risks of physical harm or abuse were disclosed during the study (Multimedia Appendices 1-3).

Results

Overview

At the beginning of the study, teens and clinicians were asked about their preference for a short (4-6 weeks) or long format (12 weeks) of BA. Most teens and clinicians voted for the short format, so we tailored our design activities to a short BA format. We observed that teen participants started dropping out around week 5. The 5 teens who completed 9-10 activities and were interviewed at the end of the study said they wanted the long format to familiarize themselves with, learn, and practice BA strategies. In the following sections, we explain three themes that emerged from our analysis of the needs of teens and clinicians for internet-based support in managing mood and depression (A1): (1) balancing the need to augment human connections and asynchronous BA support and (2) the need for boundaries around asynchronous internet-based support.

Balancing Needs for Asynchronous BA Support and Augmenting Human Connection

When presented with the idea of including an automated chatbot application on the internet-based platform, both teen and clinician participants perceived the chatbot's role as an interactive platform for learning, self-reflection, supplementing resources when therapists are not available, and supporting treatment planning. Interactive asynchronous activities included engaging with psychoeducational videos**,** tracking mood and activity, self-reflection, planning, and check-ins.

Interactive Learning

We presented mock-ups of internet-based surveys and chatbots as self-help technological adaptations of homework activities for BA. Clinicians expressed the need to include interactive, culturally, and generationally relevant features (such as images in the graphics interchange format and emoticons) to increase engagement with teens. Both teen and clinician participants appreciated the use of chatbots and their potential for responsiveness and interactivity, step-by-step guidance, availability at all times, ability to store and post lists of relevant information, and added explanations and reinforced motivation. Clinicians also perceived that teens would find it engaging and "be into it" [C8, clinician]. Clinicians brainstormed how a chatbot could provide additional information to support teens that clinicians might miss or not have time to discuss during short appointments.

Support Self-reflection

Teens found the private internet-based survey format to be simple, clear, and helpful in illustrating BA concepts by applying written examples from their own context. They explained that the prompts in the activity on upward and downward spiraling of mood (*what happened, how did you feel, what did you do,* and *how did that make you feel*) helped structure their thoughts and helped them reflect. They also found it to be a good balance between journaling both positive and negative effects of an action on mood. Two teens also found it helpful that the BA prompts forced them to write about and focus on a specific situation:

> *I think sometimes I can get overwhelmed with emotion in situations, and it really helps to take a breath and think, what triggered me? How did I feel? And how can I avoid feeling this way in the future? Writing out "I felt sad, mad and overwhelmed" really helps me process the emotions I felt!* [T4]

Clinicians highlighted that there should be some way for teens to record how they were feeling or their mood at a specific time and then get prompted to do something that could possibly *help them in-the-moment* to alleviate symptoms.

Planning Support

Planning and executing SMART goals are a crucial aspect of the BA. To learn about SMART goals and have an option where teens could interact with other teens, a moderator created four small chat groups with herself and 2 randomly paired teen peers on direct message. We asked each teen in the pair to share a SMART goal, provide feedback on the other's goal, share mini-steps to attain that goal, and set reminders for mini-steps on Slack or their phones; 2 teen pairs completed this activity:

> *Thanks! My smart goal is to write five thank you cards to teachers by the end of next week.* [T2]
>
> *Hi @T2! My smart goal is to clean up my room over the weekend. I think your goal is Very smart! It's specific (writing cards), measurable (5 cards), appealing, realistic and timebound (by the end of the week), good job :two_hearts:* [T4]
>
> *That sounds good! And thanks so much!! I like ur goal but my one question is how will you know when you are done/how can you measure your progress?* [T2]
>
> *Ooo that's a good question actually...I'll know I'm done when the entryway is cleared and everything in that area is sorted and put back!* [T4]
>
> *Sweet! Very smart :))* [T2]

In the other two groups, a teen posted their SMART goals, and the other teen did not respond. When asked to post about barriers to attaining that goal in the next week's activity on direct message, only one pair of teens completed the activity. Although we sought to foster connection and accountability, such a lack of interaction can be counterproductive for this vulnerable population. During interviews, teens speculated that this problem might be addressed if we could add more activities in the beginning for teens to get to know each other. When asked if they would prefer smaller groups, teens preferred having 4-5 peers in each group so as not to be overwhelming and still enough social capital if some were not participating. During interviews, a teen explained that the SMART goals she and her partner selected were trivial, and it would be more beneficial if they could select more appropriate goals that would benefit their mood. As they could not tell if the partner accomplished the goal other than through self-report, she said it did not help hold herself accountable. Another teen explained that they liked to work independently. Therefore, it is important to preserve a space where teens can practice and learn on their own. A clinician suggested adding digital rewards in the self-help mode if they indicated completing the mini-steps:

> *I like the chatbot mockup -- I would have it programmed so that with each mini step completion they get some kind-of visual reward like fireworks or a giphy if they complete all of their steps. Even if they do not, there could be some kind of visual message like you got this!* [C5]

Clinicians also thought that they might want to offload reminders to a chatbot, automating the process of reminding teens to complete assigned materials or activities.

Augmenting Human Connection

Most teen and clinician participants did not prefer an entirely remote-only format and wanted to increase access to human-human support for mental health. They critiqued the chatbot format, perceiving that it could be impersonal and increase isolation compared with formats that develop human connections. In addition, 3 teens mentioned that chatbots could get repetitive; thus, it would be easy to ignore notifications:

> *Being in the States I often feel isolated since people value independence and not bothering others. Yet, the way to make relationships is actually through asking for help. If the robot [chatbot] or on-line discussions are made available, it seems to be reinforcing the isolation.* [C6]

In total, 5 clinicians and 6 teens wanted one-on-one internet-based support in addition to in-person therapy (Figure 6 and Figure 7). Teens explained that they wanted to preserve the face-to-face therapy format but felt the burden of time, transportation, cost, and frequency of weekly therapy visits. They said they would prefer internet-based video chats or phone calls to connect with therapists rather than replacing in-person therapy entirely with asynchronous chat:

> *I think my challenges would be feeling lonely with a lack of human connection (especially in talking to a chat bot). I would be willing to try it, but I believe I might begin to feel isolated if the only thing that I can talk to/will listen is a programmed robot.* [T5]

A total of 6 teens preferred a group support format on the web in addition to one-on-one therapy. At the end of the study, teens mentioned that learning strategies from each other and building off each other's ideas were helpful for the Slack group. When asked what they were looking for in peer support, they elaborated—empathy, a platform to share struggles and be *heard* by a human, benefits in the ability to express themselves in writing or talking out loud, and relating to shared experiences of a peer who is going through similar difficulties:

> *Social media shows the highlights and the best moments and it's hard to remember that nobody's life is perfect. Having a platform where you can discuss your problems and give advice is refreshing.* [T6]

Clinicians also highlighted the need for an internet-based platform where their teen clients can interact with peers (who have similar struggles and cultural backgrounds) who may be difficult to access offline. A school counselor, who worked with teens that were primarily immigrants and not fluent in English, requested different languages to deliver the treatment and connect the minority population with similar peers on the web:

> *For example, if I'm seeing an Arabic speaking kid, if there is an Arabic speaking group online, I think it would be really helpful to have an additional group where he can connect with other people in their own native language. There's psychoeducation, there's a little learning, there's encouragement from his peers. I think it's great, because I think in a way it probably will help connect with people, he's not able to connect with in our school because there is not enough people in counseling, or open to counseling who also speak Arabic.* [C6]

Thus, participants emphasized the need to augment human interactions by increasing therapist-teen interactions and peer interactions using an internet-based platform.

Figure 6. Preferences for the format of the internet-based delivery of behavioral activation (individuals could select more than 1). The values represent the number of teens and clinicians who voted for the respective formats. Trend lines connecting them illustrate the similarities in preferences of clinicians and teens.

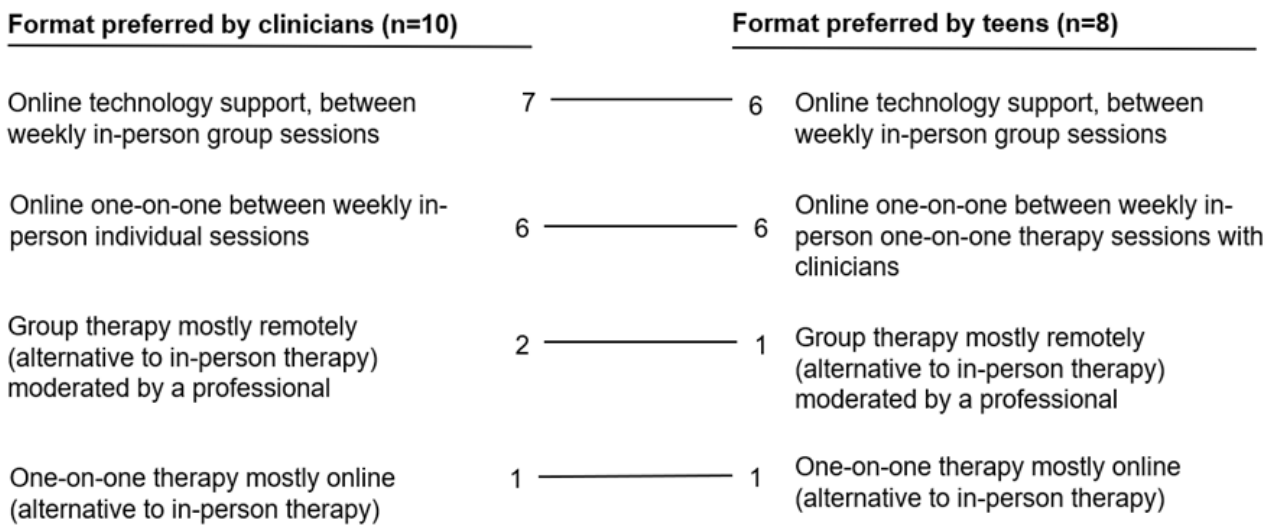


Figure 7. Teen and clinician preferences for features of internet-based support. The values represent the number of teens and clinicians who voted for the respective features. The lines facilitate the comparison of the rankings of preferences among clinicians and teens.

Need for Boundaries Around Asynchronous Internet-Based Support

The concerns of clinicians and teens using Slack during our study centered on the need for boundaries around privacy, safety during a crisis, and time burden on clinicians because of asynchronous access. They anticipated these concerns when using an internet-based platform for delivering mental health therapy.

Privacy

In our study, teens wanted to remain anonymous in the group and did not want to share identifying information such as real names, email addresses, or phone numbers. We asked all participants at the start of this study to deidentify (such as removing names and blur pictures) or not share any identifiable information about themselves and to not share information about others outside the group, even if they knew the participant in person. During the interviews, all teens expressed that these guidelines helped reduce their concerns regarding sharing in the group. However, 2 teens expressed concerns about their data being shared with people who were not a part of the group. These invisible audiences included a parent potentially finding and reading information on the group and the web company's policy around sharing data with a third party:

> *Some parents might be more intrusive—or I feel like that could be a problem for some people who might be concerned that their parents would go and—if it was text-based, go see what they've been saying and stuff like that.* [T1]

> *Oh my God, yes, a thousand [privacy] concerns. I think that is really hard to trust online services to not sell your data. And I'm with therapy, sometimes it's super confidential. So I think that it's different from person to person—my concerns would be about tech companies sharing my data.* [T2]

In contrast to this preference for *external* privacy, some teenagers felt a lack of reciprocal interactions between peers *within* the group. Teens attributed this to the inability to know other teens in the group on a *personal level*, that is, sharing their interests and values while remaining anonymous. Although it

was attributed to the lack of personal connection, Slack not being a part of the teens' regular social media use could have also contributed to this less frequent interaction.

Although participants took measures to remain anonymous, Slack did not offer end-to-end encryption or Health Insurance Portability and Accountability Act (HIPAA) protection for personal health data shared on the platform. Clinicians have brought this up as a major issue. They explained that if such a platform were to be adopted by their clinical institution in the future, it had to be HIPAA compliant.

Safety

The second major concern discussed by both teen and clinician participants was the physical and emotional safety of teens on the internet-based platform. As the discussion format is asynchronous, the current internet-based group is *available* or accessible by teens at all times. Clinician participants were concerned about unnoticed posts at nonworking hours that need urgent attention, such as indicating suicidality or self-harm. They were also concerned about secondary exposure to distress and sharing and learning unhealthy or maladaptive coping behaviors in a peer group format:

> *Issues around teens messaging a therapist when a therapist isn't available to respond—like if the teen posts at 2am that they are feeling suicidal and nobody sees it until the next day.* [C3]

> *I would be concerned about how teens' interactions would be monitored/shaped in an anonymous group – I would want to think more about safety concerns (e.g., suicidality) and how to communicate about this in a timely, safe, and not overly reactive manner.* [C4]

Some clinicians wanted the chatbot to be programmed to identify words related to crises such as suicidality and alert a human who can help or provide a list of resources to the teen.

Teens brought up similar concerns of being triggered by others' difficult experiences and not being able to share or minimize their struggles if they felt their experience was not as difficult as someone else's in the group:

> *The problems may be that hearing about others' problems more regularly thanks to the openness and limitless-ness of a chat format could have an effect on one's own mental health, especially if the chat ends up just being a place to rant and only has negative thoughts filling it up, instead of any productive or supportive conversation.* [T1]

> *One challenge/problem is that people who have mood disorders/depression might exacerbate someone else's hardships if they're having a bad time. For instance, if John is really depressed and talks about his problems at home, Joe might not feel like he can talk about his own problems because they aren't as "bad" as John's.* [T3]

Clinicians felt a need to always be available on the web for safety reasons, which would be prohibitive for their workload. They explained the concerns and needs for setting boundaries and expectations around receiving and responding to crisis messages and reviewing homework submitted on the web:

> *I would also be concerned that clients would be reliant on immediate responses from me. As they do with most social media. Would have to coach them on their expectations.* [C2]

Clinicians expressed concerns about how they would be compensated for the time spent on the web and reviewing homework. Some clinicians believed that they would have difficulty teaching content on an internet-based platform in an effective manner. They also mentioned that more monitoring or moderating of the group might take more time, possibly with an extra cost. Clinicians acknowledged the potential benefits of the internet-based platform for delivering treatment via an ARC format, and they wanted the treatment to be as effective with less added burden on them:

> *A challenge that hasn't been discussed here is billing. I know it's a little unsavory to bring up, but if there are features of this system that require monitoring by a professional, then this seems like non-billable time, which in our current healthcare system is difficult to find.* [C1]

Overall, participants indicated a low burden and high adaptability of the internet-based intervention. The poststudy survey was completed by 9 clinicians and 5 teenagers. On the user burden scale (1: not at all burdensome; 4: very burdensome) [29], participants scored an average of 1.36 (clinicians) and 0.7 (teens) on *difficulty of using Slack*, 0.4 (clinicians) and 0.5 (teens) on *mental and emotional burden*, 0.4 (both) on *privacy burden*, and 0-0.1 on all other types of burden. The interview data also reflected that the teens found no or less difficulty using Slack compared with clinicians. A teen expressed privacy concerns about how Slack shared her data. Other teens had no concerns about privacy, and all felt comfortable sharing in the group when anonymous. The clinicians talked about issues with privacy related to HIPAA, but their score on the privacy burden was low. The average scores on the acceptability, intervention appropriateness, and feasibility of intervention measures of the intervention (1: not at all; 5: very much) [28] averaged between 3.5 and 4.8, indicating high perceptions of adaptability.

Discussion

Summary of Results

The key findings of this study included the need for (1) augmenting human connection in therapy and (2) establishing boundaries around asynchronous communication for the safety and privacy of participants. Teens and clinicians both preferred the use of an internet-based platform for psychoeducation, homework activities, check-ins, reminders, and self-reflection between one-on-one therapy sessions. Both groups preferred that it not be a technology-only intervention and wanted the platform to connect teens with a therapist or peers.

Chatbots and Other Interactive Tools in Augmenting Mental Health Therapies

Clinicians recommended increasing the *human-like* conversation style of the chatbot to connect with and engage teens. However, teens did not want a chatbot to replace or emulate a human but envisioned its function as an interactive tool that scaffolded self-reflection. This is a promising approach. Research in other settings has shown that such people may prefer chatbots to questionnaires and that they may lead to greater engagement and more reliable and higher quality responses than questionnaires [32]. Conversational agents can also support reflection and self-learning in the workplace [33] or around physical activity goals [34].

However, their use is not challenging. Chatbots can fail to handle or escalate errors in the wild; people can perceive bots' human-like responses as irrelevant or eerie (also known as *the uncanny valley*), and not everyone prefers to interact with a system that emulates human behaviors [35-37].

Researchers and designers must also consider what expectations might be set by a human-like agent and whether the chatbot is up to meet those expectations before using it to offload or augment human labor. As personal safety of disclosure of suicidal content was a major concern for clinicians, they considered a task-focused bot [35] would be appropriate to flag crisis posts 24-7 and escalate it to a human clinical expert. However, any such bot would need to be extensively tested before being relied upon for such a role. It would need to be regularly re-evaluated to ensure it was staying ahead of any changes in the use of language throughout time. Such an evaluation would need to be robust across different demographic groups, with particular attention to historically marginalized groups, to mitigate bias in existing data sets. Both teens and clinicians preferred chatbots in the role of intelligent assistants [35] to send and receive reminders and check-ins. Some teens expressed concerns about potential exposure to their peers' distress, but neither teens nor clinicians wanted a chatbot to fulfill the roles of a virtual companion [35].

Considerations for Platforms to Deliver Technology Support in Interventions

Previous research has identified the feasibility of using internet-based platforms to support BA treatment with teens [12] alongside the need for mobile platforms to support varying usage times and patterns of tracking BA activity [20]. We addressed these needs by obtaining formative feedback from teens and clinicians on the design of an asynchronous, modular, and weekly approach to delivering multiple BA intervention components while enabling access and flexibility for teens in tracking, planning, and reflecting on their activities and mood in situ. On the basis of the lessons from this study, we reflected on the aspects of the internet-based platform, procedures used by researchers, and the format of integrating internet-based interventions with traditional therapy that needs to be considered when designing future internet-based mental health interventions.

Reflecting on our study procedures and the use of an internet-based platform that supports an ARC approach, changes to the structure and facilitation of the internet-based group may help balance the need for human connection with safety in a peer group format. These changes include limiting the time of access to the group, an always-visible and easy-to-reach helpline button, distributed moderation, good moderation policies and communication of those policies, and/or automated in-the-moment crisis support. When deciding on a platform for ARC to deliver mental health interventions, we list the requirements for consideration by administrators or moderators (Textbox 1). Although Slack was a helpful tool, researchers might consider alternatives such as Microsoft Teams (HIPAA compliant but not anonymous), Discord (supports anonymity) [38], Group Me, or a custom-built internet-based platform, which can still allow the option to be anonymous on the group while being intuitive, familiar to teens, and able to organize and present content. During the COVID-19 pandemic, the ARC method is a safe and accessible method for human-computer interaction and clinical research.

Textbox 1. Important requirements from internet-based platforms and moderators or admins for asynchronous remote mental health interventions.

Support and limitations of internet-based platforms

- Access
  - Users should be able to access the platform on both computers and mobile phones to be able to use it in their context (eg, at school, at home, or between work). Having both a browser option and an app option helped participants who did not want to install anything.
  - There is no additional cost for installation.
- Privacy: anonymity
  - Users should be able to use pseudonyms when signing up.
  - Administrators should have the option to hide emails and other personal identifiers on the internet-based platform.
- Privacy: health care
  - Trying to attain Health Insurance Portability and Accountability Act (HIPAA) compliance would be the gold standard.
  - If HIPAA compliance is not possible, make sure that teens are anonymous, are not interacting with clinicians, and are in separate groups in a study.
  - Consider the scalability of using the platform in the real world with clinics
- Safety
  - Internet-based platforms should allow pinned posts with 24-hour helpline numbers for crisis support to be accessible at all times.
  - Participants should be able to access moderators via direct messaging. Need clear affordances for group participants to contact moderators and helplines
  - Set expectations about moderator hours and response times (eg, expect a response within 24 hours on weekdays)
  - Have access to clinician researchers or clinical support (eg, partnering with a local clinic) on a group and have adverse events protocols in place for crisis response
  - Moderators can be supported with Chatbots to help them filter adverse events and alert them on urgent issues.
- Group norms
  - The internet-based platform should have affordances such as pinned posts or sidebars with *always-accessible* group expectations, guidelines, and norms.
- Creating apps and bots
  - Internet-based platforms should have a public application programming interface (API) to create and add bots and apps.
- Exporting data
  - API of the internet-based platform should allow exporting data
- Content organization and navigation
  - For unfamiliar platforms, moderators need to add tutorial videos and organize content so that people who join in late or miss certain weeks can trace it back and respond. Potential workarounds include the following:
    - Each week's activity can be on a separate channel or group.
    - Screen record tutorial videos and talk through functionalities such as threads, channels, and formatting

The internet-based asynchronous group format introduces *a moderation burden*, both in terms of time and effort related to monitoring for crisis support and adverse events. This was a concern for most clinicians and was also prevalent in volunteer-moderated internet-based groups [39]. To support participants in reaching moderators efficiently, the platform must have clear, discoverable methods for teens to connect with individuals moderating a group. Chatbots can also be designed to assist moderators by flagging content that needs to be reviewed by moderators and respond urgently.

Conclusions and Future Work

Our study supported gaining in-depth feedback from a small number of participants for 10 weeks, including feedback on low-fidelity prototypes. Our findings should be interpreted in this context, including its limitations. Specifically, we recruited teens with mild-to-moderate depression and who had experience with therapy. This may have biased our results toward a positive attitude toward therapy compared with teens who may have issues with accessing therapy or who prefer self-support. In total, 2 clinicians and 4 teens eventually dropped out of the

study by week 9; thus, we also do not know if those participants would have expressed different preferences in the activities they did not experience. Although participant perceptions about these mock-ups and their experiences indicate design needs and promising directions, future work should implement and evaluate these studies to assess whether and how they work in everyday practice and identify further opportunities to iterate on the design concepts presented here.

In our study, both teens and clinicians wanted to leverage the advantages of increased access to mental health care through an internet-based platform that supports an ARC approach to intervention delivery. The ARC model can act either as a supplement to face-to-face or telehealth-delivered therapy by allowing adolescents to stay engaged between visits or as a way of exclusively delivering therapeutic strategies, which can help increase the reach and access of EBPIs. We believe that the use of ARCs can be extended to other EBPIs beyond BA, although this remains to be evaluated in future work. Different care models may lend themselves particularly well to the integration of the ARC format for treatment delivery with traditional therapy, including stepped care [40], supplemented traditional care, and after-treatment care. For example, supplemented traditional care could include conducting weekly internet-based modules on a platform such as Slack during traditional therapy to decrease the number of in-person treatment sessions and support teens in their therapy goals, help with homework completion, and answer questions between in-person sessions.

Through our work, we highlight the need to integrate and support human infrastructure and digital technologies for teenage mental health. By following a human-centered co-design process with adolescents and clinicians, we have designed a delivery approach to directly engage with stakeholders and ensure that the design is well-grounded in the needs and constraints of those who will benefit from its use. By involving teens and clinicians early in the design process and presenting an empirical understanding of their needs, we hope to reduce the gap in navigating design tensions in internet-based and accessible mental health care. With the increase in mental health difficulties and the need to adapt research methods to remote format during COVID-19 quarantine, the ARC method has been useful in reaching a population of interest with minimal burden to both researchers and participants.

Acknowledgments

The authors thank all participants and are also grateful for constructive discussions with colleagues at the University of Washington. This work was funded by the University of Washington Advanced Laboratories for Accelerating the Reach and Impact of Treatments for Youth and Adults with Mental Illness (ALACRITY) Center under National Institute of Mental Health award number 1P50MH115837. This project was supported by the National Center for Advancing Translational Sciences of the National Institutes of Health under award number UL1 TR002319. The content is solely the responsibility of the authors and does not necessarily represent the official views of funding agencies.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Internet-based group guidelines.
[PDF File (Adobe PDF File), 171 KB - formative_v5i7e20969_app1.pdf]

Multimedia Appendix 2
Adverse events protocol.
[PDF File (Adobe PDF File), 276 KB - formative_v5i7e20969_app2.pdf]

Multimedia Appendix 3
Protocol for reported child abuse.
[PDF File (Adobe PDF File), 289 KB - formative_v5i7e20969_app3.pdf]

Multimedia Appendix 4
Summary of behavioral activation sessions.
[PDF File (Adobe PDF File), 135 KB - formative_v5i7e20969_app4.pdf]

Multimedia Appendix 5
Study protocols.
[PDF File (Adobe PDF File), 308 KB - formative_v5i7e20969_app5.pdf]

Multimedia Appendix 6
Codebook.

[PDF File (Adobe PDF File), 110 KB - formative_v5i7e20969_app6.pdf]

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Abbreviations

ARC: asynchronous remote community
BA: behavioral activation
EBPI: evidence-based psychosocial intervention
HIPAA: Health Insurance Portability and Accountability Act
PHQ-8: Patient Health Questionnaire-8
SMART: specific, measurable, appealing, realistic, and timebound

Edited by G Eysenbach; submitted 07.07.20; peer-reviewed by N Shen, X Huang; comments to author 27.11.20; revised version received 28.02.21; accepted 31.05.21; published 13.07.21.

Please cite as:
Bhattacharya A, Nagar R, Jenness J, Munson SA, Kientz JA
Designing Asynchronous Remote Support for Behavioral Activation in Teenagers With Depression: Formative Study
JMIR Form Res 2021;5(7):e20969
URL: https://formative.jmir.org/2021/7/e20969
doi:10.2196/20969
PMID:34255665

Original Paper

Medication Adherence Reminder System for Virtual Home Assistants: Mixed Methods Evaluation Study

Cynthia F Corbett[1,2], PhD, RN, FAAN; Elizabeth M Combs[1,2], BA, MA; Peyton S Chandarana[2,3], BSE; Isabel Stringfellow[2,4,5]; Karen Worthy[1], MPH, PhD, RN, CNE; Thien Nguyen[1,2], BSN; Pamela J Wright[1,2], MEd, MS, RN, CEN; Jason M O'Kane[2,3], PhD

[1]College of Nursing, University of South Carolina, Columbia, SC, United States

[2]Center for Advancing Chronic Care Outcomes through Research and Innovation, College of Nursing, University of South Carolina, Columbia, SC, United States

[3]College of Engineering and Computing, University of South Carolina, Columbia, SC, United States

[4]Arnold School of Public Health, University of South Carolina, Columbia, SC, United States

[5]South Carolina Honors College, Columbia, SC, United States

Corresponding Author:
Cynthia F Corbett, PhD, RN, FAAN
College of Nursing
University of South Carolina
1601 Greene St
Columbia, SC, 29208
United States
Phone: 1 8035766275
Email: corbett@sc.edu

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Abstract

Background: Medication nonadherence is a global public health challenge that results in suboptimal health outcomes and increases health care costs. Forgetting to take medicines is one of the most common reasons for unintentional medication nonadherence. Research findings indicate that voice-activated virtual home assistants, such as Amazon Echo and Google Home devices, may be useful in promoting medication adherence.

Objective: This study aims to create a medication adherence app (skill), MedBuddy, for Amazon Echo devices and measure the use, usability, and usefulness of this medication-taking reminder skill.

Methods: A single-group, mixed methods, cohort feasibility study was conducted with women who took oral contraceptives (N=25). Participants were undergraduate students (age: mean 21.8 years, SD 6.2) at an urban university in the Southeast United States. Participants were given an Amazon Echo Dot with MedBuddy—a new medication reminder skill for Echo devices created by our team—attached to their study account, which they used for 60 days. Participants self-reported their baseline and poststudy medication adherence. MedBuddy use was objectively evaluated by tracking participants' interactions with MedBuddy through Amazon Alexa. The usability and usefulness of MedBuddy were evaluated through a poststudy interview in which participants responded to both quantitative and qualitative questions.

Results: Participants' interactions with MedBuddy, as tracked through Amazon Alexa, only occurred on half of the study days (mean 50.97, SD 29.5). At study end, participants reported missing their medication less in the past 1 and 6 months compared with baseline (χ^2_1=0.9 and χ^2_1=0.4, respectively; McNemar test: P<.001 for both). However, there was no significant difference in participants' reported adherence to consistently taking medication within the same 2-hour time frame every day in the past 1 or 6 months at the end of the study compared with baseline (χ^2_1=3.5 and χ^2_1=0.4, respectively; McNemar test: P=.63 and P=.07, respectively). Overall feedback about usability was positive, and participants provided constructive feedback about the skill's features that could be improved. Participants' evaluation of MedBuddy's usefulness was overwhelmingly positive—most (15/23,

65%) said that they would continue using MedBuddy as a medication reminder if provided with the opportunity and that they would recommend it to others. MedBuddy features that participants enjoyed were an external prompt separate from their phone, the ability to hear the reminder prompt from a separate room, multiple reminders, and verbal responses to prompts.

Conclusions: The findings of this feasibility study indicate that the MedBuddy medication reminder skill may be useful in promoting medication adherence. However, the skill could benefit from further usability enhancements.

(JMIR Form Res 2021;5(7):e27327) doi:10.2196/27327

KEYWORDS

medication adherence; medication; virtual home assistants; virtual assistant; public health; health care costs; Echo device; device usability; digital health; mobile phone

Introduction

Background

Medication adherence, defined as taking medicines according to agreed-upon decisions between prescribing health care professionals and patients [1,2], is a major public health challenge. Research findings indicate that 50% or fewer people adhere to agreed-upon medication regimens [1,3]. Medication nonadherence contributes to suboptimal health management and increases overall health care costs among patients with chronic conditions [4,5]. The reasons for medication nonadherence are multifactorial [6] but often divided into intentional (eg, believing that medication is not needed or effective and stopping because of side effects) and unintentional (eg, inability to pay for medication, lack of understanding of how to properly take medications, and forgetfulness) [7]. Among unintentional reasons for medication nonadherence, forgetting to take medicine is one of the most common reasons [8-10]. Findings from a meta-analysis of medication adherence interventions among adults demonstrated that linking medication taking with existing daily routines and using behavioral strategies (eg, prompts to take medication) are the most effective strategies to promote adherence [11].

Technological advances, such as smartphones and electronic pillboxes, have been increasingly used as medication reminders [12-15]. For example, there are several smartphone apps that target disease management, including medication adherence, for people with diabetes, HIV, cancer, and other chronic conditions [16-20]. Improved rates of medication adherence have been demonstrated while using smartphone apps [16-19]. Key features of effective technological interventions include early participant input in the process to improve usability, a direct line between the patient and the people developing the technology along with the health care provider, a clear and easy-to-use interface, and the use of preexisting screening tools to measure medication adherence [20,21].

Study Objective

Research findings indicate that voice-activated virtual home assistants (VHAs) such as Amazon Echo and Google Home devices may be useful in promoting medication adherence [22,23]. Amazon currently holds more than 70% of the market share of VHAs [24,25]. Software associated with Amazon Echo VHAs are commonly referred to as *skills*. Several medication adherence skills are available for use with Echo devices [26]. However, no study has specifically evaluated users' perceptions of their effectiveness. Beaney et al [22] suggested that Amazon's medication reminder skill could benefit from more development. For example, it does not have a feature for *as-needed* medications, that is, those not taken on a regular schedule [22]. Furthermore, Amazon's general medication reminder skill provides only 1 reminder and does not allow the user to record whether the medicine was taken as prescribed. In this context, the primary purpose of this pilot project is to assess the usability and usefulness of a new medication-taking reminder skill, MedBuddy, developed by our team for use with Amazon Echo devices.

Methods

Study Design

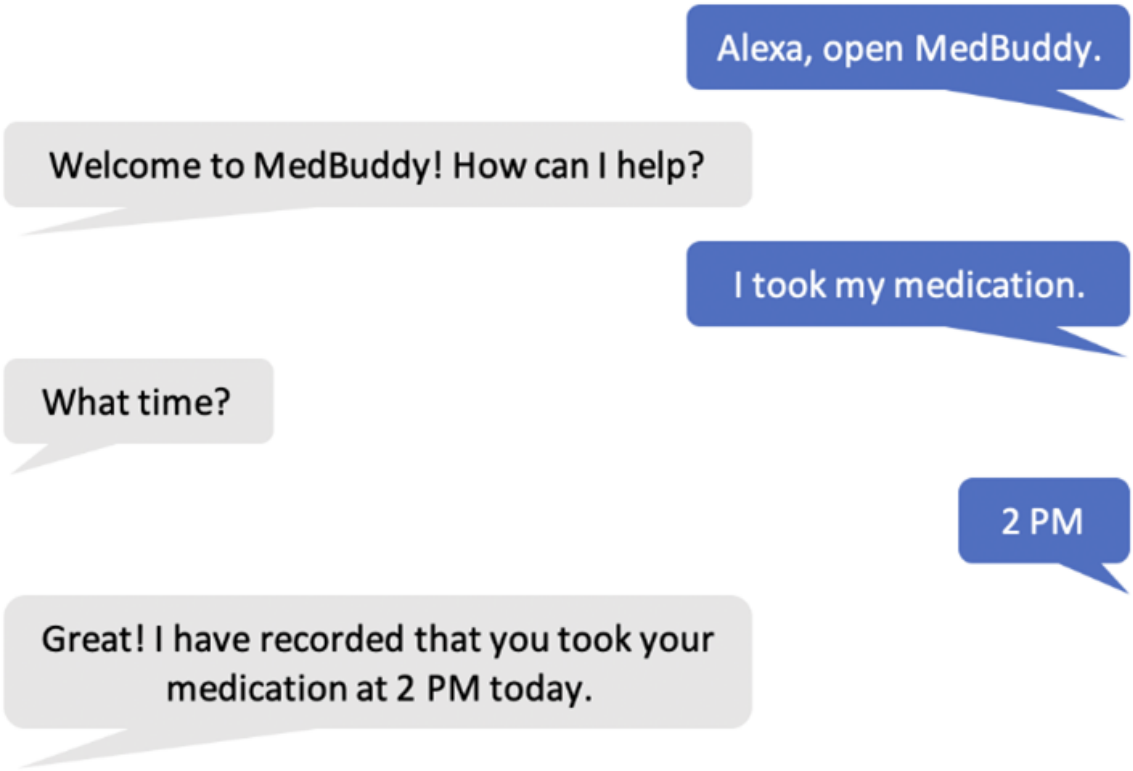
A single-group mixed methods cohort study was conducted to evaluate the usability and usefulness of the MedBuddy medication reminder skill. Usability and usefulness are related properties of human-system interaction, which in combination determine human usage and satisfaction with the system [27], in this case, the MedBuddy skill for the Amazon Echo devices. Although a variety of properties have been associated with usability (eg, learnability, efficiency, and effectiveness), we defined it more broadly as participants' likes and dislikes and whether they used the medication reminder system. Our definition of usefulness was pragmatic in investigating whether participants perceived the skill to improve medication adherence and whether they would continue its use and recommend others to use it.

Skill Development and Design

MedBuddy is a skill developed by our team for use with Amazon Echo devices. MedBuddy alerts users to take their medicines at a consistent time every day. During the development process, two aspects of usability and usefulness were considered: conversational experience with the skill and medication adherence documentation. The skill was designed for user interactions with the Echo device to be intuitive and modeled on the process of a natural conversation between 2 people. For the MedBuddy skill, the person using it starts the conversation, and then the Echo device, referred to as *Alexa*, responds (Figure 1). The skill tracks whether participants reported taking or missing their medicine and, if the medication was reported as taken, documents the time. Documentation about self-reported medication adherence and time was recorded when the participant activated the MedBuddy skill and said phrases such as "I took my medication" or "I forgot my medication."

The skill was designed for each participant to receive three separate alerts to take their medication each day. Three alerts were chosen because, during alpha testing among our research team, more than 3 alerts were deemed bothersome, which could negatively affect the user experience. The first alert was set to take place 15 minutes before the participant's desired medication-taking time. After the first alert, if the participant told MedBuddy through Echo that they took their medication, no subsequent alerts would occur. If the participant did not respond, a second alert occurred at the participant's desired medication-taking time. If there was still no response from the participant, the third alert was provided 15 minutes later.

Figure 1. Example of participant dialogue with MedBuddy through Echo.



Recruitment and Enrollment

Our team envisioned MedBuddy to be particularly useful for adults who spend most of their time at home. However, we conducted the initial usability and usefulness tests of MedBuddy with women who were college students and took oral contraceptives. We selected this population because (1) younger adults are likely to have more technological literacy than middle-aged or older adults and therefore may provide higher quality feedback about the skill with minimal frustration if it does not work as expected, (2) nonadherence to oral contraceptives is common [28,29], and (3) oral contraceptives are most effective when taken at approximately the same time every day [30]. Following the receipt of an exempt determination by the institutional review board, potential participants were recruited from an urban public university campus in the Southeastern United States. Recruitment flyers were distributed through electronic billboards, an electronic learning management system, and social media. In addition, an announcement about the research opportunity was presented to approximately 100 students who attended a university program orientation. Snowball sampling also occurred by enrolling referrals from current participants or our team's social contacts. Potential participants were directed to contact the study coordinator by phone or email. When contacted, the study coordinator explained the study purpose, potential risks, and benefits and screened the participants for eligibility. Eligibility criteria included (1) currently taking an oral contraceptive but self-reporting difficulty remembering to take the medication some days or at about the same time each day, (2) living off-campus (because of internet inconsistency or internet overload in campus housing), and (3) owning a smartphone. Students meeting the eligibility requirements were invited to participate, and, for those interested, an enrollment appointment was scheduled.

In-person enrollment took place between February 1, 2020, and March 6, 2020, at a research center on a university campus. Volunteer participants provided verbal informed consent and then completed a baseline demographic and medication information questionnaire and a 4-item questionnaire about their adherence to their prescribed oral contraceptive medicine (Multimedia Appendix 1). Each participant received an Amazon Echo Dot device and a study account for the MedBuddy skill. Participants were then instructed on setting up and using the Amazon Echo Dot and subsequently the MedBuddy skill. Participants were first familiarized with activating the MedBuddy skill, using phrases such as "Alexa, open MedBuddy." Once participants were familiar with activating the skill, the phrases for informing MedBuddy the medication had been taken or forgotten were demonstrated to participants. These phrases included "Alexa, tell MedBuddy I took my medication at 2:00 PM today" and "Alexa, tell MedBuddy I

forgot my medication." Participants were then given the opportunity to interact with Alexa and MedBuddy. Participants were also given the option of connecting the Alexa app on their smartphone to the study account, which allowed them to interact with MedBuddy through either the Echo Dot or their smartphone. Participants received a US $15 honorarium at the completion of the baseline visit.

Measures

Participants' demographic and medication-related information were collected using a baseline survey. Participants' responses to the prompts provided by MedBuddy were tracked by the research team. We tracked whether participants reported taking or missing their medicine or whether they failed to respond to the reminder. Participants also self-reported their perceived adherence to their oral contraceptives more globally by answering four questions at baseline and at the end of this study (Multimedia Appendix 1). The adherence perception questions were developed by the authors and not psychometrically tested before their use in this feasibility study. Additional usability and usefulness data were collected during structured exit interviews conducted by telephone after each participant used MedBuddy for at least 60 days (Figure 1). Participants' responses to the telephone interview questions were documented on an interview form. Notes taken by the research team in response to the open-ended questions were read back to each participant to confirm that the team member's documentation of their responses was accurate. Participants were sent a US $25 honorarium following the completion of the poststudy interview.

Analyses

Participants' demographic characteristics and medication information about their oral contraceptives were summarized using descriptive statistics. Participants' verbal responses to the Echo device, as they used the MedBuddy skill, were summarized using frequencies based on 60 days of use. We also evaluated participants' responses to MedBuddy throughout the study time. Specifically, a paired two-tailed *t* test was conducted to evaluate whether there was a significant reduction in participants' responses to MedBuddy during the first 2 weeks of the study versus the last 2 weeks of the study. Participants' self-reported medication adherence between baseline and the study's conclusion was evaluated using the McNemar chi-square test. All statistical analyses were completed using the SPSS (version 27; IBM Corp) with an α value set at .05. Data from the open-ended structured interview questions were qualitatively categorized into evaluative topics to summarize participants' perceptions of the usability and usefulness of MedBuddy.

Results

Demographic and Medicine-Taking Characteristics

Among the participants, 92% (23/25) completed the full study. The COVID-19 pandemic necessitated campus closure during the study, which resulted in an inability to follow up with 2 participants. We did not detect differences in demographic characteristics between those who did and did not complete the study. The sample was characterized by heterosexual, White women who had a mean age of 21.8 (SD 6.2) years, and none were married, but all lived with one or more other people. Most participants (14/25, 56%) started their medication week on Sunday, which is important concerning adherence because most oral contraceptives are taken for 3 consecutive weeks followed by 1 week of a placebo each month. The participants' desired time to take the medication varied, but most women took their medicine at night before bed or in the morning. Interestingly, all the women identified at baseline that they currently used a medication reminder method, with most (18/25, 72%) stating that they used a smartphone in conjunction with a reminder app or setting a smartphone alarm. Thus, MedBuddy was an adjunct or replacement of the reminder strategy currently used. Participants' demographic and medication-related characteristics are summarized in Table 1.

Table 1. Participants' demographic and medicine-taking characteristics (N=25).

Baseline demographics	Participants, n (%)
Race	
White	20 (80)
Black	1 (4)
Asian	2 (8)
Mixed race	2 (8)
Sexual orientation	
Heterosexual	23 (92)
Bisexual	2 (8)
Homosexual	0 (0)
Medication time	
Morning	9 (36)
Afternoon	1 (4)
Evening	5 (20)
Night	10 (40)
Starting day	
Sunday	14 (56)
Monday	3 (12)
Tuesday	1 (4)
Wednesday	5 (20)
Friday	1 (4)
It changes	1 (4)
Current methods of medication adherence	
Significant other	3 (12)
Parents or family	1 (4)
Medication app	2 (8)
Calendar or planner	2 (8)
Phone alarms or reminders	17 (68)

MedBuddy Use

During the study, we tracked the participants' verbal responses to MedBuddy prompts. Participants responded to MedBuddy prompts just a little more than half of the time (study days: mean 50.97, SD 29.5). The response rate ranged from 6.6% to 86.7%. MedBuddy use slightly declined from the first 2 weeks of the study (mean response 70.5%, SD 0.23) compared with the last 2 weeks of the study (mean response 59.2%, SD 0.27), (t_{23}=2.4; P=.03). Only 1 participant responded that she missed medication. All other responses noted that the medication had been administered. There were no discernable differences in participant characteristics for those who responded to MedBuddy more regularly than those who had limited responses.

MedBuddy Usability

After participants used MedBuddy for at least 60 days, we interviewed them to obtain information about their user experience. Most participants rated their overall experience with the Echo device as *good* or *very good* (18/23, 78%) and the remainder rated the experience as *neutral* (5/23, 22%). Participants rated their overall user experience with the MedBuddy skill less positively, with 56% (13/23) rating it as *good* or *very good*, 35% (8/23) rating it as *neutral*, and 9% (2/23) rating it as *poor.* However, nearly all participants (21/23, 91%) rated MedBuddy as *effective* (7/23, 30%) or *very effective* (14/23, 61%) as a medication reminder, and the remainder indicated it was mostly ineffective (1/23, 4%) or ineffective (1/23, 4%). Most participants (15/23, 65%) said they would continue to use MedBuddy as a medication reminder if provided with the opportunity. The primary reasons participants wanted to continue using MedBuddy were that (1) the external alert separated from their phone was beneficial, (2) they could hear the alert if they were in a room different from the room where the Echo Dot was located, (3) the verbal prompts from a human-sounding voice were motivating, and (4) more than 1 reminder helped prompt them to take their medicine. For instance, a participant noted:

> *I really liked that I got three reminders because I almost always ignored the first two, but it was enough reminders to force me to do it.* [Participant 110]

Two other open-ended interview questions focused on the features and aspects of MedBuddy that participants liked or disliked. The features that participants liked aligned with the reasons why they would continue to use and recommend it: (1) receipt of multiple reminders 15 minutes apart, (2) the interface between their smartphone and the Echo Dot, and (3) verbal reminders with voice interaction. A typical participant response was "I like the verbal reminders, the vocal response and prompt" (Participant 112). Another participant stated:

> *My favorite was the verbal aspects, someone that I could hear, multiple reminders, the verbal aspect of responding was attractive.* [Participant 107]

The ability to verbally report the medication action instead of the need to locate another technological device (such as a smartphone) was perceived as convenient and beneficial.

The MedBuddy features that participants disliked were consistently noted by many. These features included (1) speech recognition difficulty such that the Echo Dot or smartphone Alexa app did not open the MedBuddy skill or required several commands to open it; (2) the need to alert the Echo Dot or smartphone multiple times to stop future prompts, again because of speech recognition difficulties; (3) logging errors (eg, if the medication was taken late in the evening, MedBuddy may not have recorded the response on an intended day, but for the next day, canceling alerts for the next day); and (4) minimal ability for the user interface. Regarding the latter, some participants reported a desire to view and edit their medication history through their smartphones.

MedBuddy Usefulness

A large majority of participants (21/23, 91%) said they would recommend MedBuddy to someone who had difficulty with medication adherence. Participants stated that they would recommend MedBuddy to others because (1) it personally facilitated their own adherence; (2) helped them incorporate medication taking into their daily routine; and (3) the multiple reminders would benefit other people with trouble regarding medication adherence, including those who were older and may be at home more or those who take multiple medications. For example, a participant stated that she would have liked to have her grandmother use MedBuddy on an Echo device, stating:

> *I would recommend the MedBuddy skill because I live with some older people and they take multiple daily medications, and it would help them because it helped me.* [Participant 109]

Participants also answered questions about their perceived medication adherence before and after using the MedBuddy skill (Textbox 1). The 4-item adherence questionnaire had a Cronbach α of .77 at baseline (n=25) and .70 at the end of the study (n=23). Participants reported missing their medication less in the past 1 and 6 months at the end of the study compared with baseline (χ^2_1=0.9 and χ^2_1=0.4, respectively; McNemar test: P<.001 for both). However, there was no significant difference in participants' reported adherence to consistently taking medication within the same 2-hour time frame every day during the past 1 or 6 months at the end of the study compared with baseline (χ^2_1=3.5 and χ^2_1=0.4, respectively; McNemar test: P=.63 and P=.07, respectively).

Textbox 1. Perceptions of medication adherence questions.

Questions

1. In the past month, how often have you missed taking your birth control pill (1=never, 2=once or twice, 3=a few times, 4=several times, 5=frequently)? Please circle the appropriate response:
2. In the past month, how often would you say you have taken your birth control pill within the same 2-hour framework (1=almost never, 2=infrequently, 3=sometimes, 4=usually, 5=always)? Please circle the appropriate response
3. In the past 6 months, how often have you missed taking your birth control pill (1=never, 2=once or twice, 3=a few times, 4=several times, 5=frequently)? Please circle the appropriate response:
4. In the past 6 months, how often would you say you have taken your birth control pill within the same 2-hour framework (1=almost never, 2=infrequently, 3=sometimes, 4=usually, 5=always)? Please circle the appropriate response:

Discussion

Study Context

The purpose of this study was to evaluate the use, usability, and usefulness of MedBuddy, a medication adherence skill designed for Amazon Echo devices. Participants' recorded responses indicated that their use of MedBuddy varied widely. Participants were enrolled in February and early March 2020; many of them left their residences to travel for a spring break. Unexpectedly, the university transitioned to web-based learning directly after spring break. As a result, many of the participants were separated from their Echo devices and could not use MedBuddy. Most participants subsequently returned to their residences or downloaded the Alexa app on their phones and could resume using MedBuddy. While MedBuddy was used more frequently in the last 2 weeks of the study compared with the last 2 weeks of the study, we do not attribute the lack of use to disinterest or dissatisfaction with the skill, especially given the participants' positive perspectives on usability and usefulness during the poststudy interviews.

Usability Findings

Most participants reported at least a *good* user experience with the skill. The primary dissatisfaction with the skill was when the participant asked Echo to either open the skill or tell (the

skill) their medicine was taken (or missed), Echo had difficulty interacting with MedBuddy because of speech recognition. For instance, when some participants instructed Echo to *open MedBuddy*, Echo would open a different skill with the word *buddy* in the title. Similarly, a voice response indicating the medicine was taken or missed, which should cancel future reminders for the day, was sometimes not recorded because Echo did not recognize and communicate with the right skill. In these instances, participants received one or two additional reminders from MedBuddy after having said they had taken their medication. A participant noted that she continued to use MedBuddy because it helped her remember to take her medicine, but she stopped even trying to communicate with MedBuddy through Echo because of these described speech recognition interface problems.

Despite the speech recognition errors with the skill, participants requested more ways to interface with MedBuddy both before and after the university enacted remote learning. Participants could communicate through MedBuddy on their phone if they activated the Alexa app on their phones, which some did when they enrolled in the study and others did later during the study. Consequently, participants could communicate with Echo and MedBuddy, even if they were not currently at home. Some participants requested to see their medication history, a feature that was not available. However, our team was presumptively considering adding this feature to the second-generation version of the skill.

Usefulness Findings

Nearly all participants perceived MedBuddy as useful for medication adherence, which was particularly encouraging because all participants reported using some other reminder at baseline, with most using mobile phones as reminders. MedBuddy was reported to be useful despite the existing reminder system. A MedBuddy feature frequently mentioned as helpful was the automatic receipt of three reminders, which made the reminder more difficult to ignore than, for instance, receiving one reminder or an alarm via their mobile phones. In addition, several participants stated that reminders sounding like a human voice made them more responsive and accountable to the system. This finding resonates with other research showing that some users personify voice-activated devices [23,31]. Furthermore, being able to respond to MedBuddy using a voice command appealed to some users. The participants found the hands-free use efficient, which has also been reported among people who use VHAs for other purposes [32,33]. More than 90% (21/23, 91%) of participants reported that MedBuddy helped them take their medicine as prescribed. In the self-reports of medication adherence, participants reported missing their medicine less in the last 1 and 6 months in the poststudy versus prestudy assessment. However, there was no baseline versus poststudy difference in the frequency by which they took their medicine within the desired 2-hour time frame. More than 65% (15/23) of participants stated that they would continue using MedBuddy if given the opportunity. Several of those who declined to continue MedBuddy use stated that MedBuddy helped them develop habits for a better medicine-taking routine, so they had no need for future use.

Finally, more than 90% (21/23, 91%) of participants stated that they would recommend MedBuddy to others because they thought it would help with medication adherence as it had helped them. Many participants thought MedBuddy would be ideal for older adults, people who require multiple medicines to manage health conditions, and those who spent most of the day at home. As participants were all students at the time of the study, they considered their schedules to be more hectic and less predictable than those who may be retired or at home when medications are due. These findings were especially salient because we envision adults and people who take multiple medicines as the primary target population of MedBuddy users.

Study Limitations

This feasibility study had several limitations. We tested it with a small convenience sample consisting entirely of women, primarily young adults, White, and non-Hispanic college students living off-campus. Except for being women, participants' demographic characteristics closely represented the larger university population. For example, the university population was 77% (24,049/31,232) White, whereas our sample was 80% (20/25) White. Furthermore, because of inconsistent internet service in campus housing, our participants all lived off-campus. Freshmen at the university are required to live on campus, but among nonfreshmen, 90% (22,484/24,982) live off-campus. We encountered an unexpected challenge in that some participants were separated from their Echo device because the university transitioned to all web-based classes in March 2020 because of the COVID-19 pandemic. The unexpected change highlighted the significance of the option to use the Alexa smartphone app as a communication tool between Echo and MedBuddy. Nevertheless, the findings about participants' MedBuddy use and its' use over time may not reflect use under normal circumstances. In addition, this study only tracked users for 60 days. Therefore, it is unknown whether people would continue to use and find the medication reminder system useful for a longer period. Self-reported measures for medication adherence were developed by the authors and did not have established psychometric properties. Furthermore, subjective measures of medication adherence are known to overestimate adherence [34]. Thus, the improved medication adherence found in this study must be interpreted cautiously.

Future Directions and Implications

On the basis of the study usability findings, several improvements to MedBuddy have been made or are in progress. The skill's name was changed to improve the speech recognition interface with Echo devices. We learned that there are several existing skills with the terms *med* or *buddy* as part of the skill name. Other skills' similar names sometimes made it difficult for the Echo device to differentiate commands for *MedBuddy* versus a command for a different skill. As it seemed to be a problem for some participants and not problematic at all for others, we believe communication success may have varied based on voice tones and diction—an issue noted by users of other voice-activated devices [35]. Thus, we deemed it necessary to change the skill's name. On the basis of naming tips for skills published on the web by Amazon, named skills and other software promoting medication adherence, and our interface

tests between Echo and the skill, by using a short-list of potential names, MedBuddy was renamed as *Pill Minder*. Initial alpha tests have been positive with the new name, although excessive background noise may still interfere with device communication. To further evaluate the usefulness and accuracy of participants' communication with the renamed skill, Pill Minder, we plan to use pill bottles that electronically record cap removal. We will analyze the relationship between participants' responses to Pill Minder and pill bottle opening.

As recommended by participants, we are in the process of creating an interface that allows participants to view their personal medication history. In addition, users of our renamed skill, Pill Minder, will be able to authorize others, such as a support person, caregiver, or health professional, to see their medication use history. This change also aligns with the recommendations of participants from another study completed by our team involving dyads of older adults and their support persons [36], in which support persons indicated a desire for an Echo medication skill that enabled them to see whether their older adults had reported taking their medication. For research purposes, we will be able to view individual participants' data or aggregated data in a more user-friendly format than was the case with the original MedBuddy user data. Finally, the new version of the skill, Pill Minder, has a more streamlined user-setup process.

Another major advancement in Pill Minder is the capacity for users to receive medication reminders multiple times a day. Users can select reminder times for as many different dosing times as needed, whereas the original MedBuddy only had the capacity for 1 reminder per day. These enhancements are consistent with recommendations in the literature suggesting that medication reminder systems for Echo could benefit from further development [22].

Conclusions

Medication adherence continues to be a global public health challenge. It is a complex phenomenon, but research findings suggest that forgetting to take medicine is a factor that negatively impacts adherence for many people [8-10], including those who participated in this study. MedBuddy was designed as a medication reminder system that interfaces with Amazon Echo. The initial feasibility test was positive. Participant feedback on the MedBuddy skill usefulness was particularly positive. Overall, the most notable features were multiple verbal reminders, with the capacity for a verbal response, and receipt of reminders external to the mobile phone, but compatible with it through the Alexa app. Although most participants also positively evaluated usability, several suggestions were made to improve the skill. The next version of MedBuddy—renamed Pill Minder—has been designed with features to address study participants' suggestions. Alpha testing has been initiated within our team, and further testing will be launched outside the team soon. In summary, the medication reminder skill developed by our team was perceived as useful but requires more refinement for better usability. Once refined, we will study the usefulness and usability of Pill Minder with adults who take medicine at least twice a day.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Poststudy usability and usefulness interview questions.
[DOCX File , 17 KB - formative_v5i7e27327_app1.docx]

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Abbreviations

VHA: virtual home assistant

Edited by G Eysenbach; submitted 11.02.21; peer-reviewed by A Benis, P Cook, RJ Katz; comments to author 25.03.21; revised version received 08.04.21; accepted 31.05.21; published 13.07.21.

Please cite as:
Corbett CF, Combs EM, Chandarana PS, Stringfellow I, Worthy K, Nguyen T, Wright PJ, O'Kane JM
Medication Adherence Reminder System for Virtual Home Assistants: Mixed Methods Evaluation Study
JMIR Form Res 2021;5(7):e27327
URL: https://formative.jmir.org/2021/7/e27327
doi:10.2196/27327
PMID:34255669

Original Paper

Promoting Collaborative Goal Setting for Cancer Prevention Among Primary Care Patients Through mHealth: Mixed Methods Evaluation of a New App

Daniel Resnick[1,2,3], MD; Marilyn M Schapira[3,4,5], MPH, MD; Jazmine M Smith[2,4], MSc; Allison Bautista[2,4], BSN; Chang Xu[2,4,6], MSc; Liz Jones[7], BFA; Jaya Aysola[2,3,4,6], MPH, MD, DTMH

[1]Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA, United States

[2]Penn Medicine Center for Health Equity Advancement, Office of the Chief Medical Officer, University of Pennsylvania Health System, Philadelphia, PA, United States

[3]Leonard Davis Institute of Health Economics, University of Pennsylvania, Philadelphia, PA, United States

[4]Division of General Internal Medicine, Department of Medicine, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA, United States

[5]The Center for Health Equity Research and Promotion, Michael J Crescenz VA Medical Center, Philadelphia, PA, United States

[6]Office of Inclusion and Diversity, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA, United States

[7]Transmogrify, Conshohocken, PA, United States

Corresponding Author:
Jaya Aysola, MPH, MD, DTMH
Division of General Internal Medicine
Department of Medicine
Perelman School of Medicine, University of Pennsylvania
1229 Blockley Hall
423 Guardian Drive
Philadelphia, PA, 19104
United States
Phone: 1 215 573 9475
Fax: 1 215 573 8778
Email: jaysola@upenn.edu

Abstract

Background: Many newly diagnosed cancers are associated with modifiable lifestyle behaviors, such as diet, exercise, smoking cessation, and maintaining a healthy weight. However, primary care providers rarely discuss cancer prevention behaviors with their patients.

Objective: This study aims to assess the usability, acceptability, and user engagement of the Healthier Together mobile app, which is designed to promote cancer prevention behaviors among non-Hispanic Black primary care patients, by using social networks and goal-setting theories of behavior change.

Methods: In an 8-week pilot study, we enrolled primary care patients (N=41) and provided them with a cancer prevention mobile app that allowed them to select, track, and share progress on cancer prevention goals with other users. App usability was assessed using the System Usability Scale. We assessed the app's acceptability by qualitatively analyzing open-ended responses regarding participants' overall experience with the app. We assessed participants' engagement by analyzing the built-in data capture device, which included the number of times participants checked in (out of a maximum of 8) during the study.

Results: The mean age of the 41 participants was 51 years (SD 12), and 76% (31/41) were women. App use data were captured from all participants, and 83% (34/41) completed the exit survey and interview. The mean System Usability Scale score was 87 (SD 12; median 90; IQR 78-95). The analysis of open-ended responses revealed several key themes, and participants complemented the app's ease of use and health behavior–promoting features while also commenting on the need for more feedback and social interactions through the app. On average, participants checked in 5.7 times (SD 2.7) out of 8 possible opportunities. Of the 41 participants, 76% (31/41) checked in during at least 4 of the 8 weeks. Secondary analyses revealed that participants often accomplished their set goals (mean 5.1, SD 2.7) for each week. The qualitative analysis of comments given by participants within the app after each weekly check-in revealed several themes on how the app assisted participants in behavioral change, highlighting

that some participants created exercise programs, ate healthier foods, lost a significant amount of weight, and stopped smoking during this study.

Conclusions: The implementation of a mobile cancer prevention goal–setting app in a primary care setting was feasible, and the app achieved high usability, acceptability, and engagement among participants. User feedback revealed an influence on health behaviors. These findings suggest the promise of the Healthier Together app in facilitating behavioral change to reduce cancer risk among non-Hispanic Black primary care patients.

(JMIR Form Res 2021;5(7):e22510) doi:10.2196/22510

KEYWORDS

mHealth; cancer prevention; goal setting; social networks; health disparities; mobile phone

Introduction

Background

Each year, more than 1.7 million Americans are diagnosed with cancer [1]. A diet rich in fruits and vegetables [2,3], physical activity [4], smoking cessation [5], and maintaining a healthy body weight reduce the relative risk of developing numerous cancers. For instance, obesity alone is now thought to be associated with nearly 50% of newly diagnosed cancers in the United States in those aged 65 years or younger [6]. Despite these staggering statistics, many primary care patients do not adopt cancer prevention behaviors, and primary care providers (PCPs) rarely discuss these behaviors with their patients. Patients wish to discuss cancer prevention with their PCPs [7]; however, PCPs often cite competing priorities, limited time, and the lack of resources as reasons for not engaging patients in cancer prevention discussions [8].

Although PCPs do not routinely engage their patients in promoting healthy behaviors, mobile phone apps have emerged as a tool for promoting healthy behaviors outside of the clinical realm [9,10]. However, current behavior change apps available for public use rarely provide a theoretical explanation for how they motivate behavior or evidence to support their ability to change behaviors [11,12]. For example, many apps invite users to set behavior goals; however, few ask users to select specific time-bound goals with periodic reviews, although these latter features increase the chances of goal attainment [11,13]. Moreover, a number of apps provide “unspecified social support” [12], without encouraging users to provide more practical and emotional support to one another, despite evidence suggesting that social reinforcements increase the adoption of health behaviors [14]. A final limitation of mobile apps is that there are few apps designed specifically for minority populations, even with evidence that minority patients use their mobile phones to engage with a broad range of health materials more frequently than White patients [15,16]. Despite this, minority populations remain underrepresented in studies involving health and technology [17].

Objectives

The objective of this study is to evaluate the beta version of an evidence-based mobile app—Healthier Together—which is designed to address the limitations mentioned above and promote cancer prevention behaviors in predominantly minority populations recruited in a primary care setting. Our primary aim is to assess the usability, acceptability, and user engagement of the app during a 2-month study. Our secondary aim is to assess the relationships between app engagement, participant baseline characteristics, and participant health behavior.

Methods

Previous Work on Healthier Together

Key Features and Theoretical Basis

Healthier Together leverages both goal-setting and social network theories to motivate behavior change through 3 key features, as described later. These features aim to enhance, rather than replace, the role of a PCP in promoting cancer prevention behaviors. These features provide a starting point for patients to learn about the connection between behaviors, such as diet and exercise, and cancer risk, to set and track cancer prevention goals, and to share their progress with other app users. Patients using this app may build upon these actions and initiate cancer prevention discussions with their PCPs that would otherwise not have occurred.

The first feature asks app users to select a predetermined cancer prevention SMART (specific, measurable, achievable, realistic, and time-bound) goal [18] within 1 of the 4 goal categories: diet, activity, weight tracking, and smoking cessation. The app presents goals adapted from the recommendations of the American Cancer Society on diet, exercise, smoking cessation, and maintaining a healthy weight [19,20], linking directly to the American Cancer Society resources. The app provides the option to customize a person’s goal upon selection and modify any selected goal weekly. This key feature leverages existing evidence, demonstrating that goal setting motivates behavioral change through directing intention, building self-efficacy, fostering motivation, and serving as a reference point to invoke loss aversion [13,21,22]. Moreover, a meta-analysis of previous cancer prevention studies found that interventions that incorporated goal-setting strategies were significantly more effective in reducing dietary fat consumption and increasing fruit and vegetable consumption compared with those that did not, with small to moderate differences in effect size [23-25].

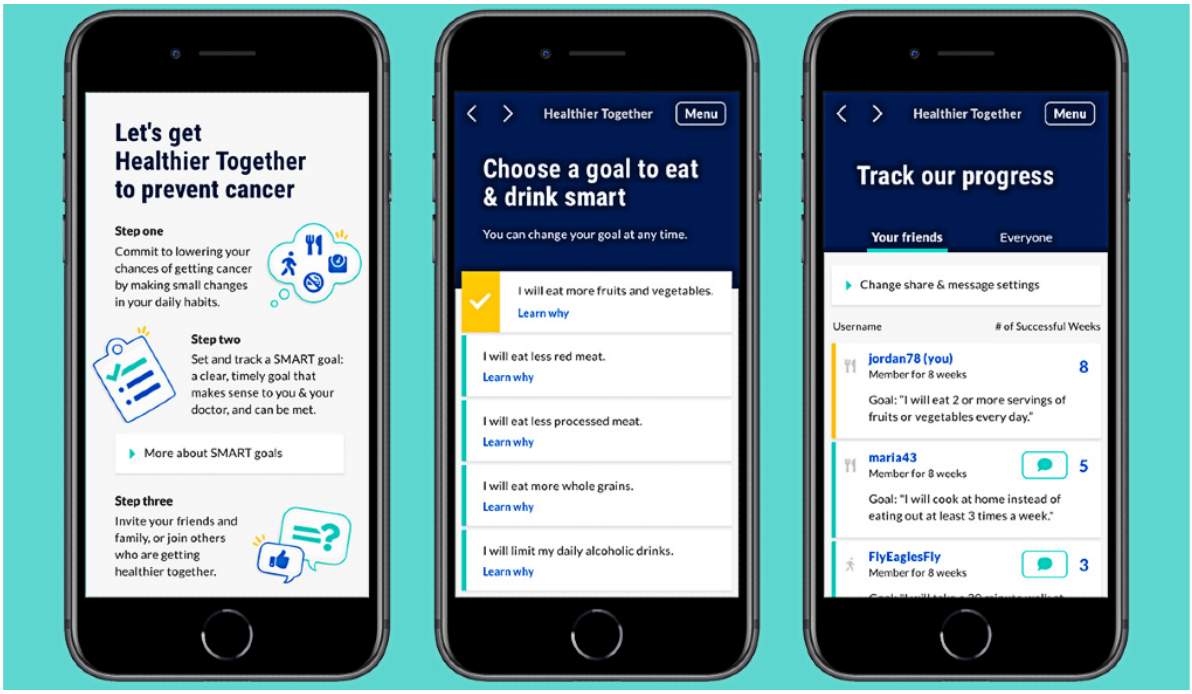
To encourage accountability to their selected goal, app users receive a weekly check-in text inviting them to mark whether they succeeded or failed to complete the goal for the week. While checking in, they can also leave a comment reflecting on their progress and change their goals if appropriate. App users can visualize their goal progress on an individual profile page and on a progress board that is potentially visible to other users.

Evidence supports the use of goal reminders, tracking, and reflections as important behavior change techniques that may slowly encourage users to develop healthy habits [26].

The third key feature allows Healthier Together app users to communicate and share goal progress with one another. App users can share this information with all app users or with users they invite directly into the app. There is also an option for users to keep all information private. If app users select to share their goal information, they can see other users' successes on a progress board and send encouraging messages to one another. The purpose of this feature is to allow users to receive social rewards and feedback. It draws upon research that demonstrates social networks with social reinforcements from multiple social ties, as compared with single ties, are associated with greater adoption of health behaviors and health-related knowledge [14,27].

The Healthier Together app (screenshot is given in Figure 1) was developed primarily for minority populations, as cancer disproportionately impacts racial/ethnic minorities in the United States [28], with additional disparities in behaviors related to cancer prevention, such as smoking [29], obesity [30], diet [31], and exercise [31]. Minority patients use mobile phones for health-related content more than their White counterparts [15,16], suggesting a mobile app may be one strategy to reduce the aforementioned disparities. In addition, prior work suggests that cancer prevention strategies involving some form of social support are more effective in changing behaviors in racial/ethnic minorities than non-Hispanic White individuals [32]. There is also evidence that minorities have denser social networks, with more reliable and frequent activation of informal social support [33,34].

Figure 1. Screenshots of the Healthier Together app.



Prior Testing and App Development Team

In keeping with best practices for health app development [35], we previously conducted iterative testing [36] with 33 non-Hispanic Black primary care patients to develop this beta version of Healthier Together. Consistent with Healthier Together's theoretical basis of enabling goal setting and developing social networks, testing revealed that end users valued app features that assist with tracking and sharing progress on health goals. These end users understood that the behaviors promoted by Healthier Together may help prevent other noncommunicable diseases, but valued the specific connection between lifestyle behaviors and cancer prevention and even asked to emphasize the connection further. Moreover, prior evidence reveals that framing the rationale for adopting healthy behaviors as a long-term gain to reduce cancer risk is effective [37-39]. The app itself was developed by Transmogrify, a firm that helps create, build, and grow digital products. The diverse research team (including DR, JMS, AB, MMS, and JA), which has expertise in qualitative methods, communicated closely with LJ, who works for Transmogrify and helped conduct user testing.

Study Overview

This 8-week mixed method intervention involved 3 key components: (1) a baseline visit that included an in-person structured interview followed by installation of the mobile app on the participant's phone and instructions on how to select a goal, choose share settings, and invite other social ties; (2) weekly text messages reminding participants to check in, share goal progress, and invite friends and family members; and (3) an exit telephone-structured interview at the end of 8 weeks.

Study Population and Recruitment

We recruited patients from 2 internal medicine primary care clinics in Philadelphia, a nonprobabilistic purposive sample of non-Hispanic Black patients that met our strict eligibility criteria detailed below. From September 2019 through October 2019,

authors DR, JMS, and AB identified potential participants in clinics' waiting rooms and invited these individuals to formally screen for the study in a private room after their appointments. Once in the private room, this research team screened potential participants to confirm eligibility, informed them of the study's app testing goals, and obtained consent to participate in the study.

To be eligible for the study, participants had to be aged more than 18 years, self-identify as non-Hispanic Black, speak English, own a smartphone, be a patient of one of the two clinics, be able to provide informed consent, and should not have participated in previous rounds of app testing. We targeted a sample size of 40 participants to obtain thematic saturation while soliciting feedback during the exit interviews [40].

Participants were incentivized US $40 to complete the baseline, in-person, 40-minute enrollment process and interview and US $60 for completing the exit 45-minute, telephone interview in an effort to maximize recruitment and minimize attrition. Authors JMS and AB attempted to contact each participant up to three times for the exit interview to further minimize loss to follow-up. There were no incentives for app use. The University of Pennsylvania Institutional Review Board approved the protocol for this study.

Study Procedure and Data Collection

After consenting to the study, we conducted a 40-minute baseline structured interview to collect participants' baseline characteristics, as detailed later. The interview included up to 79 close-ended, validated, and previously operationalized survey questions and up to 40 open-ended questions. The interview team inputted all close- and open-ended responses into REDCap (Research Electronic Data Capture; REDCap Consortium) verbatim [41].

The research team then helped the participants download the app, demonstrated each of the features detailed above, and assisted participants with selecting their initial health goal, determining their goal share settings, and sending invitations to their family and friends to download the app.

After downloading the app, participants received a weekly text message inviting them to log on to the app and check in to report whether they accomplished their goal. Participants could also log on to the app outside of the weekly check-in to explore their profile page, track other user progress (if they shared their progress with others), and read information about the relationship between lifestyle behaviors and cancer. In addition, participants received text messages to remind them to share the app with other friends and family. Participants' check-ins and other activities in the app were recorded through a built-in data capture device and served as our chief measures of app engagement, as described later.

After 8 weeks of app use, DR, JMS, and AB contacted the participants to complete a 45-minute, telephonic exit interview, primarily assessing the participants' opinions on app usability and acceptability. The exit interview also repeated questions from the baseline interview regarding cancer prevention knowledge and behaviors.

Data Measurement and Analysis

Baseline Characteristics

The baseline interview assessed participants' demographics, namely, age and sex, and close-ended questions on the following topics: technology use, as defined by what phone participants use and how often they use it; participants' comfort in sharing health information, as defined by whether participants have shared health information over the web, shared health information with social ties, or shared health goals with social ties; and participants' current health habits, as defined by whether participants currently have health goals or use some methods to track their health.

Primary Outcome Measures

Usability

We assessed app usability by asking participants during the exit interview to respond to the validated System Usability Scale (SUS), which provides a usability score of 0 to 100 for various technology products [42]. A score >70 is generally considered above average. We also assessed specific feature usability characteristics, namely, the feature's ease of use and ability to impart new information, with a modified subset of 5-point Likert scale questions from the SUS.

Acceptability

We assessed app acceptability during the structured exit interview with up to 27 open-ended questions about the participants' overall experience with the app. These questions allowed users to expand upon their close-ended responses and offer more information about what appealed (or did not appeal) to them in the app.

Engagement

We assessed engagement with the app in weekly intervals using built-in data capture device. The following measures were captured: (1) the number of check-ins to report goal progress, with the maximum allowable number of check-ins for each participant being 8 during the study; (2) goal type selected; (3) share settings selected; (4) messages to other users; (5) comments on their progress; and (6) any modifications to goals and share setting during the study period.

Secondary Outcome Measures

We examined the following measures to assess the implications of engagement with the app: (1) goal success count, defined as the total number of weeks a participant reported accomplishing his or her goal, with the maximum being 8, as recorded by the app's data capture; (2) goal reflections from participants' open-ended comments explaining the significance of goal success or failure during each check-in, as recorded by the app's data capture; (3) change in cancer prevention knowledge using survey questions that asked how important diet, exercise, smoking, and maintaining a healthy weight are to one's cancer risk using a 5-point Likert scale for each behavior, which were assessed at the baseline and exit interviews; and (4) change in participants' self-reported cancer prevention behaviors, specifically self-reported diet, exercise, smoking status, and

alcohol using validated questions asked at the baseline and exit interviews [43,44].

Analysis

First, we examined participants' baseline characteristics by tabulating the distributions or frequencies of participants' demographics, current technology use, comfort sharing health information with social ties, current health goals, and methods of health tracking. Second, we characterized app usability, app acceptability, and the nature and frequency of app engagement. Finally, in secondary analyses, we examined associations between app engagement and participant characteristics and goal success and changes in self-reported cancer prevention knowledge and behaviors.

We assessed app usability quantitatively by calculating each participant's SUS score based on validated criteria [45] and then determining the distributions of SUS scores for all participants who completed an exit survey. We also calculated the distribution of Likert scale responses, ranging from strongly disagree to strongly agree, to statements assessing specific app features.

We assessed app acceptability, using qualitative content analysis [46], among the participants who completed structured exit interviews. We used an open-coding, group-based process to generate emergent themes on areas of strength and weakness in the app that would complement our quantitative usability and engagement data. The first author (DR) read through all responses and crafted the initial codebook. JA and DR then jointly coded the first 4 interviews (4/41, 10%) during research meetings to refine the codebook and achieve full consensus on code definitions and inclusion and exclusion criteria. Special attention was paid to create codes for deviant opinions in the responses. DR then coded the remaining interviews using a constant comparison technique to examine how newly coded texts matched previously coded information. Coding was completed manually.

JA reviewed the coding process iteratively to assure a consistent code app. DR and JA then grouped the responses and comments thematically over several research meetings. Acceptability feedback on the app's 3 main features guided the process of generating themes, although we paid special attention to searching for unexpected ideas as well. JMS and LJ, who were familiar with the participants' responses but did not participate in the coding process, then reviewed the derived themes to assure the validity and interpretation of the themes.

We analyzed engagement data captured directly from the app on all participants through the following assessments. We calculated the mean number of check-ins (out of 8 possible opportunities) for all the enrolled participants. We also dichotomized the check-in variable, based on participants' median number of check-ins (7; IQR 5-8), with high use representing 7 or 8 check-ins and low use representing 0 to 6 total check-ins. We then determined the proportion of goal modifications and the types of goals selected. We also evaluated the frequencies of comments left and messages sent and how many participants sent a message in the study, commented during the study, chose to share their data with social ties or all users, and checked in after their 8-week study period was over.

In secondary analyses, we estimated associations between participant baseline characteristics and participant reported ease of use and app engagement, specifically high (7-8 check-ins) versus low (0-6 check-ins), in unadjusted logistic regression models and age- and sex-adjusted models. In addition, we examined preliminary results of app engagement by the following: (1) reported success in achieving goals; (2) coding and content analysis of comments within the app; (3) change in cancer prevention knowledge from baseline using two-tailed, paired *t* tests; and (4) change in self-reported behaviors from baseline using two-tailed, paired *t* tests. Coding and content analysis of comments were performed using the same processes as the open-ended feedback. All quantitative analyses were conducted using Stata version 15.1 (StataCorp LLC).

Results

Overview

Of the 338 individuals who were approached in the clinic waiting rooms, 171 (50.6%) met the eligibility criteria. Of those eligible, 23.9% (41/171) completed the enrollment survey, downloaded the app, and consented to have us track their use of the app. Of the 41 enrolled participants, 34 (83%) completed the exit survey after using the app for 2 months (Figure 2).

The average age of the participants was 51 (SD 12) years, and 76% (31/41) were women. Of the 41 participants, 31 (76%) reported tracking their health before the study, with 18 (44%) using some form of technology to do so. Most participants (28/41, 68%) relied on friends and family to accomplish a health goal within the past year, and 68% (28/41) participants were comfortable sharing *some* or *a lot* of their personal health information with friends and family. Conversely, fewer participants (11/41, 27%) were comfortable discussing personal health topics on the web (Table 1).

Figure 2. CONSORT (Consolidated Standards of Reporting Trials) diagram with enrollment and retention rates.

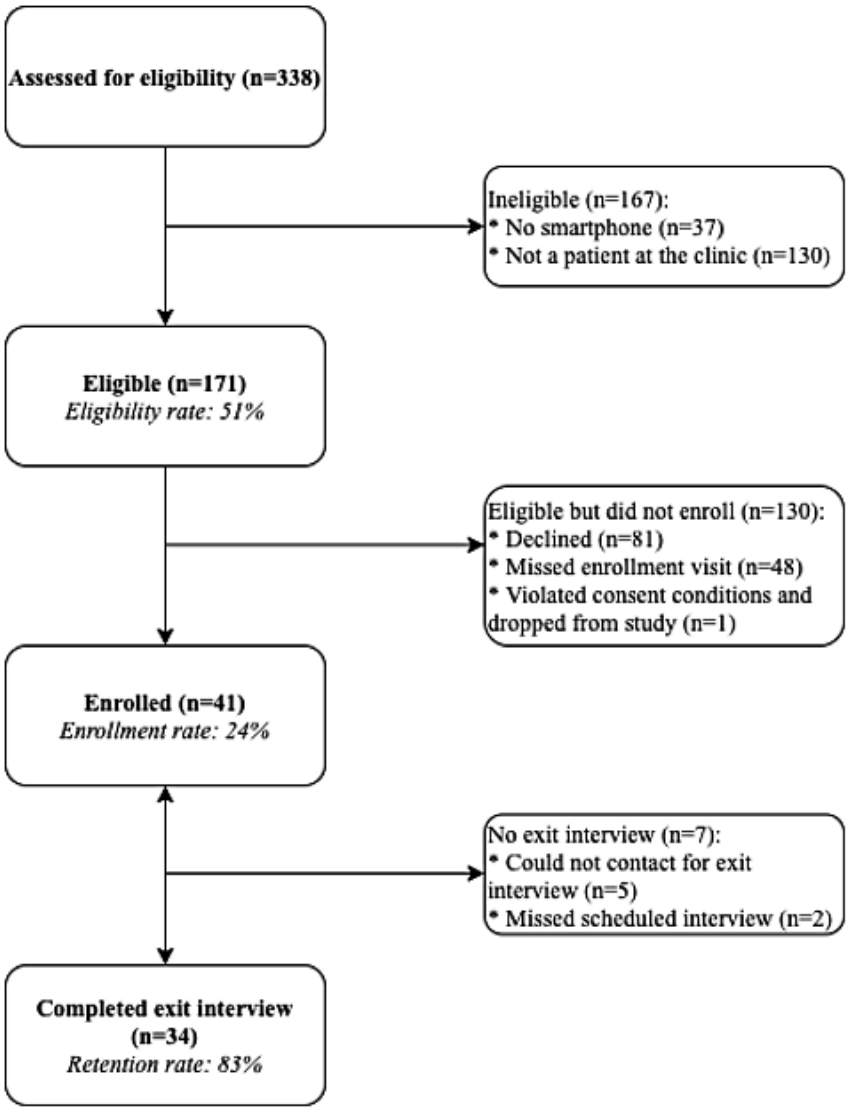


Table 1. Participant baseline characteristics (N=41).

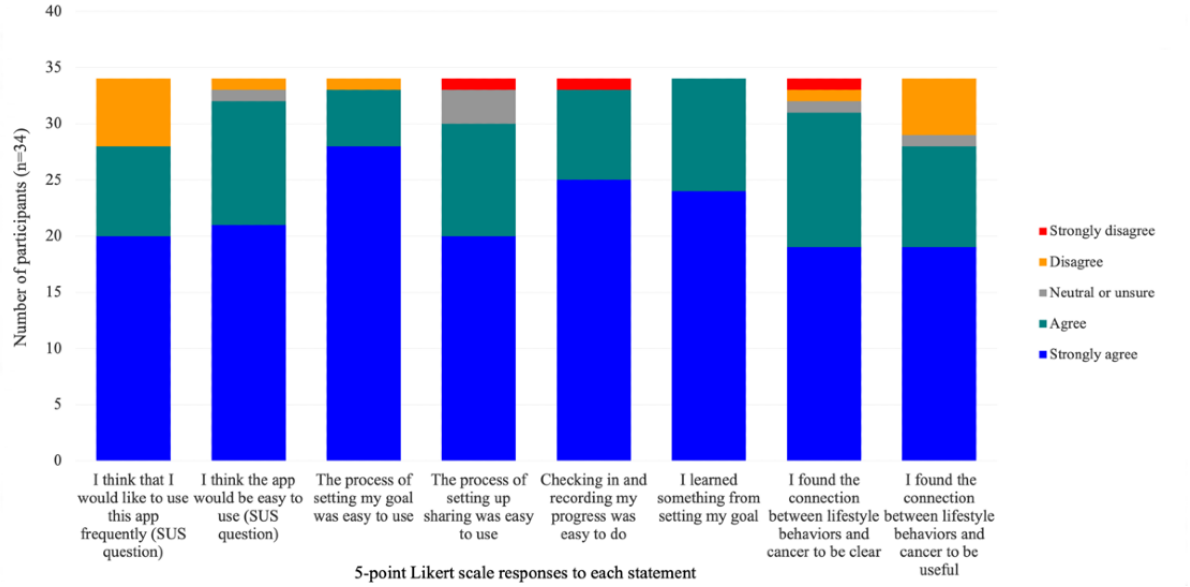
Characteristics	Values
Demographics	
Age (years), mean (SD)	51 (12)
Participants, n (%)	
Females	31 (76)
Technology use, n (%)	
Smartphone operating system	
Apple operating system	17 (41)
Android operating system	23 (56)
Missing	1 (2)
Average use of phone	
Twice or more per day	40 (98)
Nearly daily or daily	1 (2)
Comfort sharing health information, n (%)	
Discusses health topics on the web	12 (29)
Discusses personal health on the web	11 (27)
How much health information was shared with friends or family?	
None	4 (10)
A little	9 (22)
Some	6 (15)
A lot	22 (54)
How many friends or family share health information?	
None	1 (2)
1-5	18 (44)
5-10	14 (34)
10-15	4 (10)
>15	4 (10)
Health behaviors, n (%)	
Set a health goal within last month	30 (73)
Currently tracking health	31 (76)
Methods have used to track health	
Uses technology to track health (eg, phone app, eHealth tracker, and patient portal)	18 (44)
Tracks health manually (eg, health journal)	16 (39)
Relied on friends or family to accomplish the health goal in previous year	28 (68)

Usability and Acceptability of Mobile App

The majority of participants who completed the exit survey (82%, 28/34) reported positive experiences with the app. The app's mean SUS score was 87 (SD 12; median 90; IQR 78-95). Specifically, 94% (32/34) of the participants agreed that the app was easy to use and 82% (28/34) agreed that they would like to use the app frequently. Figure 3 illustrates the distribution of responses to the Likert scale statements about app feature ease of use and knowledge delivery.

Analysis of open-ended responses revealed several key themes depicting both excitement about the app and opportunities for app refinements, with many participants expressing the need for more personalized feedback and social interactions (Textbox 1).

Figure 3. Participant feedback by feature. The first two questions are taken from the System Usability Scale.



Textbox 1. Themes from participant open-ended feedback on app acceptability.

Ease of use is a major strength

- "It was very helpful. Simple. I don't get a lot of notifications which was great." [Participant 7]
- "Not difficult at all. It was easy to do it on the go. Very convenient." [Participant 32]

Features encourage app use and motivate behavioral change

- "The text message reminders were helpful and it keeps people on track." [Participant 31]
- "...it is encouraging to see other people doing what you're doing. It felt like you were doing it as a group." [Participant 15]
- "The goal options were good and [it] helped me change my lifestyle." [Participant 24]

Request for more avenues for social interaction

- "I would like meetings for help setting up these goals [and] to share goals and conquests." [Participant 2]
- "It would have been nice to be able to talk more about goals with others in the app." [Participant 22]

Request for personalized feedback to facilitate goal completion

- "Give us recipes for healthier foods would be nice." [Participant 3]
- "So when I didn't meet my goal I wish that there were tips given to me or more info to help me achieve it next." [Participant 22]

Engagement

We captured participant engagement with the app using check-ins during and after the 8-week study period, as depicted in Figure 4. Out of 8 possible weekly check-ins during the study period, the mean number of check-ins per participant was 5.7 (SD 2.7). Of the total number of participants, 76% (31/41) participants checked in at least four times, 56% (23/41) checked in seven or eight times, and 10% (4/41) never checked in after downloading the app. Participants continued to receive check-in invitations after they completed the 8-week study period, and 51% (21/41) participants checked in at least once during the postintervention period.

In terms of goal selection, activity-related goals were initially the most commonly selected, but participants switched to diet-based and weight-tracking goals as the study progressed. Regular users (31/41, 76%) on average set 2.1 goals during the 8 weeks. Participants who selected diet or weight-tracking goals were also more likely to check in than participants who selected activity or smoking cessation goals (Figure 5).

Figure 4. App engagement during and after the 8-week study period.

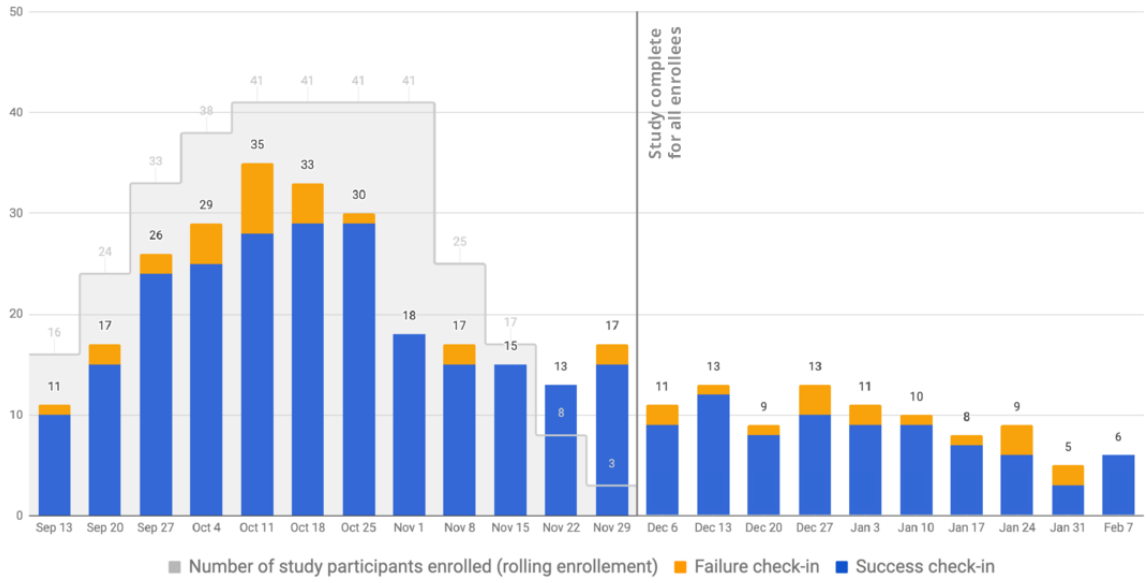
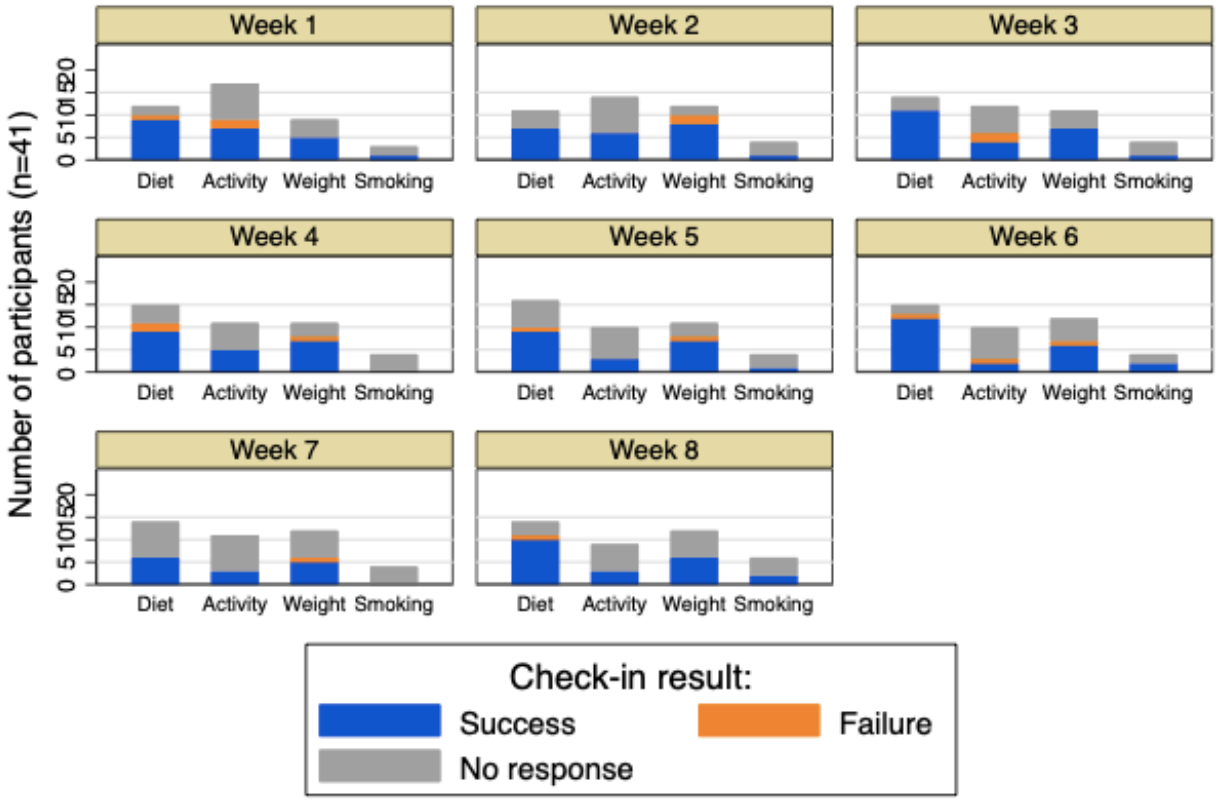


Figure 5. Goal selection and attainment by goal type and study week.



Among the 41 participants, 34 (83%) opted to share progress with their social ties and 18 (44%) opted to share their progress with all app users. A majority of participants used the app's comments box (29/41, 71%), which allowed participants at each check-in to reflect on their weekly progress. Fewer participants (8/41, 20%) used the app's messaging feature, possibly because of the incomplete functionality of this feature in the beta version of the app. Participants left a total of 111 comments and sent 26 messages during the study period. In these comments, participants described both facilitators and barriers to goal success, left inspiring messages, and linked goal success to overall improvements in their health and well-being (Textbox 2). Of those 34 participants who completed the exit interview, 23 (68%) reported visiting the app at least once outside the weekly check-in to view other users' progress or read the health information on the app.

Textbox 2. Themes on how participants used the comment section of the app.

Identified barriers that led to an unsuccessful week

- "Hi, I've just been super busy, sometimes not stopping to eat until the evening. Thanks for contacting me. I needed a reminder." [Participant 32]
- "I got weak and started craving french fries. They just were so tempting and I failed but I know I'll be able to get past these cravings." [Participant 40]

Described facilitators of weekly goal success

- "I had to push myself, even when I didn't want to do it. I am not a excise person that [goes] to the gym so I just start walking around my block 2 times. Then when it got easy then I add more times that I walk around my block." [Participant 34]
- "I have been determined to keep to my goal of lessening processed foods. I hope to continue this as well as engaging my family. Thank you." [Participant 22]
- "I was successful because I had help from my friends to work out." [Participant 42]

Left inspiring messages

- "I try to keep my eyes on the gold." [Participant 14]
- "Everything is good if you stay positive will be good." [Participant 2]

Detailed impact on health and overall well-being

- "Me and my grandkids play in the park. I even try to run a little bit. Still no smoking. Feel good." [Participant 2]
- "Accountability, My Fitness Pal, drop in lbs. & new burst of energy! Liking this New Me!" [Participant 4]
- "I actually increased my walk to 45 min. The more I do the more motivated I become. I have also started doing 20 min of stretches for seniors. Youtube...first thing after tea in morning before walk. I'm loving it!" [Participant 25]

Celebrated success and major health improvements

- "I have lost 45 pounds and I feel great." [Participant 2]
- "I really had to really work on me to stop smoking but I did it." [Participant 28]

Factors Associated With App Engagement

We did not find any participant baseline characteristics to be significantly associated with app engagement. We found significant univariate associations between low app engagement and loss to follow-up, as well as low app engagement and the belief that the app was too complicated, although these associations disappeared after age and sex adjustment (Table 2).

Table 2. Differences in app engagement by participants' characteristics (N=41).

Characteristics	Low app user (0-6 total check-ins; n=18), n (%)	High app user (7-8 total check-ins; n=23), n (%)	Unadjusted OR[a] (95% CI) for high app engagement	Adjusted OR (95% CI) for high app engagement[b]
Baseline characteristics				
Sex				N/A[c]
Female	16 (89)	15 (65)	Reference	
Male	2 (11)	8 (35)	4.27 (0.78-23.4)	
Age (years)				N/A
20-39	5 (28)	2 (9)	Reference	
40-59	10 (56)	13 (57)	3.25 (0.52-20.37)	
60-79	3 (17)	8 (35)	6.67 (0.81-54.96)	
Health tracking				
Does not track health	3 (17)	4 (17)	Reference	Reference
Tracks health manually	7 (39)	9 (39)	0.96 (0.16-5.80)	1.21 (0.15-9.48)
Tracks health with technology	8 (44)	10 (43)	0.94 (0.16-5.46)	2.89 (0.31-26.71)
Postuse characteristics				
Filled out an exit survey				
No	6 (33)	1 (4)	Reference	Reference
Yes	12 (67)	22 (96)	11 (1.18-102.4)[d]	6.11 (0.59-63.3)
Thought app was too complex (n=34)				
No	8 (75)	21 (95)	Reference	Reference
Yes	4 (25)	1 (5)	0.10 (0.01-0.99)[d]	0.10 (0.01-1.15)
Thought app was too simplistic (n=34)				
No	11 (92)	18 (82)	Reference	Reference
Yes	1 (8)	4 (18)	2.44 (0.24-24.8)	1.49 (0.12-17.7)

[a]OR: odds ratio.

[b]Adjusted for sex and age (as a continuous variable).

[c]N/A: not applicable.

[d]Statistically significant result at $P<.05$.

Implications of App Engagement on Goal Success and Behavioral Change

Most participants reported accomplishing their selected health goals each week, with the average participant succeeding in 5.1 out of the 8 weeks (SD 2.7). Of the 328 total check-in opportunities (41 participants×8 weeks), 211 (64.3%) were marked as successful. Participants selected a failure only 6.7% (22/328) of the time, with the other 28.9% (95/328) of opportunities yielding no response. Using two-tailed, paired *t* tests, we found that cancer prevention knowledge increased from baseline, with participants being more likely to recognize the link between the lack of exercise and unhealthy weight with cancer. Two-tailed, paired *t* tests also showed an improvement in diet scores among participants who selected a diet-related goal. We also found that 25% (2/8) of the participants who selected smoking cessation as their goal no longer reported smoking at the exit interview. As noted in Textbox 2, the open-ended comments that participants left after each check-in also suggested that the app was able to motivate behavioral change.

Discussion

Principal Findings

Prior meta-analyses reveal mixed evidence about the ability of health promotion mobile apps to change behavior in a quantifiable manner (eg, significantly increase physical activity) [47] or improve tangible health outcomes (eg, reduce blood pressure or cholesterol levels) [48]. This may be in part because of the fact that many apps are developed without user testing or constructed without a coherent behavior change framework [11,12]. In this pilot study, we examine the Healthier Together mobile app, which was developed through iterative user testing and is grounded in social network and goal-setting theories of behavior change. We found that the app strongly engaged our target population, even beyond the study period, with promising results on participants' knowledge of cancer prevention

behaviors and success in achieving their cancer prevention behavioral goals.

Consistent with prior research showing that minority populations frequently use their mobile phones to obtain health information [15,16], almost half of the participants in our study (18/41, 44%) used various forms of technology to track their health before participation. Participants in the study also reported that they were comfortable discussing their health with their social networks. After interacting with the Healthier Together app for 2 months, the participants supported the usability and acceptability of the app. The app's mean SUS score of 87 indicates that the app is very usable [42], and the vast majority of participants (28/34, 82%) indicated that they would like to use the app frequently if available. The open-ended responses further showcased the participants' beliefs in app acceptability and overall utility. For example, the fact that nearly all participants identified one or more of the app's features as facilitators of goal success shows that the participants understood and used the theoretical basis of the app to their advantage.

Our findings suggest that the high usability scores and acceptability of this app by participants translated into their high engagement: most participants missed only 1 check-in out of 8 and over 50% (21/41) continued to check in after the 8-week study was over. This high engagement is especially encouraging, as participants were not incentivized to engage with the app and only incentivized to complete the baseline and exit surveys. Engagement with the app extended beyond weekly check-ins to report goal achievement. Most participants (23/34, 64%) logged on to the app outside of the weekly check-in to explore the app's other features, whereas many users (29/41, 71%) left unprompted comments when they checked in to highlight their progress or troubleshoot barriers to goal success.

Our study suggests that app engagement, in turn, appears to motivate behavioral change. First, most participants reported accomplishing their weekly health goals. On average, participants reported success in goal attainment of 64.3% (211/328) of the time. These successes represent health behaviors that the participants may not have undertaken if not enrolled in the study. Through the comments participants left when checking in, we found evidence of how these successes translated to tangible behavior changes and health outcomes: participants reported building up exercise programs, eating healthier foods, losing a significant amount of weight, and smoking cessation. We were able to partially capture these effects quantitatively, with participant diet scores and cancer prevention knowledge increasing after the study. Future work should enlist a larger sample size and conduct a randomized controlled trial to further evaluate the effectiveness of this intervention as well as determine what participant characteristics may better forecast app engagement. In this study, we found that neither age nor prior health tracking methods predicted app engagement, which may suggest that the app has a broad appeal.

This study also yielded important data to improve the Healthier Together app. For example, many participants wanted the app to both provide them with additional feedback about how to attain their health goals and facilitate easier ways to connect with other users working on similar goals. We hope that the future iteration of the Healthier Together app will have a group chat feature that allows users to work on goals collectively with other users, potentially with the input of a health provider that occasionally checks the chat. Research suggests that decentralized social networks, such as those envisioned by Healthier Together, can harness social influence to amplify social learning and enhance group intelligence on topics including finance and health [27]. Therefore, rather than the Healthier Together staff providing individualized feedback to each user, users could solicit feedback and recommendations from their peers.

Notably, of the 328 check-ins, there were 22 reported failures, 211 successes, and 95 nonresponses, suggesting that participants were more likely to check in if they met their weekly goal. This may be explained by a number of cognitive biases, such as social desirability bias, with participants not wanting to publicly admit an unsuccessful week [49]. Future versions of the app should aim to reframe unsuccessful weeks as opportunities for feedback and goal reflection rather than as reasons to disengage from the app. This study also found a lower rate of engagement with the app when users selected activity-based goals and an overall shift from activity-based goals to diet-based and weight-tracking goals as the study progressed. One potential reason for this observation is that the study occurred during the fall of 2019 in Philadelphia, and the colder weather may have disincentivized some participants from exercising [50]. Participants may have also been more conscious of their diet, given the upcoming holiday season [51]. Future versions of the app will aim to adjust the predetermined SMART goals to account for such variations.

Strengths and Limitations

The success of this study in showing Healthier Together is engaging, usable, and acceptable and in providing the development team with important feedback for future versions of the app must be framed within certain limitations. First, this study was not powered to detect changes in health behavior among participants, nor did it randomize participants to test its effectiveness. The focus of this pilot study on usability and acceptability rather than effectiveness is commonplace for the initial stages of app development [52,53] and is consistent with the use of an iterative process to build health apps [35]. Quantitative analysis of close-ended questions in this study was descriptive and designed to inform future inquiries. Second, we focused on recruiting non-Hispanic Black primary care patients using purposive sampling and could not generalize these results if Healthier Together was downloaded in a nonclinical setting. However, we chose this methodology given the objective of Healthier Together is to facilitate cooperation between primary care patients and their providers on health goals. We did not independently code our structured interviews and, therefore, did not generate an intercoder reliability statistic [54]. Our analytic approach allowed us to better generate themes that enhanced our primary quantitative usability and engagement data. We also took the following key steps to assure the validity of the coding process consistent with external guidelines: (1) 2 coders achieved full consensus on code definitions reaching consensus on any deviant opinions, and (2) 2 additional independent researchers reviewed and edited the themes [55].

Conclusions

In conclusion, this study showed that non-Hispanic Black primary care patients found Healthier Together, an evidence-based mobile app that focuses on cancer prevention behaviors, both engaging and valuable. We hope that the results of this study will inform future research on the development of health behavior interventions for minority populations, especially those that aim to leverage goal setting, social cooperation, and health technology.

Acknowledgments

The authors would like to thank all of the participants who diligently engaged with the Healthier Together app and provided the team with thoughtful feedback. JA was supported by the American Cancer Society Tri-State CEO's Against Cancer Mentored Research Scholar Grant, MRSG-17-155-01-CPPB. In addition, this study was supported in part by the 2018 Abramson Cancer Center Population Science Pilot Award Program, Abramson Cancer Center Support Grant, P30-CA016420. The funders had no role in the design and conduct of the study; the collection, management, analysis, and interpretation of the data; or the preparation, review, or approval of the manuscript.

Conflicts of Interest

LJ was employed by the app developer Transmogrify. Transmogrify had no input in the study design or evaluation.

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Abbreviations

PCP: primary care provider
REDCap: Research Electronic Data Capture
SMART: specific, measurable, achievable, realistic, and time-bound
SUS: System Usability Scale

Edited by G Eysenbach; submitted 14.07.20; peer-reviewed by J Makin, X He; comments to author 20.10.20; revised version received 12.12.20; accepted 07.05.21; published 14.07.21.

Please cite as:
Resnick D, Schapira MM, Smith JM, Bautista A, Xu C, Jones L, Aysola J
Promoting Collaborative Goal Setting for Cancer Prevention Among Primary Care Patients Through mHealth: Mixed Methods Evaluation of a New App
JMIR Form Res 2021;5(7):e22510
URL: https://formative.jmir.org/2021/7/e22510
doi:10.2196/22510
PMID:34259162

Original Paper

User Engagement and Usability of Suicide Prevention Apps: Systematic Search in App Stores and Content Analysis

Chelsey R Wilks[1], PhD; Carol Chu[2], PhD; DongGun Sim[3], EdM; Josh Lovell[4], MA; Peter Gutierrez[5,6], PhD; Thomas Joiner[7], PhD; Ronald C Kessler[8], PhD; Matthew K Nock[9], PhD

[1]Department of Psychological Sciences, University of Missouri-St. Louis, St Louis, MO, United States
[2]Minneapolis Veterans Affairs Health Care System, Minneapolis, MN, United States
[3]School of Theology, Boston University, Boston, MA, United States
[4]Department of Psychology, Hofstra University, Hempstead, NY, United States
[5]Rocky Mountain Regional VA Medical Center, Denver, CO, United States
[6]University of Colorado Anschutz Medical Campus, Denver, CO, United States
[7]Department of Psychology, Florida State University, Tallahassee, FL, United States
[8]Department of Health Care Policy, Harvard Medical School, Boston, MA, United States
[9]Department of Psychology, Harvard University, Cambridge, MA, United States

Corresponding Author:
Chelsey R Wilks, PhD
Department of Psychological Sciences
University of Missouri-St. Louis
1 University Way
St Louis, MO, 63121
United States
Phone: 1 (314) 516 5383
Email: chelseywilks@umsl.edu

Abstract

Background: People with suicidal thoughts are more inclined to seek technology-delivered interventions than in-person forms of treatment, making mobile apps for suicide prevention an ideal platform for treatment delivery. This review examines apps designed for suicide prevention, with a specific focus on user engagement.

Objective: This study aims to update the literature and broadly evaluate the landscape of mobile health apps for suicide prevention; examine apps with key features and primary approaches to suicide prevention; and systematically evaluate the engagement, functionality, aesthetics, and information of the apps.

Methods: All apps related to suicidal thoughts and behaviors were identified in the Google Play and iOS app stores and were systematically reviewed for their content and quality. The mobile app rating scale (MARS) was used to evaluate app usability and engagement.

Results: Of the 66 apps identified, 42 (64%) were specifically designed for people with suicidal ideation, and 59 (89%) had at least one best practice feature for suicide risk reduction. The mean overall MARS score of all apps was 3.5 (range 2.1-4.5), with 83% (55/66) of apps having a minimum acceptability score of 3. The total MARS score was not associated with the user app rating (r=−0.001; P=.99) or the number of features (r=0.24; P=.09).

Conclusions: This study identified many usable and engaging apps in app stores designed for suicide prevention. However, there are only limited apps for clinicians. Thus, mobile apps for suicide prevention should be carefully developed and clinically evaluated.

(JMIR Form Res 2021;5(7):e27018) doi:10.2196/27018

KEYWORDS

suicide; mHealth; usability; engagement; mobile phone

Introduction

Background

Suicide is the second leading cause of death in the United States among people between the ages of 10-34 years. Suicidal thoughts and behaviors are difficult to treat, and only a few treatments with evidence of efficacy are widely disseminated. Unfortunately, treatment engagement among suicidal patients is low, particularly among those experiencing frequent and intense suicidal ideation [1-3]. Fortunately, although some high-risk suicidal individuals avoid face-to-face intervention, they may be inclined to anonymously seek out help through technology [4-6].

One cost-effective and convenient avenue for mental health delivery is through mobile mental health apps (ie, mobile health [mHealth] apps). There has been an increase in the number of mHealth app targeted for mental health problems in general [7,8] and suicide in particular [9,10]. mHealth may be a novel strategy to target suicide among those in high-income countries, with over 95% of US adults reporting that they own a smartphone [11]. In addition, approximately 64% of adolescents reported using apps to manage their mental health symptoms [12].

The number of mental health–related apps available to users has increased dramatically, with recent estimates suggesting that more than 10,000 such apps have been created [13]. Unfortunately, only a few mHealth apps have demonstrated efficacy [14,15]. In addition, 74% of users reported that they stopped using mHealth apps after only 10 uses [16]. Thus, there is a significant deficit in studies investigating the efficacy and engagement levels of mHealth apps, as well as those particularly focusing on suicide prevention. For instance, Larsen et al [10] identified 49 apps specifically designed to prevent or reduce suicide and concluded that although many apps contained some elements of best practices, none of the apps provided evidence supporting their efficacy. Best practices for suicide prevention include strategies with consistent evidence for reducing suicide and have been outlined in detail in previous reviews [17]. For example, means safety, defined as the removal of lethal means, has consistently been identified as an effective suicide prevention intervention [18]. Other best practices include providing access to suicide hotlines, crisis planning, and social support [19,20]. De La Torre et al [9] performed a more comprehensive review and identified 20 apps related to suicide prevention and 6 published scholarly articles describing the features and clinical utility of mobile apps for suicide prevention. However, neither of these reviews critically evaluated the user experience of mHealth apps related to suicide prevention. In this context, user experience comprises usability and engagement. Usability refers to how simple and intuitive it is to access computing technology [21], whereas engagement refers to the degree to which user interest is maintained when interacting with computing technology [22]. User engagement can be evaluated using objective metrics (eg, downloads, popularity, and dwell time) and expert ratings [23].

Objectives

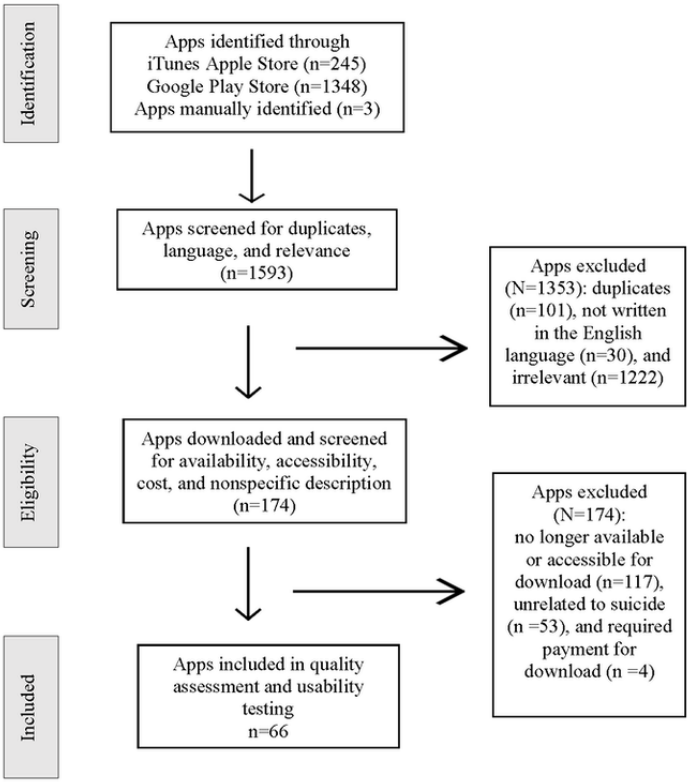
As mHealth apps have the potential to monitor and mitigate suicidal crises, it is important to assess the features and quality of smartphone apps currently available. Apps that can engage users toward more effective coping behavior in lieu of suicidal acts could have a sweeping public health impact but only if the user is prompted to open the app during critical times. Therefore, the objectives of this study were to (1) update the literature and broadly evaluate the landscape of mHealth apps for suicide prevention, (2) examine the key features and primary approaches to suicide prevention of these apps, and (3) systematically evaluate the engagement, functionality, aesthetics, and information of the apps. The systematic evaluation of usability and engagement was difficult until the development of mobile app rating scale (MARS), a tool for classifying and rating the quality of mHealth apps [24]. This review aims to help users make more informed decisions by assessing the features, usability, and engagement of apps designed to prevent suicide.

Methods

App Selection

Apps were initially identified in October 2018 and rereviewed in October 2020 through a systematic search of the US iTunes and Google Play stores. Search terms included *suicide*, *suicidal ideation*, *suicide ideation*, *thoughts about suicide*, *suicidal thinking*, *ideation*, *thinking about suicide*, *self-harm*, *self-injury*, *nonsuicidal self-injury*, and *NSSI*. Apps were included if they (1) were smartphone based, (2) used Android or iOS operating systems, (3) were in the English language, (4) had one or more of the aforementioned search terms in the app description, and (5) were available for download in the US app store (iTunes or Google Play). Apps were excluded if they (1) did not primarily target suicidal thoughts, behaviors, or self-injury; required payment for download; or were no longer available or accessible for download (Figure 1). iPhone apps were downloaded and tested using an iPhone 7 and an iPhone 11 in iOS 11, whereas Android apps were downloaded and tested using a simple mobile phone and One Plus 7 Pro Android in version Oreo 8.1 and Oxygen OS 10.3.2, respectively.

Figure 1. Systematic app selection.



Data Extraction

The following data about all apps were recorded: app name, platform (ie, Android or iOS), current version, cost, number of installs (Android only), and user ratings (1-5 stars). The intended best practice prevention strategy of each app is noted using the relevant portion of the coding scheme by Larsen et al [10], including means safety (ie, reducing access to lethal means of suicide), support (ie, providing access to social support networks, such as through a message board), access to crisis support or helpline, psychotherapies (cognitive behavior therapy or dialectical behavior therapy), and safety planning. Discrepancies were resolved by discussion among the authors until a consensus was reached. As suicide prevention can encompass numerous strategies from support to immediate crisis intervention, we identified four approaches that each app used as its main prevention strategy: providing psychoeducation, teaching coping skills, documenting a crisis plan, and providing social support. Apps that reportedly targeted suicide risk but did not fall into those four categories were classified as *other*.

App Quality

All apps were rated by 2 independent reviewers using the MARS. The 23 items in the MARS were identified from a review of existing criteria for rating app quality. Each item was rated on a 5-point scale (ie, 1=inadequate; 2=poor; 3=acceptable; 4=good; and 5=excellent) with descriptors provided for each anchor rating. MARS grouped the items into four categories, namely engagement (5 items), functionality (4 items), aesthetics (3 items), and information quality (7 items), and a subjective quality scale (eg, worth recommending and overall satisfaction; 4 items). The dimension of subjective quality in MARS was excluded from the analysis to ensure objectivity and consistency of the assessment process. Previous studies using MARS have also excluded the subjective quality dimension for this reason [24]. The MARS was scored using a mean for each category and an overall mean score. The MARS demonstrated good internal consistency (α=.90) and interrater reliability (intraclass coefficient=0.79) in previous research [24].

Before the app assessment, the 4 reviewers (CRW, CC, DS, JL) discussed the use of the MARS for apps intended for people with suicidal thoughts and behaviors. Evaluating the quality and user experience of mobile apps can be unreliable [25]. The first author (CRW) has extensive research experience in developing mobile apps, conducting user research with mobile and web-based applications, and human-computer interaction. We based the target audience on the following: patients or consumers, clinicians, teens, and family or friends. As recommended by the developers of the MARS, the reviewers considered all items of the MARS and confirmed that all were applicable to apps for suicide prevention and that no additional app-specific items were required.

After a consensus was reached with regard to MARS, the reviewers independently rated the included apps. Each reviewer interacted with the identified app for several minutes, ensuring that all aspects of functionality were tested and evaluated. When reviewers had questions or concerns related to the apps, these issues were discussed among the authors and a consensus was reached.

Statistical Analyses

Scores were calculated for each MARS item, along with the total mean score. The interrater reliability of the MARS subscales and total quality score was calculated using the

intraclass correlation coefficient two-way random-effects model of absolute agreement between single ratings. The mean value for each dimension of MARS was calculated. The difference in app quality between affiliations was analyzed using analysis of variance to examine the moderating effect of developers. Spearman correlations among the four dimensions of MARS, the number of downloads, and average rating were also analyzed. All statistical analyses were performed using SPSS, version 24 (IBM Corporation).

Results

Search Results

A total of 1593 apps (iTunes Apple store, n=245; Google Play Store, n=1348) were initially screened or manually identified. In the screening stage, 1353 apps were excluded as they were either duplicates, not written in the English language, or irrelevant (eg, games, wallpapers, and quotes). Of the 240 apps that were downloaded and tested for eligibility, 174 (72.5%) were excluded as they were no longer available or accessible for download, unrelated to suicide, or required payment for download. The remaining 66 apps were included in the quality assessment and usability evaluation (Figure 1).

Descriptive Characteristics

The characteristics and the mean MARS scores of the 66 included apps are presented in Multimedia Appendix 1. The average user rating of the apps was 3.5 (range 1-5). Although all included apps were free, 2 offered paid upgraded versions at a cost between US $0.99 and US $149.99 for in-app purchases. A total of 35 apps were found in both iOS and Android app stores, whereas 19 were iOS only and 12 were Android only. More than half (37/66, 56%) of the apps included a privacy policy.

The five features considered to be best practices for suicide prevention were examined for each app and are presented in Table 1. None of the apps had all five features, and only 4 apps had four of the five best practices: *Prevent Suicide: Dumfries & Galloway, ReMinder Suicide Safety Plan, SafetyNet: Your Suicide Prevention App,* and *Don't Panic–depression and panic help.* The average number of features across apps was 1.7. None of the features was found in the following 7 apps: *SafeUT, R U Suicidal?, Self Harm Recovery, A Teen Suicide Prevention Anime, Seeking the Military Suicide Solution, Elijah,* and *Suicide Prevention-Ways to Help a Suicidal Friend.* The most common of the five features included were access to a crisis line (37/66, 56%), support (33/66, 50%), and a safety plan (22/66, 33%), whereas means safety was the least integrated feature (8/66, 12% of apps). The apps were most often designed for persons experiencing suicidal thoughts (49/66, 74%), followed by friends and family (11/66, 16%), teens (6/66, 9%), and clinicians (1/66, 2%; Multimedia Appendix 1). On the basis of the Android apps alone, the apps with the most downloads were *Calm Harm, Talk Life,* and *Mood Tools* with over 100,000 downloads.

Table 1. Best practice features for suicide prevention of included apps (N=66).

App name	Means safety	Support	Crisis line access	Treatment	Safety plan
Calm in the Storm: Stress Management					✓[a]
INSIST		✓			
MY3 Support Network			✓		✓
TalkLife for Stress & Anxiety		✓			
SafeUT					
First Step OR		✓	✓		
MoodTools-Depression Aid				✓	✓
HOPE-Broome County Mental Health		✓	✓		
STOPP app		✓		✓	
Jason Foundation A Friend Asks		✓	✓		
Suicide Safety Plan	✓				✓
Safe Students		✓	✓		
Got your back			✓	✓	✓
Stanley-Brown Safety	✓		✓		✓
Operation Reach Out	✓	✓			✓
trustTalk247		✓	✓		
Just in Case for Colleges		✓	✓		
Relief Link			✓		
Ulster County Speak		✓	✓		
Friend2Friend		✓			
be safe suicide safety plan			✓	✓	✓
Every Teen Seen		✓			
distract					✓
Be Safe			✓		✓
Calm Harm-manages self harm				✓	
R U Suicidal?					
Say Something		✓	✓		
Anemone Crisis App			✓	✓	✓
Prevent Suicide-Highland		✓	✓		✓
There is Hope		✓	✓		✓
A.L.E.R.T.			✓		✓
Self Harm Recovery					
Suicide? Help? Tayside					✓
Stay Alive					✓
Dutchess County HELPLINE		✓	✓		
The LifeLine			✓		✓
DMHS[b]: Suicide Prevention Info		✓			
Is S/O Suicidal?		✓			
Did someone you know suicide?		✓			
Step Up and Speak Out		✓	✓		
Kokua Life		✓	✓		✓

App name	Means safety	Support	Crisis line access	Treatment	Safety plan
MSE&SUICIDE ASSESSr		✓			
Calm Care			✓	✓	
My Shiny Thing				✓	
PMCS Combating Suicide			✓		
SeeSave/See Something Save Someone		✓	✓		
Community Stress First Aid		✓			
iHelp Sunshine Coast	✓	✓	✓		
MS DMH-Shatter in the Silence			✓		
Better Stop Suicide	✓				✓
SCNG[c] Suicide Prevention		✓			
Alaska Careline		✓	✓		
Prevent Suicide: Dumfries & Galloway		✓	✓	✓	✓
TheHopeLine		✓	✓		
MYPLAN-your safety plan			✓		✓
ReMinder Suicide Safety Plan	✓	✓	✓	✓	
SafetyNet: Your Suicide Prevention App	✓	✓	✓	✓	
TUFMINDS			✓	✓	
UnCut App		✓			
Don’t Panic–depression and panic help	✓		✓	✓	✓
Emotional Support Helpline Directory			✓		
Yellow Ribbon Foundation			✓		
A Teen Suicide Prevention Anime					
Seeking the Military Suicide Solution					
Elijah					
Suicide Prevention-Ways to Help a Suicidal Friend					

[a]Feature present.

[b]DMHS: Durham Mental Health Services.

[c]SCNG: South Carolina National Guard.

Usability and App Quality

The mean overall MARS score of all apps was 3.5 (range 2.1-4.5), and 83% (55/66) of apps had a minimum acceptability score of 3.0 (Table 2). In general, the *Calm Harm: Manages self harm* app had the highest MARS overall score (4.5), followed by *INSIST* (4.49), *MY3 Support Network* (4.4), and *Talklife for Stress and Anxiety* (4.4). Apps with the highest MARS scores and at least three of five best practice features for suicide prevention were *Got your back*, *Stanley-Brown Safety*, and *Operation Reach Out*.

Data on the MARS subscale scores and the overall MARS scores categorized according to the main app approaches are presented in Table 2. The interrater reliability was within the acceptable range for each subscale (0.73-0.94), with the highest interrater reliability for information (0.94) and the lowest for function (0.73). Apps with the primary function of providing users with support had the highest overall MARS (mean 3.7, SD 0.8). Coping skills apps scored the highest in engagement (3.2) and function (4.0). In the aesthetics and information subscales, support apps (3.8 and 4.2, respectively) had the highest scores.

Table 2. Mobile app rating scores according to main approach (N=66).

Main approach	Count, n (%)	Engagement, mean (SD)	Functionality, mean (SD)	Aesthetics, mean (SD)	Information, mean (SD)	Overall, mean (SD)
Crisis plan	12 (18)	3.13 (0.77)	3.96 (0.59)	3.38 (0.70)	3.64 (1.16)	3.53 (0.76)
Support	24 (36)	2.91 (0.76)	3.86 (0.71)	3.82 (0.72)	4.23 (0.53)	3.70 (0.83)
Psychoeducation	17 (26)	2.56 (0.65)	3.80 (0.54)	3.34 (0.66)	3.70 (1.00)	3.35 (0.87)
Coping skill	10 (15)	3.24 (0.64)	4.00 (0.64)	3.43 (0.83)	3.69 (0.87)	3.59 (0.78)
Other	3 (5)	2.40 (0.35)	3.4 (0.88)	2.50 (0.50)	3.66 (1.44)	2.99 (0.96)

Correlation Analysis

The total and subscale MARS scores were all significantly correlated, indicating that app quality was consistent across all areas assessed (eg, apps scoring high on engagement also tended to score high on function, aesthetics, and information). The overall MARS score was neither correlated with user app rating (r=−0.001; P=.99) nor with the number of features included within the app (P=.09; Table 3).

Table 3. Correlations among total mobile app rating scale (MARS) score, four MARS dimension scores, rating, and number of features.

Characteristics	MARS[a]					Rating	Number of features
	Total	Engagement	Function	Aesthetics	Information		
MARS							
Total	1.00	—[b]	—	—	—	—	—
Engagement							
Correlation factor	0.72	1.00	—	—	—	—	—
P value	<.001	—	—	—	—	—	—
Function							
Correlation factor	0.80	0.40	1.00	—	—	—	—
P value	<.001	<.001	—	—	—	—	—
Aesthetics							
Correlation factor	0.83	0.60	0.50	1.00	—	—	—
P value	<.001	<.001	<.001	—	—	—	—
Information							
Correlation factor	0.82	0.35	0.63	0.56	1.00	—	—
P value	<.001	.002	<.001	<.001	—	—	—
Rating	−0.01	−0.01	−0.04	−0.01	0.05	1.00	—
Number of features	0.20	−0.02	0.22	0.09	0.32[c]	0.24	1.00

[a]MARS: mobile app rating scale.

[b]Not applicable.

[c]P=.006.

Discussion

Principal Findings

We examined the user experience, usability, and engagement of mHealth apps designed for suicide prevention. There are three main findings of this study. First, although the majority apps included elements of best practices to reduce suicide risk, none included all these features. Second, most of the reviewed apps were designed for suicidal individuals, rather than for clinicians, friends, and families. Third, the MARS score of the majority of apps was in the *acceptable* range, with the apps designed for support receiving the highest rating; however, the star ratings of users were not correlated with MARS scores, suggesting that star ratings may be indicative of another construct rather than app quality.

Since the app review by Larsen in 2016 [10], nearly twice as many apps designed to reduce suicide have been introduced in app stores. The majority of the apps (59/66, 89%) reviewed in this study have at least one best practice element for suicide prevention. The most common feature across the apps was the inclusion of a crisis line access (37/66, 56%); however, only 12% (8/66) of apps included a means safety feature. Mean safety

is considered one of the most potent suicide prevention strategies [26]; thus, it is surprising that it was the least integrated feature. However, integrating content into mobile devices requires intentional design considerations, such as interaction or navigation, which can influence how users learn and engage with the material [27]. In addition, including content on means safety may have been difficult to design and implement. We found no association among the number of best practice elements, MARS scores, or app ratings, indicating that app quality is not solely driven by content, but rather how the content functions and is designed. Notably, an app that implements one aspect well, such as developing a safety plan, may be a better app than one that tries to integrate several features. The apps that yielded the highest MARS scores had a narrow scope. However, this review did not clinically evaluate or evaluate the available research on any of these apps; therefore, it is unclear whether these apps are effective at reducing suicidal crises.

The majority of the apps (49/66, 74%) were specifically designed for suicidal individuals, only 15% (10/66) of which were designed for friends or family and 2% (1/66) for clinicians. This highlights a potential deficit in apps that are designed to treat, manage, or cope with individuals at risk of suicide. A major obstacle in overall suicide prevention is the lack of willingness in treating suicidal individuals among mental health providers [28]. In a previous study, a technology-delivered suicide risk assessment and management tool was associated with reduced fear and increased self-efficacy among clinicians treating suicidal individuals [29]. Given that suicidal people tend to avoid face-to-face treatment [1-3], one avenue to potentially reduce suicide risk could be through a suicide prevention app for friends and family. Although these apps exist in app stores, it is unclear whether they are effective or widely used. Overall, more research is needed to develop and evaluate suicide prevention apps for individuals who work or live with suicidal patients.

Most mobile apps in this review were at least moderately usable and engaging. Although 17% (11/66) of apps yielded unacceptable scores, the average MARS scores were in the acceptable range, indicating that the apps were generally usable and engaging. However, it is unclear whether the apps designed to reduce suicide are reaching the appropriate audience or designed according to what suicidal users need or want. The user context or environment may be a significant driver of the determination of engagement. A suicide app designed to help clinicians assess and manage suicide will likely need to be highly functional, but not necessarily fun to use. In contrast, in apps designed to help users reduce suicidal crises, ongoing app engagement may not be a goal, as app developers hope that suicidal crises will eventually be reduced. This makes the iterative design of suicide-related apps challenging because repeated use may not be an ideal outcome. Traditionally, app developers can use objective measures, such as *time spent on app* and *daily uses*, as outcomes to fine-tune and optimize content delivery; however, these metrics may indicate different factors. An engaging suicide app may be one that is immediately accessible to users during key moments, and previous research on user engagement with mHealth apps indicates that immediate access to resources is an integral aspect that can keep users engaged [30]. As 73% of users tend to stop using a mental health app after 10 uses [16], it is important to understand what factors are associated with discontinued use, such as poor user experience versus *no longer in crisis*. In addition, it may not be profitable to develop a tool to reduce suicide, which may partially explain the relatively large number of nonusable apps designed for suicide. Because developing, publishing, and maintaining mobile apps is time-consuming and expensive, a different funding structure may be required to produce high-quality mobile apps for high-risk users.

In general, there is a lack of research on consumer apps for suicide prevention. Melia et al [31] identified only 7 mobile mental health apps with published outcomes in randomized clinical trials. Although there are apps available to consumers with research support, such as Tec Tec [32] and the Virtual Hope Box [33], these apps were not identified during our search procedure, highlighting a deficit in search term strategy when these apps were released to the public. We were only able to find these apps when we searched for them by name but not when we used our search terms. The function of this review is *user-centered*, as is the case when users search for apps for suicide or self-harm. Researchers who design and develop apps may benefit from the increased marketing of their apps. In addition, users may not be willing to scroll past the first page of results to search for an app, highlighting the importance of the search term strategy and how apps are weighted in the app store search algorithm. Given that star ratings may not accurately reflect app quality, app store algorithms may benefit from another strategy to move quality apps up the list.

Limitations

Although this paper is the first review to specifically examine the user experience of mobile apps specifically designed for suicide, there are some limitations to the study worth discussing. First, as we only searched on app stores and systematic literature search was not performed, web-based apps that are not featured in app stores were, therefore, not included. Owing to the ease of development and maintenance of web-based apps compared with native apps [25], it is important to include these apps in future research. Second, we only reviewed the user statistics at one time point, and variables such as the number of downloads and user ratings vary over time. Third, as noted previously, some notable and research-supported apps were missing from this study. We believe this illustrates the *lab to marketplace* gap, which is prevalent in all aspects of mental health research but especially in research on dissemination and implementation [34]. Finally, we opted not to evaluate apps that required payment upfront, which limited the scope of our review.

Conclusions

Although this study identified many usable and engaging apps designed for suicide prevention in app stores, there are several opportunities for mobile app development and enhancement. In particular, there is a lack of apps designed to assist clinicians in treating suicidal patients. In addition, there is a need for more clinical evaluation of suicide prevention apps found in app stores. In general, mobile apps for suicide prevention should be carefully developed and clinically evaluated.

Conflicts of Interest

CRW receives consulting fees from Mindstrong Health, Click Therapeutics, and Behavioral Tech. In the past 3 years, RCK was a consultant for Datastat Inc, Holmusk, RallyPoint Networks Inc, Sage Pharmaceuticals, and Takeda. He has stock options in Mirah, PYM, and Roga Sciences. MKN receives text book royalties from Macmillan and Pearson publishers and has been a paid consultant in the past year for Microsoft and for a legal case regarding a death by suicide. He is an unpaid scientific advisor for TalkLife and Empatica. All other authors deny conflicts of interest.

Multimedia Appendix 1
Characteristics and mean mobile app rating scale scores of mobile apps (N=66).
[DOCX File , 25 KB - formative_v5i7e27018_app1.docx]

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Abbreviations

MARS: mobile app rating scale
mHealth: mobile health

Edited by G Eysenbach; submitted 07.01.21; peer-reviewed by C Smith, B Loo Gee; comments to author 18.02.21; revised version received 15.04.21; accepted 29.04.21; published 14.07.21.

Please cite as:
Wilks CR, Chu C, Sim D, Lovell J, Gutierrez P, Joiner T, Kessler RC, Nock MK
User Engagement and Usability of Suicide Prevention Apps: Systematic Search in App Stores and Content Analysis
JMIR Form Res 2021;5(7):e27018
URL: https://formative.jmir.org/2021/7/e27018
doi:10.2196/27018
PMID:34259163

Original Paper

Barriers to the Use of Web-Based Mental Health Programs for Preventing Depression: Qualitative Study

Heidi Eccles[1], MSc; Molly Nannarone[1], MPH; Bonnie Lashewicz[2], PhD; Mark Attridge[3], PhD; Alain Marchand[4,5], PhD; Alice Aiken[6], PhD; Kendall Ho[7], MD; JianLi Wang[1,8,9], PhD

[1]The Institute of Mental Health Research, University of Ottawa, Ottawa, ON, Canada

[2]Department of Community Health Sciences, Cumming School of Medicine, University of Calgary, Calgary, ON, Canada

[3]Attridge Consulting, Inc, Minneapolis, MN, United States

[4]School of Industrial Relations, University of Montreal, Montreal, QC, Canada

[5]Public Health Research Institute, University of Montreal, Montreal, QC, Canada

[6]Faculty of Health, Dalhousie University, Halifax, NS, Canada

[7]Department of Emergency Medicine, University of British Columbia, Vancouver, BC, Canada

[8]Shandong Key Laboratory of Behavioral Medicine, School of Mental Health, Jining Medical University, Jining, China

[9]School of Epidemology and Public Health, Faculty of Medicine, University of Ottawa, Ottawa, ON, Canada

Corresponding Author:
JianLi Wang, PhD
The Institute of Mental Health Research
University of Ottawa
Room 5404, 1145 Carling Ave
Ottawa, ON, K1Z 7K4
Canada
Phone: 1 6137226521 ext 6057
Email: jlwang@ucalgary.ca

Abstract

Background: Depression has a profound impact on population health. Although using web-based mental health programs to prevent depression has been found to be effective in decreasing depression incidence, there are obstacles preventing their use, as reflected by the low rates of use and adherence.

Objective: The aims of the study are to understand the barriers to using web-based mental health programs for the prevention of depression and the possible dangers or concerns regarding the use of such programs.

Methods: BroMatters and HardHat were two randomized controlled trials (RCTs) that evaluated the effectiveness of e–mental health programs for preventing workplace depression. In the BroMatters RCT, only working men who were at high risk of having a major depressive episode were included. The participants were assigned to either the control group or 1 of 2 intervention groups. The control participants had access to the general depression information on the BroMatters website. Intervention group 1 had access to BroMatters and BroHealth—the depression prevention program. Intervention group 2 had access to BroMatters and BroHealth along with weekly access to a qualified coach through telephone calls. The HardHat trial targeted both men and women at high risk of having a major depressive episode. The participants in the intervention group were given access to the HardHat depression prevention program (which included a web-based coach), whereas HardHat access was only granted to the control group once the study was completed. This qualitative study recruited male participants from the intervention groups of the two RCTs. A total of 2 groups of participants were recruited from the BroMatters study (after a baseline interview: n=41; 1 month after the RCT: n=20; 61/744, 8.2%), and 1 group was recruited from the HardHat RCT 1 month after the initial quantitative interview (9/103, 8.7%). Semistructured interviews were performed with the participants (70/847, 8.3%) and analyzed using content analysis.

Results: There were both personal and program-level barriers to program use. The three personal barriers included time, stress level, and the perception of depression prevention. Content, functionality, and dangers were the program-level barriers to the use of web-based mental health programs. Large amounts of text and functionality issues within the programs decreased participants' engagement. The dangers associated with web-based mental health programs included privacy breaches and inadequate help for severe symptoms.

Conclusions: There are personal and program-level barriers to the use of web-based mental health programs. The stigmatization of help seeking for depression symptoms affects the time spent on the program, as does the public perception of depression. Certain barriers may be mitigated by program updates, whereas others may require a complete shift in the perception of depression prevention.

(JMIR Form Res 2021;5(7):e16949) doi:10.2196/16949

KEYWORDS

prevention; mental health; depression; problem solving therapy; barriers; web-based program; qualitative study

Introduction

Background

Major depressive episodes (MDEs) have a considerable impact on human health, with an annual prevalence of 4.7% in Canada [1], and they affect 350 million people worldwide [2]. MDEs cause workers to be less productive while at work (presenteeism) or completely absent from work (absenteeism). Presenteeism and absenteeism cost Canada approximately Can $2.5 billion (US $2.0 billion) and Can $6.8 billion (US $5.5 billion), respectively, in 2015 [3]. Preventive strategies have been shown to decrease the incidence of depression, thereby decreasing presenteeism and absenteeism [4,5].

Web-based mental health programs can play an important role in the prevention of depression by increasing accessibility, confidentiality, and sustainability [6], and those based on cognitive behavioral therapy (CBT) have been shown to be effective at decreasing stress [7]. A recent study found that web-based mental health programs were perceived by users to increase both individual and societal mental health awareness [8]. However, the rates of use and adherence to such programs can be low and inconsistent, with completion rates in randomized controlled trials (RCTs) ranging from 14% to 90% [9,10]. The frequency of completing web-based programs is lower than that in face-to-face therapies [10]. The level of use and adherence can have a direct impact on the effectiveness of e–mental health programs. Thus, it is important to understand the barriers associated with the use of e–mental health programs.

The demographic characteristics of age and sex seem to influence the use of web-based depression prevention resources. Web-based mental health programs are also less likely to be perceived as helpful by older populations [11]. Women and men favor different web-based mental health program designs and content [12], making it difficult to develop an inclusive program. In existing studies, the barriers associated with accessing web-based mental health programs include stigma, concerns regarding privacy, lack of time, impersonal nature, and a lack of perceived knowledge and confidence about web-based programs [11,13,14].

Objectives

Although studies to date offer some insight into this topic, there are limited studies on the aversion to using web-based programs and examining other concerns or dangers that limit their use. The aims of this study are to (1) understand the barriers to using web-based mental health programs for the prevention of depression and (2) explore any possible dangers or concerns regarding the use of such programs.

Methods

Design

This qualitative study was embedded in two RCTs that each examined a different web-based program to prevent mental illness (BroHealth and HardHat, as described below). This project was approved by the research ethics board of the Royal Mental Health Centre in Ottawa, Canada.

BroHealth

BroHealth is a web-based program that was evaluated in the BroMatters RCT. It aims to reduce the risk of depression among working men at high risk of having an MDE. Details of the BroMatters RCT can be found in a previous publication [15]. The development of BroHealth was informed by the results of a national survey in the target population about the preferences of men classified as high risk for the design features of e–mental health programs [11]. The development was guided by a committee of research team members with expertise in psychiatry, epidemiology, eHealth, occupational psychology, addiction, information technology, and software programming. BroHealth includes modules on workplace depression, mental health information, and self-assessment tools. BroHealth is also linked to a UK-based CBT program, *Living Life to the Full*. Before finalization, BroHealth was pilot-tested among team members, stakeholder advisory committee members, and members of the general public recruited through personal networks and social media.

The participants in the BroMatters study were recruited using random digit dialing across Canada. These participants were working men at high risk of having an MDE. Their risk was calculated using a multivariable risk prediction (MVRP) algorithm, which is used to estimate the chances of developing depression in the next 4 years [16]. The participants were randomly assigned to 1 of 3 groups: group 1 had access to the BroHealth web-based program (intervention group 1), group 2 had access to both BroHealth and a coach (intervention group 2), and group 3 had no access to either the program or the coach but had access to general depression information on the BroMatters website (control group). The BroHealth program consists of self-checks, self-help modules, general depression information, and goal-setting materials. The participants in intervention group 2 could schedule optional telephone sessions with a coach once per week. Reminders were sent every other week through email to prompt program use in the intervention groups. The participants were interviewed at baseline, 6 months, and 12 months, and they were given a monetary incentive (Can $25 [US $20] gift card) to complete each interview.

HardHat

HardHat is an enhancement of BroHealth, targeting both men and women in the workplace. It encompasses enhanced visual design, depression information, self-assessment tools, and nine work-focused CBT and problem-solving therapy (PST) sessions designed by a psychiatrist with expertise in CBT and PST. Each session includes a 5-minute video recorded by professional voice actors in both English and French, in addition to in-class and/or homework assignments. Users are required to submit assignments for review and approval by a coach before moving on to the next session. Before finalization, HardHat was pilot-tested among 12 potential users from the community and revised based on feedback.

The target population of the HardHat RCT was working men and women who were at high risk of having an MDE but were not currently experiencing one. The risk of MDE was calculated using the same sex-specific MVRP algorithms [16] as the one used in the BroMatters RCT. The participants in the HardHat study were recruited through Green Shield Canada (GSC). A link was posted on the GSC website, and people were invited to complete an eligibility questionnaire. The eligible participants were randomly assigned to the intervention group (access to the HardHat program, including a coach) or a waitlisted control group that did not have access until after the final follow-up interview. The HardHat program includes five compulsory sessions and four supplementary sessions. The sessions are based on the principles of CBT and PST and are designed to help participants work through the problems that cause them stress. Each participant was assigned a coach who was available through the chat function to assist them throughout the program and answer any questions. To encourage the use of the program, emails were sent every other week as a reminder. As in the BroMatters study, each participant completed three structured interviews and was given a Can $25 (US $20) gift card at the end of each interview. The HardHat participants were also given incentives to complete the program's sessions, unlike those who participated in the BroMatters study. To complete each session, the HardHat participants were given 100 GSC points and were included in a monthly draw to win a Can $100 (US $80) Amazon gift card.

Participant Recruitment for Qualitative Study

Originally, the qualitative interviews were only planned to be conducted after the completion of the BroMatters RCT; however, because of low use throughout the duration of both RCTs, an additional round of interviews was conducted to investigate the reasons for the low use. The participants for this qualitative study were randomly selected from the intervention groups (ie, those given access to BroHealth or HardHat). A total of 3 different groups were recruited from the 3 different sample sets. Group 1 consisted of participants from the BroMatters RCT who had little or no use of BroHealth (maximum of one log-in). The interviews were conducted 1 month after the RCT began. Participants were randomly selected and interviewed until 41 participants were reached and code saturation was reached within these interviews. Group 2 was recruited after the BroMatters RCT was completed. Overall, 20 of these participants were randomly selected from either of the intervention groups and interviewed, and code saturation was reached within these interviews. The total population size for groups 1 and 2 was 744 individuals; thus, our use of 61 participants for qualitative data collection represents 8.2% (61/744) of the total population of participants in the BroMatters source study. Group 3 was recruited from the HardHat RCT 1 month after the study began; this study had a total of 103 participants to sample from. The participants were randomly selected if they had a maximum of one log-in, and they were interviewed until code saturation was reached. To maintain the homogeneity of the study sample for this analysis, we included nine interviews conducted with male participants from the HardHat trial, representing 8.7% (9/103) of the HardHat population.

Data Collection

The semistructured interview guides were designed by the team members; different interview guides were used for each group, but the questions included similar topics. The questions focused on the lack of program use, motivations, and program perception. The qualitative interview guides are included in Multimedia Appendix 1. The telephone interviews were conducted in English or French by research staff not involved in the RCT data collection. The average length of the interviews was 9 minutes. All interviews were audio recorded and transcribed verbatim by the members of the research team.

Sample Size Justification

The principle of data saturation was used to determine the sample size for this qualitative study. Data saturation allows for a complete picture to be formed about participant perceptions on the topic. For this study, data saturation was defined as *the point where no novel information relevant to the topic is being gathered in the interviews*. To ensure that the sample would reach data saturation, the study by Sim et al [17] was drawn upon to determine appropriate sample sizes. They inferred that many qualitative research projects reach data saturation with between 10 and 40 participants. A rough sample size of 41 was chosen for the first set of qualitative interviews (group 1: BroMatters low use); once the 41 interviews were completed, it was realized that saturation occurred well before the final interview. Therefore, a sample size of 20 participants was chosen for groups 2 and 3; in both cases, saturation was reached within these interviews.

Data Analysis

Inductive content analysis was conducted using NVivo version 12 (QSR International) [18,19]. Content analysis has been effectively used in various mental health research studies to understand perceptions of symptoms and treatment interventions [20]. The second author (MN) read several of the transcripts and identified key findings that were of interest, after which the first author (HE) read all transcripts multiple times to become familiar with the data. Subsequently, HE performed open coding to identify themes in the data, and short phrases (ie, codes) were developed to represent each theme. Next, HE amalgamated the codes into broader categories to develop a coding framework. The codes did not need to be reported in a set number of interviews to be included in the framework because of the

semistructured nature of the interviews; interviews that follow a semistructured design may vary from participant to participant, and unique questions may arise that may not have been part of the broad interview guide. Next, a third researcher assessed the coding framework to ensure that it fully represented the interview themes. At this point, the authors noted that the categories fell into two very general groups and were therefore categorized one more time. Subsequently, the transcripts were recoded by HE using the final framework. Finally, the coding framework prepared by HE was compared with a preliminary analysis performed by MN for consistencies.

Results

Overview

A total of 70 participants completed the semistructured telephone interviews—61 and 9 participants from the BroMatters and HardHat RCTs, respectively. The demographic characteristics of each group are presented in Table 1. Although the population sizes for each program were very different, the demographics were very similar. The average ages of the participants in the HardHat, BroMatters low use, and BroMatters post-RCT studies were 43.0, 39.5, and 42.7 years, respectively, and most participants in all these studies resided in Ontario. The average program use, measured in terms of log-ins, of all participants in the BroMatters study was 1.75 log-ins; similarly, most HardHat participants did not complete the program. Furthermore, the average depression risk scores calculated by using the MVRP algorithms were 32.3 and 19.8 in HardHat and BroMatters, respectively.

A total of 6 barriers to using web-based mental health programs were described. These six barriers were categorized as personal-level barriers that revolved around the personality of the user and program-level barriers that were specific to the web-based program itself. The personal-level barriers included lack of time, level of stress, and disbelief in prevention, whereas the program-level barriers included content complexity and redundancy, program functionality, and perceived dangers (Textbox 1).

Table 1. Demographics for the participants in the different participant groups (N=70).

Demographics	All participants (N=70)	BroMatters low use (n=41)	BroMatters after RCT[a] (n=20)	HardHat, (n=9)
Age (years), mean (range)	40.6 (20-67)	39.5 (20-63)	42.7 (27-66)	43.0 (22-67)
Location, n (%)				
British Columbia	12 (17)	7 (17)	3 (15)	2 (22)
Alberta	8 (11)	5 (12)	3 (15)	0 (0)
Saskatchewan	4 (6)	3 (7)	1 (5)	0 (0)
Manitoba	1 (1)	1 (2)	0 (0)	0 (0)
Ontario	35 (50)	21 (51)	7 (35)	7 (78)
Quebec	5 (7)	1 (2)	4 (20)	0 (0)
New Brunswick	1 (1)	0 (0)	1 (5)	0 (0)
Nova Scotia	4 (6)	3 (7)	1 (5)	0 (0)
Depression risk score (%), mean (range)	23.1 (7-84)	19.2 (7-84)	20.4 (7-84)	32.3 (22-67)
Number of log-ins, mean (range)	—[b]	1.2 (0-11)	2.3 (1-8)	—
Completer, n (%)				
Complete	—	—	—	2 (22)
Partially	—	—	—	3 (33)
Not started	—	—	—	4 (44)

[a]RCT: randomized controlled trial.

[b]Not available.

Textbox 1. Summarization of resulting categories.

Personal barriers

- Lack of time
  - Life is busy.
  - People do not prioritize stress prevention.
- Level of stress
  - Too little stress, and people do not think they need it
  - Too much stress, and people cannot find the time and motivation
- Disbelief in prevention
  - Stigma
  - People do not focus on depression.

Program barriers

- Content complexity and redundancy
  - Text heavy
  - People do not like activities in program
  - Redundant information
- Program functionality
  - Disorganized flow
  - Broken links
  - Internet as a medium
- Perceived dangers
  - Privacy
  - Using it as a treatment instead of seeking help

Personal Barrier

Lack of Time

Most participants reported a lack of time or an inability to prioritize use as the largest barrier to program use. For instance, one participant said the following:

> *...it's in my list of things to get to but life is like super busy, I have a young kid and a newish job and so it's there, but I haven't gotten to it.* [BroMatters low use; age: 42 years]

Prioritizing other aspects of their lives often caused the participants to forget about the program entirely. A participant commented as follows:

> *...I keep forgetting. It's in the pile of things to do and I keep forgetting to go back and look at it again.* [BroMatters low use; age: 51 years]

Level of Stress

The level of participant stress, both high and low, emerged as a barrier to program use. Some participants neglected to use the web-based programs because they believed that they did not need to use it:

> *I didn't really need anything because work's going pretty well.* [BroMatters low use; age: 32 years]

Others managed their stress well using other support, including therapy, medication, and self-management strategies. For instance, one participant mentioned not using the program:

> *...because I currently have a psychologist...and I've been meeting with that doctor on a regular basis.* [BroMatters low use; age: 36 years]

The participants may also have been disinclined to use the program because they were struggling to manage their mental health; hence, they felt overwhelmed and unable to avail themselves of the web-based program. For instance, one participant said the following:

> *...over the past month...my mental state of mind has deteriorated. I just got no determination or willpower to do anything.* [HardHat; age: 55 years]

These participants were often overwhelmed by the content when they tried to use the programs. One participant explained as follows:

> *I was already pretty stressed out and a little overwhelmed and had high levels of anxiety as a*

> *result, and so when I got to the website and saw the information that there was, I had to like pull back because it was too much.* [BroMatters post-RCT; age: 42 years]

Disbelief in Prevention

In multiple cases, participants were skeptical as to whether anyone would use the program as a preventive measure before developing symptoms of depression:

> *I don't think people are going to use the resource before they have depression...people don't turn to something until they have it.* [BroMatters low use; age: 36 years]

Program use as a preventive measure was also hindered by the stigma associated with getting mental health help. One participant stated:

> *There's some stigma attached to the whole idea of not being mentally well, so I think it's something that people like to keep private.* [BroMatters low use; age: 43 years]

Program Barrier

Content Complexity or Redundancy

Content that is difficult to digest or redundant when considering the information available elsewhere is a barrier to program use. Some participants felt that the programs were too text heavy, thus deterring participation and causing them to lose interest in the program. One participant remarked the following:

> *I think what it comes down to is the amount of reading. If there is a lot of reading, it's just kind of a put off.* [BroMatters post-RCT; age: 47 years]

Some participants felt that the modules were too long to complete in one sitting, and they neglected to either start the modules or return to complete them. In addition, some participants found the program content to be redundant when considering other resources that they had access to elsewhere, leading to the limited use of the programs. One participant explained this as follows:

> *...after a half a dozen times I found that the content was redundant with what I had already gotten from my healthcare provider.* [BroMatters post-RCT; age: 37 years]

For some participants, the types of activities did not align well with their preferences. For example, one participant said the following:

> *I'm not the type of person to divide a problem up into six component pieces.... My personality is a type where I don't care about how many different parts of the problem there are.* [HardHat; age: 67 years]

Functionality

Another topic discussed by the participants was how the program functioned. Functionality issues such as broken links and disorganized flow discouraged the use of the programs. When the participants had difficulty using the program, they felt discouraged and were less likely to return to it. The internet itself was also perceived to be problematic as a medium for the delivery of mental health prevention resources. Some participants did not like using the internet at all or did not use it often enough. Many participants also had an aversion to using the internet as a resource for mental health prevention. For instance, one participant said the following: "When you're stressed out or something like that, last thing you want to do is go on your phone and tell your phone how stressed you are." [BroMatters post-RCT; age: 47 years].

Perceived Dangers

Overall, very few participants reported concerns about personal dangers or negative impacts of web-based mental health programs. A few of the participants voiced concerns about privacy. For example, one participant described how navigating contemporary times that are pervaded by telephone and email scams leaves them skeptical about the legitimacy of certain websites. For instance, a participant commented as follows: "...there's so many traps for an old man to fall into" (BroMatters low use; age: 63 years). Furthermore, he provided additional context: "...99% of these emails and phone calls and people at my door are scammers wanting money" (BroMatters low use; age: 63 years). In addition, the programs' focus on personal mental health left some participants concerned about privacy:

> *I'm a very private person and so the fact that I opened up as much as I did in the first call kind of concerned me, and so I'm hesitant just to spill my guts when I don't really know who it is I'm talking to.* [BroMatters low use; age: 48 years]

The other danger that the participants conveyed was the possibility that individuals with severe symptoms may use the program at the expense of specialized treatment and thus may not receive the care that they need. One participant explained this as follows:

> *...if somebody would try to use this to replace seeking other help or talking to someone else about their issues.* [BroMatters post-RCT; age: 46 years]

Group Differences

Most categories were consistent across the interview groups and programs. However, the participants who were interviewed only 1 month after the RCT started (both BroMatters and HardHat) reported *time* as the biggest barrier to program use, whereas the participants who had completed more of the program and who were interviewed after the RCT (BroMatters only) was completed stated that *need* was the biggest barrier. Moreover, the BroMatters participants had greater difficulty with program functionality and flow than the HardHat participants, which was in part due to the fact that the CBT program (*Living Life to the Full*) in the BroHealth program was externally linked. The challenges identified by the HardHat participants focused more on not receiving emails and not understanding how to access the site.

Discussion

Principal Findings

This study found that barriers to program use exist at both personal and program levels. Personal-level barriers affected initial use of the program. Many participants did not prioritize their mental health, citing that time constraints or a busy lifestyle did not allow them the time to use the program. This led many participants to believe that depression cannot be prevented. Although all participants in the study had a high risk of MDE, some did not believe that they had a stressful life and therefore did not believe that they needed to use the program. The barrier of continued use was discussed when the program itself was up for discussion. Content had a large effect on continued use. When content was perceived as redundant or not applicable to the participants, they discontinued use. Similarly, if program use caused frustration because of technical problems or the participants' dislike of the internet as a medium, they were less likely to use the programs. Some participants were also concerned about the possibility of privacy breaches resulting from program use.

The results of our study are consistent with previous research in terms of personal and program-level barriers (lack of time, stress, content and medium, and privacy concerns) [21-23]. One important difference between our study and previous research is that BroHealth and HardHat were designed for prevention purposes (rather than treatment), and there are limited studies on the lack of interest in preventing depression as a barrier to program use. This is an important finding that highlights a significant gap in the current knowledge of web-based mental health programs for preventing depression.

The design and development of BroHealth and HardHat were informed by a large national survey and several rounds of usability testing. Nevertheless, the use of these programs was not optimal. This qualitative study uncovered several barriers to web-based program use and has significant implications for mental health. Lack of time and perceived stress are the main personal barriers. It should be noted that the RCTs evaluating these two web-based programs were conducted from 2017 to 2019. The reported barriers reflect how potential users perceived web-based mental health programs during that time. Such barriers may be different in the context of COVID-19 with the closure of in-person health services [24]; implementation of web-based health services [25-27]; physical distancing; isolation; and widely reported feelings of loneliness, depression, and anxiety [28] due to these public health measures. The COVID-19 crisis and public health restrictions could accelerate the use of mobile and digital health [29]. Therefore, studies on this topic, both during the pandemic and in the postpandemic era, are needed. BroHealth functionality and technological problems were related to an external link to a CBT program. Such a linkage should be avoided in future web-based programs or apps because technical issues may occur in unpredictable ways. Other program functionality issues were also evident, highlighting the importance of a user-friendly design and interface. In addition, many HardHat participants did not receive the reminder emails that were sent, thus limiting their effectiveness [8]. The qualitative results also shed light on the importance of program personalization and balancing text and video and audio content, and these findings should be taken into consideration in the design of future digital mental health programs. Adapting web-based mental health programs into web-based or mobile app personal informatics (PI) systems has the potential to mitigate some barriers to program use. PI systems, which collect and store personal data that can be accessed by users for a number of purposes, would improve the need for program personalization. PI systems can be websites and mobile apps that can be seamlessly integrated into daily life, thus improving engagement. One salient example of the positive effects of PI systems is activity trackers that users can use to monitor their activity level, set goals, and monitor progress; such trackers have been shown to improve physical activity among users [30].

Many participants believed that depression cannot be prevented. This mistaken view leads to a reluctance to use programs aimed at prevention, including web-based mental health programs. This finding is echoed in previous studies [11,31-33]. People who believe that depression cannot be prevented tend to prioritize other activities over their mental health, perhaps because of the lack of emphasis that society places on mental health and social norms related to the male sex. To mitigate barriers to program use, program modifications alone are not sufficient; a shift toward depression being perceived as a preventable illness is imperative, especially among men. Important steps would be for society to prioritize mental health alongside physical health, raise awareness about mental health, increase mental health literacy, and develop effective depression-risk communication. Such population-level mental health education and promotion efforts may improve societal acceptance of the notion of prevention so that maintaining good mental health would become a more mainstream and socially acceptable priority. For example, the historic change in how breast cancer prevention has progressed from a private issue to a widely promoted public health goal could be considered a relevant precedent. This study contributes to the first step by identifying depression as a continuing problem in the mental health field. Regardless of the effort put into identifying motivators and effective programs, for people to choose to partake in such programs, mental health must be made a top priority in society. Increased focus on mental health at all levels of government and at workplaces is a good first step to increase the perceived importance of mental health. An increase in government resources allocated to digital mental health care and preventive services on the web in conjunction with the application of artificial intelligence technologies could improve the promotion of mental health and better adaptation. As people spend many hours at work every day, workplaces are an ideal environment to promote positive mental health and implement digital preventive mental health programs.

Limitations

This study includes some limitations. First, some participants were interviewed a number of months after having used the program. As such, for some, recalling the program details was difficult. In addition, because demographic data were not collected, the results of this study cannot be extrapolated to

larger populations. Furthermore, the barriers described in this study were specific to the BroHealth and HardHat programs; therefore, the barriers in this study, such as functionality, reminders, and content, cannot be generalized to other programs.

Conclusions

Although the use of web-based mental health programs to decrease the prevalence and incidence of depression has been shown quantitatively to be effective, there are barriers to their use. Barriers such as time and the perception of depression prevention need to be changed at the population level. Increasing the perceived importance and priority of depression prevention is likely to mitigate these barriers; therefore, research into these areas is imperative. Having easy-to-use programs with minimal text may improve engagement with web-based mental health programs, especially among those who may have had difficulty with previous attempts to use such programs.

Acknowledgments

This study was supported by a grant from the Movember Foundation. The funder played no role in the study design and interpretation of the results.

Authors' Contributions

All authors contributed to the study design, data interpretation, and the review and final approval of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Qualitative interview guides.
[DOCX File , 21 KB - formative_v5i7e16949_app1.docx]

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Abbreviations

CBT: cognitive behavioral therapy
GSC: Green Shield Canada
MDE: major depressive episode
MVRP: multivariable risk prediction
PI: personal informatics
PST: problem-solving therapy
RCT: randomized controlled trial

Edited by G Eysenbach; submitted 07.11.19; peer-reviewed by E Montague, C Stiles-Shields; comments to author 26.10.20; revised version received 09.12.20; accepted 19.05.21; published 15.07.21.

Please cite as:
Eccles H, Nannarone M, Lashewicz B, Attridge M, Marchand A, Aiken A, Ho K, Wang J
Barriers to the Use of Web-Based Mental Health Programs for Preventing Depression: Qualitative Study
JMIR Form Res 2021;5(7):e16949
URL: https://formative.jmir.org/2021/7/e16949
doi:10.2196/16949
PMID:34264195

Original Paper

Using Social Media for the Prevention of Pediatric Burn Injuries: Pilot Design and Usability Study

Nikita Batra[1], BS; Cindy D Colson[1], MSN, RN; Emily C Alberto[1], MD; Randall S Burd[1], MD, PhD

Children's National Hospital, Washington, DC, United States

Corresponding Author:
Randall S Burd, MD, PhD
Children's National Hospital
111 Michigan Ave NW
Washington, DC, 20010
United States
Phone: 1 202 476 2151
Fax: 1 202 476 6704
Email: rburd@cnmc.org

Abstract

Background: Most pediatric burn injuries are preventable. Social media is an effective method for delivering large-scale messaging and may be useful for injury prevention in this domain.

Objective: This study evaluates the feasibility of creating a social media campaign for pediatric burn injury prevention.

Methods: Ad spots containing a headline, short introduction, and video were created and posted on Facebook and Instagram over 4 months. Ad spots were targeted to parents and caregivers of children in our region with the highest number of burn injuries. We assessed the impact of each ad set using ThruPlays, reach, and video plays.

Results: We created 55 ad spots, with an average length of 24.1 (range 10-44) seconds. We reached 26,496 people during the campaign. The total ThruPlays of the 55 ad spots were 14,460 at US $0.19 per ThruPlay. Ad spots related to home safety had a significantly higher daily ThruPlay rate than those related to fire safety (6.5 vs 0.5 per day; $P<.001$).

Conclusions: Social media is a feasible modality for delivering public health messages focused on preventing pediatric burn injuries. Engagement with these ads is influenced by ad presentation and the focus of the underlying injury prevention message.

(JMIR Form Res 2021;5(7):e23242) doi:10.2196/23242

KEYWORDS

accident prevention; burns; pediatric; public health; social media

Introduction

Burns are a leading cause of injury among children 5 years old and younger in the United States. Approximately 50,000 children were treated in the emergency department for unintentional burns in 2018 [1]. Among all etiologies, scald burns are the most common type sustained by children. Most scald burns are related to spills or contact with hot food, beverages, or tap water, making the kitchen and the bathroom common locations for these injuries in the home [2]. Although most pediatric burns are minor and can be managed in an outpatient setting, children with severe burns require acute and long-term management at a pediatric burn center [3,4]. The medical cost of pediatric burn–related hospitalizations was close to $150 million in 2010 [5]. In addition to the associated cost, burn injuries can cause significant psychological burdens on patients and their families [6]. Because pediatric burn injuries are mostly preventable, outreach programs have successfully increased parental knowledge of possible dangers and reduced hospitalization rates of burn injuries in children [7,8].

Mass media campaigns that use radio, television, newspapers, and the internet have successfully encouraged behaviors that reduce sports-related injuries and injuries from motor vehicle crashes [9]. Social media has emerged as a new platform for health promotion in many areas, including smoking cessation, exercise, and diet [10-12]. In addition to reaching large numbers of people, social media supports information sharing by users, further amplifying its impact. Social media may be more influential than traditional media campaigns because of the interaction between users and the produced content [13,14]. Although utilizing social media for injury prevention is

relatively new, initial experience suggests that this approach is feasible and effective for delivering this type of message [15,16].

To address the burden of pediatric burn injuries in our region, we collaborated with a creative marketing company to create a social media advertising campaign targeted at the caregivers of children in our area. This study aimed to assess the feasibility of and potential factors for determining the success of a social media campaign for pediatric burn injuries.

Methods

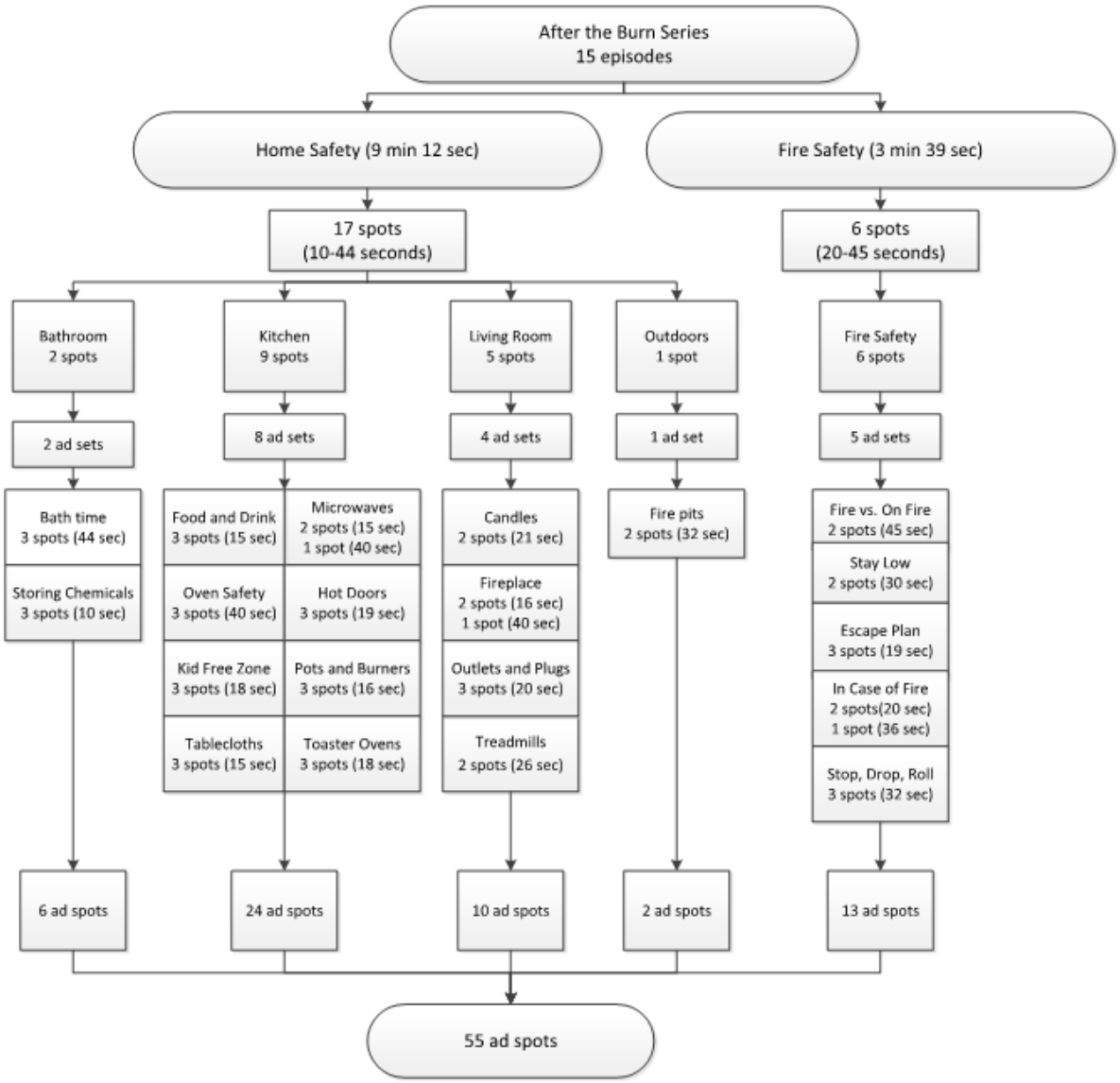
Overview

Children's National Hospital is a regional pediatric burn center designated by the Maryland Institute for Emergency Medical Services Systems that treats more than 850 burn patients annually in both inpatient and outpatient settings. In 2018, we created the "After the Burn" series to provide burn prevention education and information on treatment and recovery following a pediatric burn injury. The video content was generated from over 35 interdisciplinary interviews conducted at our institution and has been available on YouTube since October 2018 [17]. The video series contains 15 episodes, with 2 focusing on burn injury prevention, 12 on the care of the burned child from injury through recovery, and 1 spotlighting the collaboration between our organization and the District of Columbia Firefighter's Burn Foundation.

To deliver pediatric burn injury prevention information to a larger audience within our community, we collaborated with Getfused, a creative marketing company from Boston, MA. They generated a burn prevention ad campaign using the two burn injury prevention episodes from the "After the Burn" series [17]. This collaboration enabled us to achieve our goal of distributing content to the prespecified target audience. At Children's National Hospital, the injury prevention coordinator was responsible for content approval and worked with the Getfused team in preparing and optimizing the ad campaign content. Getfused segmented the "home safety" (runtime: 9 minutes 12 seconds) and "fire safety" (runtime: 3 minutes 39 seconds) videos into spots (ie, short clips from the full-length episode) based on the different locations and mechanisms of burn injuries that could be sustained in the home (Figure 1) [18,19]. The "home safety" episode was divided into 17 spots that included 4 locations where injuries could occur (bathroom, kitchen, living room, and outdoors) [18]. The "fire safety" episode was segmented into 6 spots based on the different actions one must take during a fire [19]. The spots in each category were used to create 20 ad sets. Each spot (10-45 seconds) was combined with a headline and a short introductory text (less than 55 words) to create unique ad spots. Ad sets contained 2 to 3 versions of an ad spot. For most ad sets, the versions included the same spot with either a different headline, introduction, or both. For 3 ad sets (ie, "in case of fire," "microwaves," and "fireplace"), the versions had different spots of varying lengths.

The resulting ad spots were formatted for distribution on Facebook's news and video feeds and Instagram's feeds and explore pages. Demographic targeting was used to direct the ad sets to parents with a child younger than 18 years of age or household managers or nannies in the District of Columbia who were aged between 24 and 44 years. We ran this campaign on Facebook and Instagram from September 2019 until December 2019.

Figure 1. Ad set distributions.



Outcome Assessment

We assessed the impact of each ad set using metrics from Facebook Business Manager, including ThruPlays, reach, and video plays. Based on the definition from Facebook, a ThruPlay is the number of times a spot is played to completion or for at least 15 seconds. For spots longer than 15 seconds, a ThruPlay is counted when at least 15 unique seconds of the spot are played. If the spot is shorter than 15 seconds, a ThruPlay is counted when the spot is played to completion [20]. Reach is defined as the number of people who saw an ad spot at least once on their social media feed during a campaign [21]. Reach is not counted when an ad spot is viewed more than once by the same person. A video play is defined as the number of times a spot starts to play, excluding replays (ie, when a spot is paused and then started again). A video play can occur when a spot plays automatically or when a spot is clicked on to play [20]. We grouped video plays into categories based on the percentage of the spot length (25%, 50%, and 100%) played, including plays that skipped to parts of the videos within these percentages of play [20]. Cost per result is a metric used for ad campaigns that report the amount spent per result, where the result is defined based on the objective of the campaign [21]. For this study, we used ThruPlays because they best reflect the attention focused on the intended video messaging.

We used aggregate data from Facebook and Instagram for our analyses. Aided by these performance metrics, Getfused team members modified the ad campaign biweekly to generate the highest possible engagement within the target audience. The injury prevention coordinator from Children's National Hospital received bi-weekly updates on campaign statistics and provided input during each change. Changes included modification of ad spot headlines or introductions within an ad set. Ad spot versions were removed from the campaign when performance indicators showed limited views. The runtime reflects the average number of days that an ad spot version in an ad set was run. Performance metrics were averaged among different versions of the ad spot within each ad set. We also summed the performance metrics

across all ad spots to generate the overall campaign performance. We conducted comparisons between ThruPlay rates using the Poisson exact test that evaluates the null hypothesis about the difference between rates. Ad spots derived from the "home safety" episode were compared to ad spots derived from the "fire safety" episode. Among ad spots derived from the "home safety" episode, those in the "kitchen" category were compared to all other ad spots. We made this comparison because most pediatric burn injuries at home occur in the kitchen [22,23]. The "storing chemicals" ad set was the only ad set that included ad spots less than 15 seconds. Because a ThruPlay is counted when ad spots less than 15 seconds long are played to completion, we evaluated daily ThruPlay rates with and without the inclusion of this ad set to assess the impact of short duration videos on rate differences. A multiple linear regression was performed to evaluate the association of ad spot category with ThruPlay rate, controlling for video duration. We defined significance at $P<.05$.

Results

We created 55 ad spots, with an average length of 24.1 (range 10-44) seconds. The runtime of the ad spots averaged 44.7 (range 3-109) days (Table 1). We reached 26,496 unique people during the campaign. These individuals collectively executed 14,460 ThruPlays of the 55 ad spots (average 239 ThruPlays per ad spot). The "storing chemicals" ad set had the highest average of ThruPlays (36.1 per day). Among ad sets with durations longer than 15 seconds, the "oven safety" ad set had the highest average of ThruPlays (7.3 per day), while the "candles" ad set had the lowest average of ThruPlays (0.1 per day). Our advertising budget for the campaign was US $2750, which translated to US $0.19 per ThruPlay based on the number of individuals reached (cost per result). The costs of content preparation, development of a campaign strategy, and campaign optimization were separately funded.

Ad spots derived from the "home safety" episode had a higher daily ThruPlay rate than ad spots derived from the "fire safety" episode (6.5 vs 0.5 per day; $P<.001$). The difference between these groups remained significant when the "storing chemicals" ad set was excluded (2.5 vs 0.5 per day; $P<.001$). Among all the ad spots derived from the "home safety" episode, ad spots in the "kitchen" category had a lower ThruPlay rate than other ad sets (3.4 vs 10.6 per day; $P<.001$). When the "storing chemicals" (short duration) ad set was excluded, this difference was reversed. ad spots in the "kitchen" category had a higher daily ThruPlay rate than other ad spots (3.4 vs 1.1 per day; $P<.001$).

Among ad spots that included videos longer than 15 seconds (ie, excluding "storing chemicals" ad spots), the "home safety" episodes had a higher ThruPlay rate than "fire safety" episodes (an increase of 1.8 ThruPlays per day; $P=.02$), controlling for the duration of the video. The total video plays of the 55 ad spots were 293,109. Although only 4.1% (n=12,090) of initiated views were played to completion, 24.2% (n=27,178) of initiated watches were played for more than 50% (range 5-22.5 seconds) of the video length. Consistent with its short length, the "storing chemicals" ad set had the most video plays to completion per day (35 video plays per day; Table 2).

Observational analysis, obtained during ad modifications by Getfused, showed two features of the ad spot that improved performance: (1) introductory text with specific objects that caused burns rather than the general locations where burns occurred, and (2) headlines starting with the word "prevent" or the specific household item that could cause burns. Examples of headlines in these two categories include "chemicals can cause burn risks to your child" and "prevent chemical burns from happening to your child," respectively.

Table 1. Ad set summaries.

Ad sets	Runtime (days), average	Reach (people per day), average	ThruPlays (views per day), average
Home safety: bathroom			
Bath time	56	30	2
Storing chemicals	67	144	36
Home safety: kitchen			
Food and drinks	30	35	3
Microwaves (15 sec[a])	49	39	3
Microwaves (40 sec)	3	2	0
Oven safety	56	64	7
Hot doors	55	48	3
Kid free zones	51	70	5
Pots and burners	55	22	1
Tablecloths	45	27	2
Toaster ovens	50	34	2
Home safety: living room			
Candles	27	4	0
Fireplaces (16 sec)	42	16	1
Fireplaces (40 sec)	55	12	1
Outlets and plugs	38	11	1
Treadmills	55	17	1
Home safety: outdoors			
Firepits	42	28	2
Fire safety			
Escape plan	32	8	0
Fire vs. on fire	54	16	1
In case of fire (20 sec)	17	10	0
In case of fire (36 sec)	11	7	0
Stay low and go	54	11	0
Stop, drop and roll	40	9	0

[a]sec: seconds

Table 2. Ad set video plays.

Ad Sets	Video plays at 25% (plays per day), average	Video plays at 50% (plays per day), average	Video plays at 100% (plays per day), average	Total video plays (plays per day), average
Home safety: bathroom				
Bath time	2	1	1	38
Storing chemicals	167	83	35	712
Home safety: kitchen				
Food and drinks	7	4	2	42
Microwaves (15 sec[a])	7	4	2	51
Microwaves (40 sec)	0	0	0	2
Oven safety	19	10	5	151
Hot doors	7	4	2	62
Kid free zones	14	7	3	97
Pots and burners	4	2	1	26
Tablecloths	5	3	1	34
Toaster ovens	5	3	2	38
Home safety: living room				
Candles	0	0	0	4
Fireplaces (16 sec)	2	1	1	17
Fireplaces (40 sec)	1	1	0	14
Outlets and plugs	1	1	1	13
Treadmills	2	1	0	19
Home safety: outdoors				
Firepits	3	1	1	35
Fire safety				
Escape plan	1	1	0	7
Fire vs. on fire	1	0	0	17
In case of fire (20 sec)	1	1	0	10
In case of fire (36 sec)	0	0	0	6
Stay low and go	1	0	0	10
Stop, drop and roll	0	0	0	10

[a]sec: seconds

Discussion

Principal Results and Comparison With Prior Work

Social media has grown in popularity over the last decade, with Facebook reporting more than 1.4 billion daily adult users and Instagram more than 500 million daily users [24,25]. Given the number of people using social media, organizations interested in health care promotion have evaluated this modality to encourage healthy behaviors. Examples of health promotion campaigns using social media include those that promote smoking cessation, diabetes management, and obesity prevention [26-28].

Although social media may have a similar value in injury prevention, few studies have evaluated its use in this domain. For instance, an Instagram account posting messages promoting adolescent seat belt use over 3 months was introduced at a high school health fair. Using "likes" as a metric of a successful campaign, posts presented positively or those involving celebrities or humor received the most attention [15]. In another study, Facebook advertising was used to disseminate information about fall prevention in an elderly population, reaching more than 140,000 people in British Columbia, Canada. Among the people the ad reached, 3% engaged with the content through link clicks, reactions, comments, and shares [29]. These studies show the feasibility of a social media injury prevention campaign and initial evidence of its potential impact [15,29].

The use of video advertising contributed to the success of our campaign. Before designing the campaign, the "After the Burn" series was created to provide clear and detailed explanations of

each step in the recovery process following a pediatric burn injury. The goal of this video series was to decrease parental stress, improve the quality of life for the child, and improve postinjury medical outcomes [17]. We posted these on YouTube, allowing access to individuals in the general population who might be seeking burn injury prevention information online. We also directed hospitalized patients with burn injuries and their parents or guardians to these videos in their discharge instructions. The purpose of this campaign was to expand the reach of the injury prevention videos using social media as a platform for targeting populations in our region.

Traditional television, radio, or print campaigns can often reach large audiences. By targeting specific populations, social media campaigns have an advantage over these traditional campaigns [30]. Specific audience targeting also led to the success of our ad campaign. Our campaign directed content to individuals for whom pediatric burn injury prevention was most relevant: the parents, guardians, and caretakers of children. As a result, the number of individuals reached was significantly higher than would be reached at a typical health fair [31-33]. In addition, the cost per result of the ad campaign was lower than the industry standard of $1 per ThruPlay, supporting the cost efficiency of this campaign. We selected ThruPlays as the outcome metric for our campaign, aligning with our initial objective to promote video play among reached individuals. The use of ThruPlays for this purpose assumes that watching 15 seconds of a video delivers the ad's main message sufficiently. Facebook research supports this assumption, showing that even plays of less than 15 seconds can increase ad recall, brand awareness, and purchase intent [34].

Video length is a factor that can be modified to influence user engagement. In this study, the "storing chemicals" ad set had the highest average ThruPlay rate, consistent with having videos with the shortest duration. According to Facebook video statistics, engagement with video content occurs with a watch duration longer than 10 seconds [35]. Many of the videos in our ad campaign meet this benchmark. However, video duration was not associated with the ThruPlay rate for ad spots longer than 15 seconds. This observation suggests the length of the video, observable in the progress bar, may not discourage individuals from watching for longer durations.

Our observation aligns with evidence that viewer engagement remains constant for videos up to 2 minutes long, after which engagement declines [36]. Although the standardization of video length would allow for the evaluation of the impact of video length on user engagement, the differing content of each ad makes this type of standardization challenging. In future evaluations of the impact of social media campaigns, modifying the standard Facebook definition of a ThruPlay will better assess the impact of video duration on engagement.

Although up to 90% of pediatric burns occur in the home, many parents are unaware of the risks that can lead to burn injuries in this setting [23,37-39]. Parents are also often unaware that pediatric burn injuries in the home occur most often in the kitchen [22,23,40]. After excluding the short duration "storing chemicals" ad set, ad spots in the kitchen category had a higher ThruPlay rate than other ad spots derived from the "home safety" episode. Two factors may account for these differences: (1) interest may be higher for ad spots that are more relevant to everyday life in the home, such as kitchen-related activities, than less frequent fire safety events, and (2) individuals may also have established knowledge on fire safety from previous successful media campaigns, increasing the novelty of the "home safety" ad spots [41-43]. Establishing the reasons for the differences in the ThruPlay rates is needed to optimize the impact of social media campaigns.

Based on an assessment of available ad spot metrics used by Getfused, we observed that modifications in the headlines and introductory text improved ad spot performance for pediatric burn injury prevention. Previous social media campaigns have established the impact of front-end content on ad reach and engagement [15,44]. Modifying front-end factors, such as the introductory text, can increase positive engagement with ads by as much as 2-fold in social media campaigns [15,44]. Several approaches can be used to evaluate the optimal ad spot presentation, including A/B testing, multivariate testing, and multipage testing. Our campaign used video-sharing as its medium because of the content available in this format. Several other advertising media can be used to create ad campaigns, including photo sharing, text sharing, and microblogging.

Limitations

Our study had several limitations. First, although we identified several parameters for optimizing a burn injury prevention campaign using social media, we did not evaluate whether this campaign changed the incidence of burn injuries in our region. This pilot study showed the potential role of a social media campaign for sharing burn injury prevention information and the features that can be modified to optimize its reach. We are developing a follow-up campaign optimized based on this study in which the impact on burn incidence will be measured. Second, although data from our burn database shows that young children are more likely to sustain scald burns, we could not target parents based on the age of their children. As a result, we could not evaluate whether the parents of younger children were more likely to watch the videos. Third, understanding key performance metrics before the campaign launch would have allowed us to obtain more specific reports during the optimization phases. The creative marketing company made several changes in the presentation of the ad spots during predetermined optimization periods using standard industry practices. It is common to use this "on the fly" approach without a defined feedback loop or set evaluation metrics [45]. These changes were made rapidly, precluding objective evaluation of each (eg, headline or introductory text) in this pilot. Finally, we used ThruPlays as the primary metric for viewer engagement. A follow-up social media campaign will include an assessment of which metrics most influence the impact of each ad.

Conclusions

Pediatric burn injuries can have significant long-lasting physical and psychological impacts on patients and their families. Because these injuries are mostly preventable through actions taken by parents and caretakers, increasing awareness of these injuries and the mechanisms will reduce the associated health burden. Although mass media campaigns have reduced the risk

of injury by other means, using social media specifically for this purpose has only recently received attention. Although it is challenging to define benchmarks for success given the many factors related to burn injury in children, our burn prevention campaign exceeded published standards as measured by ThruPlays, total campaign reach, and the cost per result. Successful injury prevention ad campaigns should ideally use video (specifically short videos), use audience targeting, implement predetermined performance metrics, and apply optimization methods to improve performance.

Acknowledgments

We would like to thank Getfused for their commitment to this project and assistance in engaging Children's National Hospital in pediatric burn injury prevention strategies.

Conflicts of Interest

None declared.

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Edited by G Eysenbach; submitted 05.08.20; peer-reviewed by R Thakkar, A Lau; comments to author 03.09.20; revised version received 12.10.20; accepted 17.05.21; published 15.07.21.

Please cite as:
Batra N, Colson CD, Alberto EC, Burd RS
Using Social Media for the Prevention of Pediatric Burn Injuries: Pilot Design and Usability Study
JMIR Form Res 2021;5(7):e23242
URL: https://formative.jmir.org/2021/7/e23242
doi:10.2196/23242
PMID:34264194

Original Paper

Evaluating Simplified Web Interfaces of Risk Models for Clinical Use: Pilot Survey Study

Louis Beaubien[1], PhD; Colin Conrad[2], PhD; Janet Music[2], MA; Sandra Toze[2], PhD

[1]Rowe School of Business, Faculty of Management, Dalhousie University, Halifax, NS, Canada

[2]School of Information Management, Faculty of Management, Dalhousie University, Halifax, NS, Canada

Corresponding Author:
Louis Beaubien, PhD
Rowe School of Business
Faculty of Management
Dalhousie University
Kenneth C Rowe Management Building
6100 University Ave
Halifax, NS, B3H 4R2
Canada
Phone: 1 902 494 7080
Email: louis.beaubien@dal.ca

Abstract

Background: In this pilot study, we investigated sociotechnical factors that affect intention to use a simplified web model to support clinical decision making.

Objective: We investigated factors that are known to affect technology adoption using the unified theory of acceptance and use of technology (UTAUT2) model. The goal was to pilot and test a tool to better support complex clinical assessments.

Methods: Based on the results of a previously published work, we developed a web-based mobile user interface, WebModel, to allow users to work with regression equations and their predictions to evaluate the impact of various characteristics or treatments on key outcomes (eg, survival time) for chronic obstructive pulmonary disease. The WebModel provides a way to combat information overload and more easily compare treatment options. It limits the number of web forms presented to a user to between 1 and 20, rather than the dozens of detailed calculations typically required. The WebModel uses responsive design and can be used on multiple devices. To test the WebModel, we designed a questionnaire to probe the efficacy of the WebModel and assess the usability and usefulness of the system. The study was live for one month, and participants had access to it over that time. The questionnaire was administered online, and data from 674 clinical users who had access to the WebModel were captured. SPSS and R were used for statistical analysis.

Results: The regression model developed from UTAUT2 constructs was a fit. Specifically, five of the seven factors were significant positive coefficients in the regression: performance expectancy (β=.2730; t=7.994; P<.001), effort expectancy (β=.1473; t=3.870; P=.001), facilitating conditions (β=.1644; t=3.849; P<.001), hedonic motivation (β=.2321; t=3.991; P<.001), and habit (β=.2943; t=12.732). Social influence was not a significant factor, while price value had a significant negative influence on intention to use the WebModel.

Conclusions: Our results indicate that multiple influences impact positive response to the system, many of which relate to the efficiency of the interface to provide clear information. Although we found that the price value was a negative factor, it is possible this was due to the removal of health workers from purchasing decisions. Given that this was a pilot test, and that the system was not used in a clinical setting, we could not examine factors related to actual workflow, patient safety, or social influence. This study shows that the concept of a simplified WebModel could be effective and efficient in reducing information overload in complex clinical decision making. We recommend further study to test this in a clinical setting and gather qualitative data from users regarding the value of the tool in practice.

(JMIR Form Res 2021;5(7):e22110) doi:10.2196/22110

KEYWORDS

risk model; electronic records; user interface; technology acceptance

Introduction

Background

Information overload negatively affects the decision effectiveness of clinical medical staff and ultimately impacts patient safety [1-3]. Clinical medical staff who are tasked with assessing patient outcomes are often required to use complex outcome and risk models in a spreadsheet format. In response to this challenge, we developed a mobile web model that simplifies the information presented to clinical medical staff and expedites the decision process. However, new electronic technologies often face barriers to adoption that inhibit their use in clinical settings [4,5].

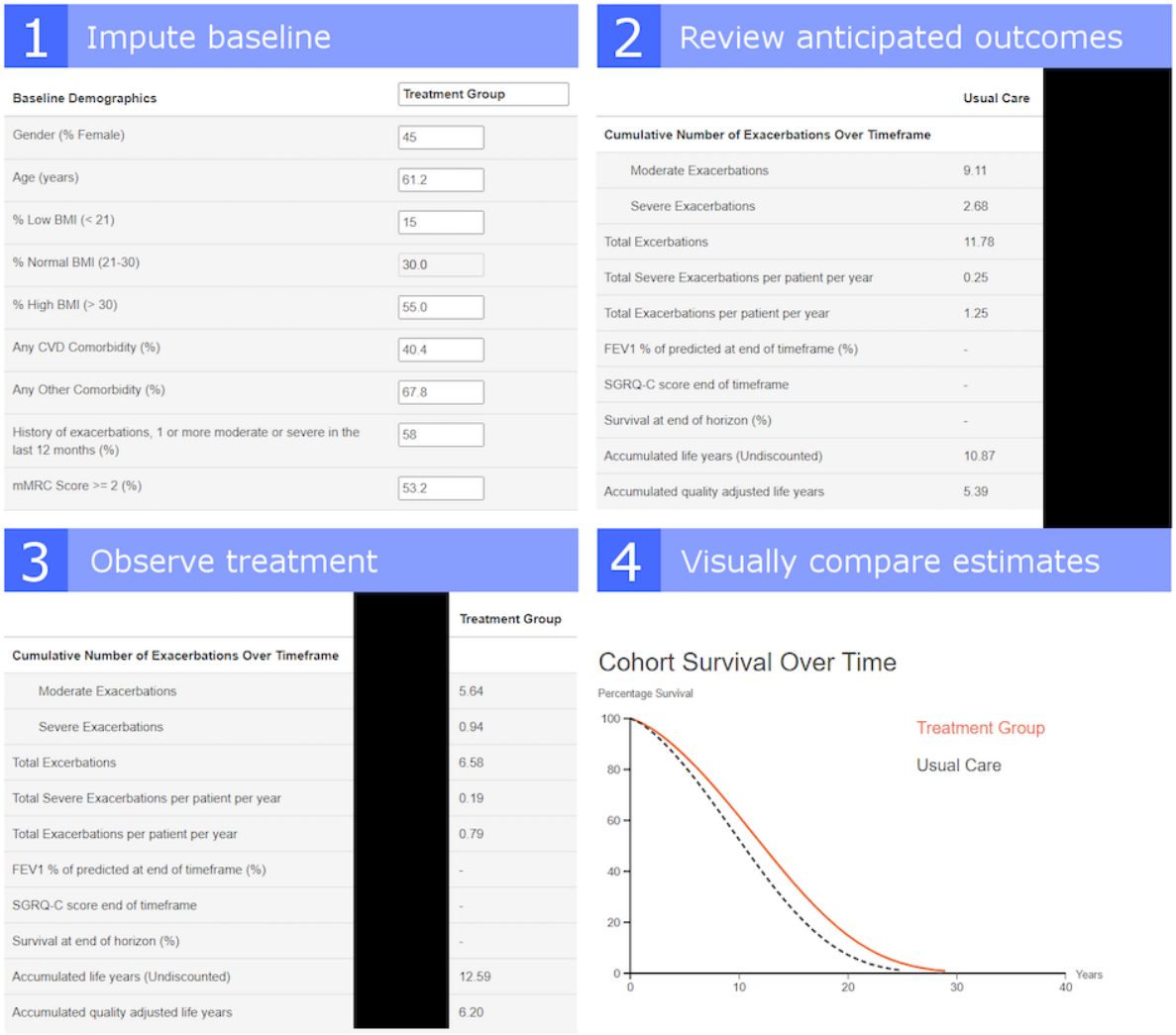
In this pilot study, we investigate sociotechnical factors known to influence technology adoption through potential user feedback and assessment of a mobile web model designed for clinical decision support. The unified theory of acceptance and use of technology (UTAUT) is one of the most widely used models to predict voluntary user adoption and behavior toward a given information system. Employed in user-centered research in mobile web [6], consumer, and clinical health [7,8] contexts, the model is well-validated against four key constructs: (1) performance expectancy, (2) effort expectancy, (3) social influence, and (4) facilitating conditions [9]. In recent expansions of the model, three additional antecedents (hedonic motivation, price value, and habit) were added to UTAUT [6]. We investigate these factors predicted to influence technology adoption decisions by applying the UTAUT2 model in the context of an interface designed for clinical medical staff to assess options for treating chronic respiratory illness among the general population.

Interface Development

A web-based mobile user interface (hereafter referred to as “the WebModel”) was developed to improve functionality and information consumption, following the common approach of using models to provide clinical insight and cost-effectiveness models based on large data sets in Microsoft Excel (Microsoft Corp). Cost-effectiveness models are commonly developed as Excel spreadsheets [10,11] and provide calculated forecasts of health outcomes and treatment costs based on a variety of possible inputs including health status, demographic characteristics, and cost factors. However, the development of these models is complex [12], and validation is an intense process [10]. The possibility of user error in the construction of the cost-effectiveness projections and the difficulty in interpreting information increases with the intensity and number of calculations that must be performed and the volume of information presented to the user. In this specific case, information overload was caused by the added presence of calculation details in the Excel spreadsheets and the production of results being spread across multiple spreadsheet tabs.

The WebModel is designed to address issues of information overload through a simplified interface, to limit extraneous information (Figure 1). Information overload inhibits clinical medical staff from making effective decisions based on electronic medical records [13] and may contribute to errors or clinician burnout [14]. Other literature has found that overly informative medical data interfaces can increase clinical medical staff members’ cognitive workload, ultimately impairing patient outcomes [15]. Simplified electronic interfaces have been used to improve outcomes in intensive care units, which motivated our approach to design as we aimed to determine whether these results generalize to a less-urgent setting [16]. Although Excel provides a powerful and relatively simple way to perform complex calculations, including the large data sets and intricate calculations—in particular, nested regressions—often found in cost-effectiveness models taxes the capabilities of the software, compromises its reliability, and contributes to information overload [17]. We developed the WebModel using JavaScript to construct the mobile user interface and handle data interface between the presentation layer and the model. The underlying calculations are performed in equations modelled in Python on the server layer, which limits potential user errors and is a reliable means of performing complicated calculations [18]. The model is based on a data set of 20,000 simulated patient files. The data are intended to simulate response in the interface, rather than to represent clinical accuracy. The application at this stage is not meant to have clinical validity, but rather is being used to test the form and presentation of information in terms of its ability to visualize information. The next stage of investigation is to continue to develop the system and interface and introduce actual data.

Figure 1. User flow of risk model calculator for respiratory disease interfaces.



The WebModel provides users the opportunity to work with the regression equations and their predictions to evaluate the impact of background characteristics or differences in treatment on long-term predictions of accrued survival time, exacerbation frequency, health-related quality of life (HRQL), and health resource use (HRU)/costs of treatment of chronic obstructive pulmonary disease (COPD) [10]. The WebModel shows the direct relation between an underlying model input (ie, specific characteristics related to a patient) and the linked outcomes. The goal is to limit the number of webform inputs presented to a user to between 1 and 20, depending on their desired comparison, rather than the dozens of detailed calculations that they would normally see in the Excel file. Figure 1 illustrates the elements of an output comparison of cohort survival of hypothetical treatment and nontreatment groups over time. The WebModel is intended to extend the understanding of respiratory illness through interactive access and provide clinical medical staff the opportunity to evaluate the model and the statistical relations it represents. The application uses a responsive design and can be rendered on either desktop or mobile devices by any user's device that can access the website. It only takes information about cohorts and calculates results in the front end; in the current version, no patient information is transmitted by the user's computer or back to the website origin server.

Methods

A minimum viable mobile app was developed to replicate the use of a cost-effectiveness model. As noted above, simulated patient data populates the system, and an interface allows the clinical user to input patient demographic and statistical data (eg, age, height, weight). The system also allows the user to input patient information on the presentation of respiratory illness (eg, incidence of coughing spasms). The resulting outputs would indicate possible therapeutic approaches, and provide (simulated) historical outcomes. An adaptation of the UTAUT scale [6] is used to collect user responses on the perceived usefulness and usability of the system. The research is focused on the assessment of the usability of the interface and the value it may provide. The study did not examine the clinical value of the WebModel.

A questionnaire (Multimedia Appendix 1) was designed with items adapted from a prior literature review and administered online to 1231 clinical users with access to the WebModel

interface. The study population was 843/1231 (68.5%) male, 4/1231 (0.32%) nonbinary, and the rest female. We targeted clinical medical staff who were within 5 years of completing their program, with 1114/1231 (90.5%) aged 20-29 years. As the questionnaire did not request it, we do not have demographic information for the respondents. The study was live for one month, and participants could start the study and continue it over the month. This design provided flexibility, in recognition of the busy schedules of the participants, and allowed them to play with the interface over time. We speculate, however, that this design might have led to a high dropout or incomplete rate because participants began the survey but forgot to come back to complete it. Due to incomplete surveys, we conducted analysis on 674 observable results. The questionnaire had two sections consisting of 29 items from the major constructs included in the proposed model. The first section probed respondents on the perceived efficacy of the WebModel. The second section included the original items from the UTAUT2 [9], modified and adapted from the mobile web framework to include the following: performance expectancy, effort expectancy, social influence, facilitating conditions, hedonic motivations, value, habit, and behavioral intent. Questions in the second section were measured using a 7-point Likert scale ranging from “strongly disagree” (1) to “strongly agree” (7).

Statistical analysis was conducted with IBM SPSS Statistics (version 25; IBM Corp) and the R programming language. As this is an exploratory study, we did not investigate actual use behavior and instead investigated the factors that influence behavioral intention to use. Reliability of the attitudinal scales was assessed by calculating internal consistency (Cronbach α) and multiple linear regression was used to explore the significance of the antecedents of adoption.

Results

Multiple linear regression of the UTAUT2 factors to predict behavioral intention to use the WebModel was significant ($F_{7,672}$=135.4; R^2=0.5851; P<.001). We found that 5 of the 7 factors were significant positive coefficients in the regression: performance expectancy (β=.2730; t=7.994; P<.001), effort expectancy (β=.1473; t=3.870; P<.001), facilitating conditions (β=.1644; t=3.849; P=.001), hedonic motivation (β=.2321; t=3.991; P<.001), and habit (β=.2943; t=12.732; P<.001). Social influence was not a significant factor in the regression (β=–.0149; t=–.661; P=.51). Price value was found to have a significant negative influence on the regression (β=–.1566; t=–4.406; P<.001).

Discussion

Principal Findings

Ash found that more than 80% of health information technology adoption is not related to the underlying data in the system, but to the presentation of the information [19]. The results of the WebModel study suggest there are multiple influences on intent to use the application, many of which may relate to its technical efficiency in presenting clear information. However, the data suggest that sociotechnical factors [20] that include perceptions of how technology fits into workflow, interface design, and the perceived ability of the user also relate to the willingness to adopt the technology. One component that consistently impacts positive adoption is perceived failures in patient safety (eg, inaccurate output) resulting from system use [21,22]. As the WebModel was not tested for clinical use, and the system was deemed to be accurate and validated for the purpose of this study, it is not possible to draw conclusions about the impact of perceptions of patient safety. Future research would benefit from considering the WebModel as a valid model that might be applicable in clinical contexts. UTAUT constructs such as performance expectancy and effort expectancy were nonetheless positively correlated with intention to use the tool, perhaps reflecting that perceptions of time saved were determinants of use.

It was surprising that the price value of the system was found to be a negative factor in the decision to adopt the WebModel, as this is in contrast to the plurality of research on user adoption [6] that suggests perceptions of price value of the technology, or perceived value gained by using the technology relative to the price paid, will enhance adoption. One possible explanation is that health workers are removed from purchasing decisions in hospitals and are not equipped to weigh this factor. Alternatively, studies in extant literature suggest that an impediment to adoption of health technologies is the inability to input information in the form and expression that normal (nontechnological) workflows might allow [23]. For instance, while it may be possible to input values of moderate versus severe exacerbations in a model, there is no opportunity to make expressive additions to the notation. By contrast, entering information into a patient’s chart, or reading information from such a chart, allows for text written boldly, in all capitals, or circled aggressively, which might denote preference for more expressive options. Further study on user adoption of clinical decision support systems and cost-effectiveness models should examine perceptions of value gained through use of the system.

Finally, social influence was found to be nonsignificant in relation to adoption. User adoption literature suggests that peers would stimulate higher rates of adoption, and health care is no exception [24,25]. However, clinical users were provided access to the WebModel in isolation and provided no information that would suggest high or low rates of adoption or acceptance by peers. Therefore, the study is not adequately framed to examine the influence of peer users on the intention to adopt the technology. Future studies on system development and user adoption of the WebModel will examine the system operating in a clinical environment where user perceptions of value, usability, and utility of the system could be shared among study participants.

Conclusion

Clinical decision making requires complex outcome and risk assessments based on large data sets, leading to information overload and the possibility of error. This pilot study investigated how a simplified mobile web model could reduce information overload in these situations and measured the usefulness and usability of this prototype. The results indicate that clinical medical staff would use the WebModel and find it

useful, and that five of the key UTAUT2 factors significantly predicted intent. Further research to test the WebModel in a clinical setting is recommended to allow the factors of social influence and value to be examined as they relate to practice. The collection of qualitative data from users would help researchers better understand the value of this tool in relation to other systems, and how it might fit with workflows.

Acknowledgments

Dalhousie University research funds were the sole source of funding.

Authors' Contributions

CC developed the web model. LB conducted the study. CC and JM conducted the analysis. LB, CC, JM, and ST wrote the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Questionnaire instrument.
[DOCX File , 15 KB - formative_v5i7e22110_app1.docx]

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Abbreviations

COPD: chronic obstructive pulmonary disease
UTAUT: unified theory of acceptance and use of technology

Edited by G Eysenbach; submitted 03.07.20; peer-reviewed by G Trivedi, C Gibson; comments to author 27.08.20; revised version received 14.02.21; accepted 31.05.21; published 16.07.21.

Please cite as:
Beaubien L, Conrad C, Music J, Toze S
Evaluating Simplified Web Interfaces of Risk Models for Clinical Use: Pilot Survey Study
JMIR Form Res 2021;5(7):e22110
URL: https://formative.jmir.org/2021/7/e22110
doi:10.2196/22110
PMID:34269692

Original Paper

Decision Making When Cancer Becomes Chronic: Needs Assessment for a Web-Based Medullary Thyroid Carcinoma Patient Decision Aid

Danielle Shojaie[1*], MPH; Aubri S Hoffman[2*], MS, PhD; Ruth Amaku[1], MPH; Maria E Cabanillas[3], MD; Julie Ann Sosa[4], MA, MD; Steven G Waguespack[3], MD; Mark E Zafereo[5], MD; Mimi I Hu[3], MD; Elizabeth E Grubbs[1], MD, FACS

[1]Department of Surgical Oncology, The University of Texas MD Anderson Cancer Center, Houston, TX, United States

[2]Department of Gynecological Oncology and Reproductive Medicine, The University of Texas MD Anderson Cancer Center, Houston, TX, United States

[3]Department of Endocrine Neoplasia and Hormonal Disorders, The University of Texas MD Anderson Cancer Center, Houston, TX, United States

[4]Department of Surgery, University of California San Francisco, San Francisco, CA, United States

[5]Department of Head and Neck Surgery, The University of Texas MD Anderson Cancer Center, Houston, TX, United States

[*]these authors contributed equally

Corresponding Author:
Elizabeth E Grubbs, MD, FACS
Department of Surgical Oncology
The University of Texas MD Anderson Cancer Center
1400 Pressler Street, Unit 1484
Houston, TX, 77030
United States
Phone: 1 713 745 3715
Fax: 1 713 792 4689
Email: eggrubbs@mdanderson.org

Abstract

Background: In cancers with a chronic phase, patients and family caregivers face difficult decisions such as whether to start a novel therapy, whether to enroll in a clinical trial, and when to stop treatment. These decisions are complex, require an understanding of uncertainty, and necessitate the consideration of patients' informed preferences. For some cancers, such as medullary thyroid carcinoma, these decisions may also involve significant out-of-pocket costs and effects on family members. Providers have expressed a need for web-based interventions that can be delivered between consultations to provide education and prepare patients and families to discuss these decisions. To ensure that these tools are effective, usable, and understandable, studies are needed to identify patients', families', and providers' decision-making needs and optimal design strategies for a web-based patient decision aid.

Objective: Following the international guidelines for the development of a web-based patient decision aid, the objectives of this study are to engage potential users to guide development; review the existing literature and available tools; assess users' decision-making experiences, needs, and design recommendations; and identify shared decision-making approaches to address each need.

Methods: This study used the decisional needs assessment approach, which included creating a stakeholder advisory panel, mapping decision pathways, conducting an environmental scan of existing materials, and administering a decisional needs assessment questionnaire. Thematic analyses identified current decision-making pathways, unmet decision-making needs, and decision support strategies for meeting each need.

Results: The stakeholders reported wide heterogeneity in decision timing and pathways. Relevant existing materials included 2 systematic reviews, 9 additional papers, and multiple educational websites, but none of these met the criteria for a patient decision aid. Patients and family members (n=54) emphasized the need for plain language (46/54, 85%), shared decision making (45/54, 83%), and help with family discussions (39/54, 72%). Additional needs included information about uncertainty, lived experience, and costs. Providers (n=10) reported needing interventions that address misinformation (9/10, 90%), foster realistic expectations (9/10, 90%), and address mistrust in clinical trials (5/10, 50%). Additional needs included provider tools that support

shared decision making. Both groups recommended designing a web-based patient decision aid that can be tailored to (64/64, 100%) and delivered on a hospital website (53/64, 83%), focuses on quality of life (45/64, 70%), and provides step-by-step guidance (43/64, 67%). The study team identified best practices to meet each need, which are presented in the proposed decision support design guide.

Conclusions: Patients, families, and providers report multifaceted decision support needs during the chronic phase of cancer. Web-based patient decision aids that provide tailored support over time and explicitly address uncertainty, quality of life, realistic expectations, and effects on families are needed.

(JMIR Form Res 2021;5(7):e27484) doi:10.2196/27484

KEYWORDS

patient decision aids; decision support techniques; oncology; medullary thyroid cancer; targeted therapy; clinical trial; mobile phone

Introduction

Background

As diagnoses and treatments continue to improve, chronic cancer is increasingly recognized as a unique phase in the cancer care continuum. During this time, many patients face difficult decisions such as whether to try novel therapeutics emerging on the market, whether to enroll in clinical trials, and when to stop treatment. New medicines offer hope but may provide only limited efficacy in select groups, have significant risks of side effects, or involve high out-of-pocket costs for the family. Many clinical trials cover the costs of treatment but involve accepting unknown potential benefits and risks. For some patients, even successful therapeutic effects do not last, and a decision needs to be made about whether to switch therapies or stop treatment. These decisions are classified as *preference-sensitive* because they involve 2 or more medically relevant options, uncertain benefits, notable risks, and variation in how patients and families value the potential process and outcomes [1].

A prime example is medullary thyroid carcinoma (MTC), a rare thyroid tumor. More than half of patients with MTC develop an advanced or chronic disease and live for years to decades with slowly progressing, often terminal cancer [2,3]. The US Food and Drug Administration approved 3 oral targeted therapies—vandetanib, cabozantinib, and selpercatinib—for the treatment of progressive MTC. Large phase 3 trials comparing vandetanib and cabozantinib with placebos showed improved progression-free survival; however, improvement in overall survival was only observed in small select groups [4,5]. These drugs are costly (US $200-US $600 per day) and can cause significant diarrhea, weight loss, hypertension, hypertensive crises, profound fatigue, or death [4,6]. Selpercatinib has been recently approved for a subset of patients and has been reported to be well tolerated with fewer side effects; however, overall survival benefits have not been shown [7]. Several clinical trials are ongoing; however, patients must be willing to accept randomization and unknown side effects. When discussing a new targeted therapy or clinical trial, it is also important to clarify the conditions under which patients would want to switch or end treatment. These decisions are often revisited iteratively over months or years, with much of patients' deliberations occurring between clinical consultations. Hence, providers have expressed interest in web-based approaches to helping patients and families learn about and prepare to discuss these preference-sensitive decisions [8].

In preference-sensitive care, the best decision involves integrating medical evidence and informed patient preferences. Shared decision-making interventions such as decision coaching and patient decision aids are the gold standard for optimal preference-sensitive care [9-11]. Decision coaching involves semistructured discussion to ensure that patients are well informed, have realistic expectations, are clear about their decision-making values, and have appropriate resources and support to implement the mutually agreed upon choice [12]. Patient decision aids are tools that provide up-to-date, balanced evidence about the options and activities to promote preparation for decision making, values clarification, communication, and engagement [13]. Patient decision aids may be delivered before, during, or between consultations. Multiple Cochrane Collaboration systematic reviews report that patient decision aids help patients become well informed, form more realistic expectations, clarify which risks and benefits matter most to them, and prepare for discussing these decisions with their clinical teams [13-15]. Decision counseling and patient decision aids also address patients' decisional conflict, a state of anxiety that blocks taking action [16]. Previous studies have reported that for each point increase on the 0-100 Decisional Conflict Scale, patients were 23 times more likely to delay their decision, 59 times more likely to change their mind, 5 times more likely to express decision regret, and 19% more likely to blame doctors for bad outcomes [17].

Objectives

The International Patient Decision Aid Standards Collaboration provides guidelines for evidence-based systematic development of patient decision aids [18], including reviewing the literature for up-to-date clinical information, assessing the quality and relevance of any existing tools, and conducting a formal decisional needs assessment to identify high-priority decision-making needs. The guidelines chapter, *Delivering Decision Aids Using the Internet* [19], also recommends a user-centered design process to ensure that the tools are accessible, usable, and meaningful. The long-term goal of this research program is to develop patient- and provider-facing decision support tools for chronic cancer. As a first step, the objectives of this study are to (1) engage users in a stakeholder advisory panel to guide development; (2) review the existing literature and available tools; (3) assess the decision-making

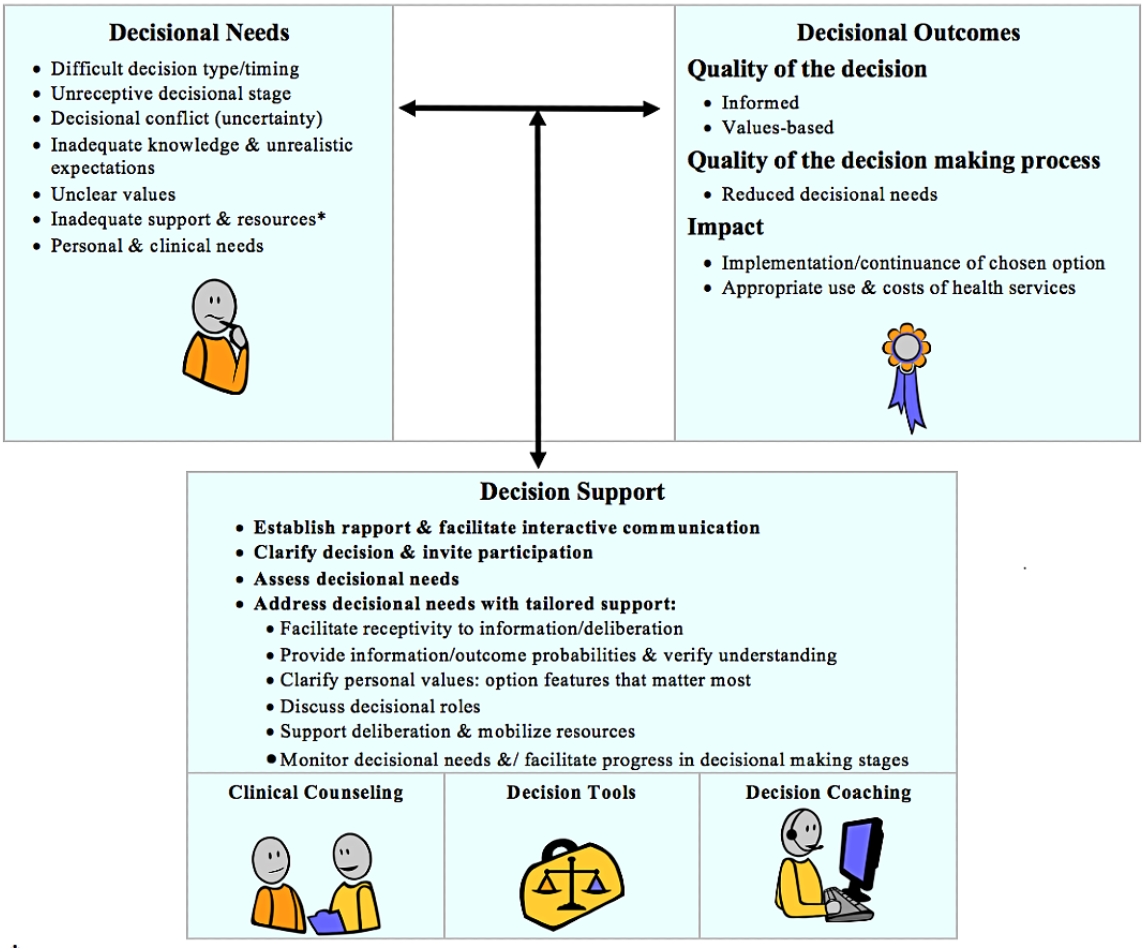
experiences, needs, and recommendations of patients with MTC, family members, and providers; and (4) identify shared decision-making approaches to address each need.

Methods

Conceptual Framework

This initial study (part of a larger trial; NCT03892993) followed the multidisciplinary decisional needs assessment approach outlined by the patient decision aid development guidelines [18,19]. One of the key theoretical models underlying this approach is the Ottawa Decision Support Framework [16,20], which has been used to develop decision support interventions in more than 100 studies across 18 countries. This framework applies behavioral, cognitive, and economic decision theories [21-24] to preference-sensitive health care decisions. For example, it postulates several modifiable decision-making needs such as lack of awareness, knowledge, clarity, or support that can be addressed to ensure a high-quality decision-making process (Figure 1).

Figure 1. The Ottawa Decision Support Framework. *Inadequate support and resources to make/implement the decision include: information inadequacy/overload; inadequate perceptions of others' views/practices; social pressure; difficult decisional roles; inadequate experience; self-efficacy, motivation, skills; inadequate emotional support, advice, instrumental help; and inadequate financial assistance, health/social services. Copyright 2019, Ottawa Hospital Research Institute [16,20].



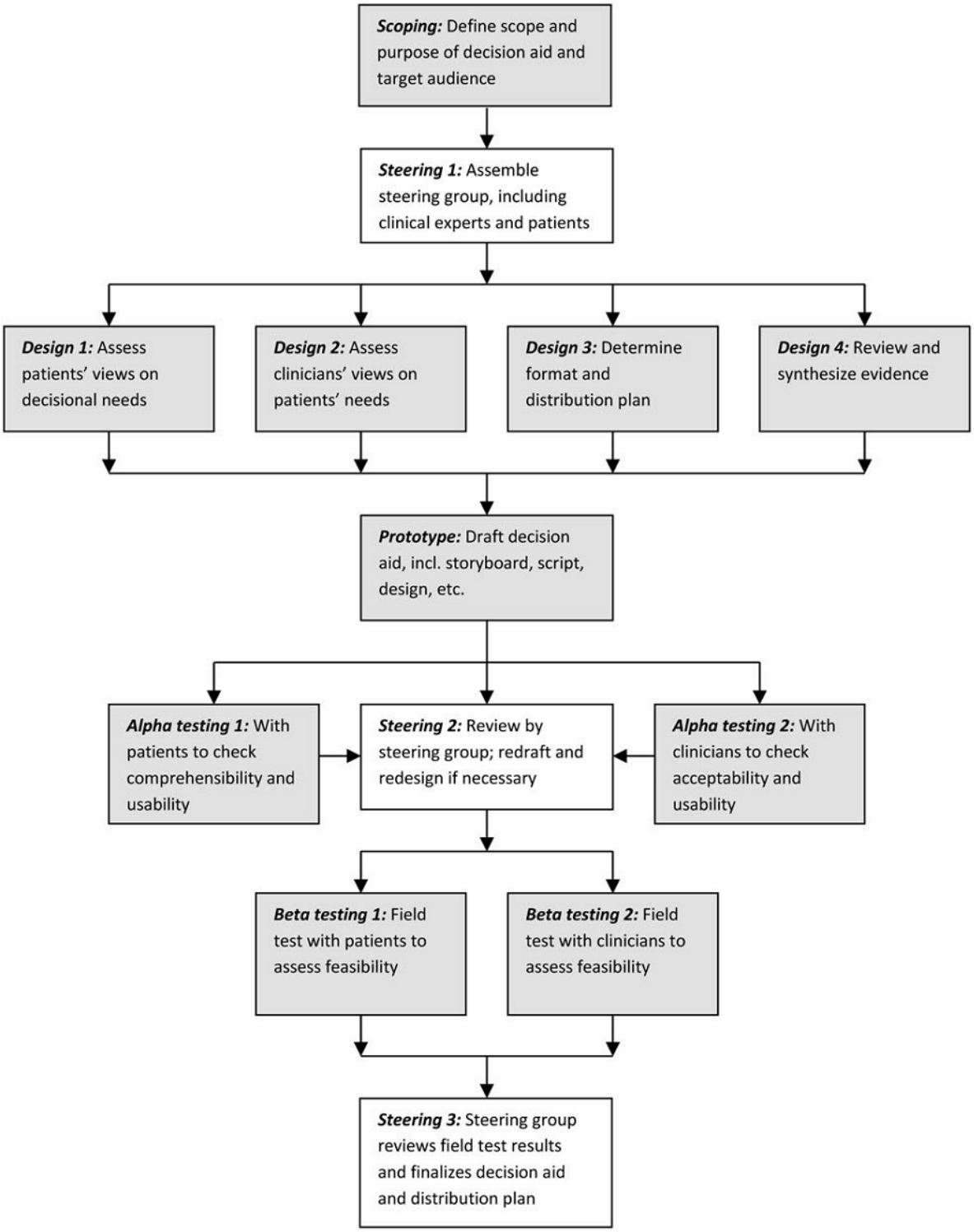
To support rigorous systematic development, this framework was operationalized in 1999 as the Decisional Needs Assessment in Populations [25]. This approach has been used across a wide variety of clinical contexts to assess patients', families', providers', and community members' decision-making experiences, processes, unmet needs, and recommendations for designing meaningful, understandable, and feasible tools [18,25-29]. It involves a series of steps using mixed methods with an emphasis on user-centered design and practical thematic analysis focused on unmet decision-making needs.

Procedures

Overview

Following the guidelines for systematic development [18] (Figure 2) and delivery using the internet [19], this study proceeded in 4 steps: (1) engaging a stakeholder advisory panel, (2) reviewing existing literature and tools, (3) administering a decisional needs assessment questionnaire, and (4) developing a decision support design guide to inform the future design of a patient decision aid. The institutional review board of the University of Texas MD Anderson Cancer Center provided ethical review and approval.

Figure 2. The International Patient Decision Aid Standards Collaboration model for the systematic development of a patient decision aid [18].



Engaging Users in a Stakeholder Advisory Panel

To guide the overarching program of research, the study team purposefully invited a diverse group of potential users and key stakeholders, including patients, family members, surgeons, oncologists, and advanced practice providers. Advisory panel members were not participants but partners in the research process who provided guidance on the study methods, proposed questionnaire, potential sources, data interpretations, and the final design guide. The advisory panel meets at least twice per year to discuss the overarching program of research and was engaged in 2 study planning calls and multiple calls and emails as needed to review, edit, and approve study documents, results, interpretations, and this manuscript. Notably, they proposed that the project scope includes both targeted therapies and clinical trials as well as recommendations for a web-based patient decision aid to deliver timely information to patients living in the community.

Review of Existing Literature and Tools

A total of 2 reviews of MTCs had been completed in 2016 [30,31]. Therefore, a scoping review [32] was conducted to identify newer publications, and an environmental scan approach [33] was used to identify and assess the quality of existing materials. First, the research team members searched Web of Science, PubMed, and Google Scholar for *advanced medullary thyroid carcinoma*, *decision support*, *patient decision aid*, *vandetanib*, *cabozantinib*, *surveillance*, and *clinical trial participation*. Next, they used Web of Science to conduct a 1-generation forward and backward citation analysis of the references of the 2 systematic reviews and the papers that referenced the systematic reviews. Finally, the team conducted a gray literature search [34], which involved reviewing relevant websites, brochures, drug labels, and infographics using Google Scholar; web-based patient decision aid libraries; and relevant clinical, advocacy, and survivor support group websites. All reviews were conducted in English, included all time frames and countries, excluded advertisements, and retained only the most recent version of the edited documents or websites.

Decisional Needs Assessment

The decisional needs assessment questionnaire [25] includes 10 open-ended items assessing respondents' previous experience, decision-making needs, and recommendations for the design of a decision support intervention such as a web-based patient decision aid. We tailored the questionnaire for patients, family members, and providers (eg, "Which of the following decisions [have you considered/have you discussed with your loved one/have you discussed with patients]?"). Patients and family members also responded to 14 items assessing their characteristics. To inform future implementation, providers responded to 2 questions about care pathways. The stakeholder advisory panel and institutional review board reviewed, revised, and approved the questionnaire.

The participants were English-speaking adult patients with MTC, informal caregivers or family members (on their own or with a patient or survivor), and clinicians who treat patients with MTC. The research coordinator recruited eligible patients and family members from the MTC Registry, which includes more than 1500 individuals from 20 states and 6 countries. The study team purposefully recruited patients across the disease spectrum, excluding individuals for whom participation could have caused distress (eg, recently diagnosed or bereaved). The provider participants included endocrinologists, medical oncologists, and surgeons purposefully recruited for their significant expertise and diversity of perspectives. All participants provided informed consent.

Members of the MTC Registry are active on the web and well known to each other and to MTC providers; therefore, additional attention was given to ensuring confidentiality while maximizing access. The research coordinator called each individual and offered an informational email that explained the purpose of, and process for, participating, including the opportunity to respond confidentially and securely on the web (or on paper or by phone, if requested). The email provided the link to a closed web-based questionnaire hosted on REDCap (Research Electronic Data Capture; Vanderbilt University) version 9.1.0 (May 31, 2019) [35]. A total of 2 reminder emails were sent to the nonresponders. All participants completed the questionnaire between May and September 2019. Patients and family members received a US $10 gift card after participating.

Statistical Analysis

This exploratory study was not designed to test a hypothesis or generate a theory. Sample sizes were based on the international guidelines and were consistent with previous studies [18,19,28,36-39]. For the questionnaire, the research team used descriptive statistics to summarize quantitative responses and semantic, critical realist thematic analyses [40] to analyze qualitative responses. Beginning with a deductive approach, one author (ASH) hand-coded responses using core concepts from the Ottawa Decision Support Framework [16] (eg, uncertainty and need for information) and clinical literature (eg, side effects and costs). If a new concept arose in 2 or more responses, a new code was proposed, reviewed by a second author (DZS), and used to recode previous records. Conflicts and questions were discussed by 2 authors (EGG and MIH). The full research team met and reviewed the coding and findings twice and then presented all results and findings to the advisory panel to confirm meaningful interpretation and contextualization.

Decision Support Design Guide

The purpose of a decision support design guide is to identify top-priority design needs (ie, clinical content, decision support activities, graphics, delivery etc) and to propose design solutions to address each need. Consistent with the conceptual framework, the research team organized the needs according to the modifiable factors that contribute to high decisional conflict (ie, feeling uninformed, unclear, unsupported, uncertain, and ineffective) [16] and added a delivery or accessibility category focusing on web-based delivery. Responses were retained if they were top rated or most endorsed across both groups. To identify best practices in decision support and patient decision aid design, the research team consulted the International Patient Decision Aid Standards chapters [12,19,41-46], the Cochrane Collaboration reviews [13,14], selected decision support experts, and the advisory panel. The team aligned the best practices parallel to each need to create a decision support design guide.

Results

Engaging Users in a Stakeholder Advisory Panel

The stakeholder advisory panel consisted of 4 patients and family members, 2 oncologic endocrinologists, 1 head and neck surgeon, and 1 advanced practice provider. Their experience and diverse perspectives complemented the expertise of the research team, which included a surgical oncologist, an oncologic endocrinologist, a decision scientist, and a trained research assistant. The advisory panel participated meaningfully in all aspects of the study, from the protocol design to writing this manuscript.

Review of Existing Literature and Tools

In addition to the previous 2 systematic reviews [30,31], the scoping review and citation analysis identified 9 papers specific to decision making for MTC [3,47-53]. Two papers focused on

improving diagnosis and staging, 6 papers reported studies of targeted therapeutics, and the remaining paper provided updated clinical practice guidelines. No studies on patient decision aids for starting or stopping targeted therapies were identified. A total of 3 studies of patient decision aids for clinical trial enrollment exist in other contexts [54-57], along with a conceptual framework for development [58]. The environmental scan and gray literature search identified 56 blogs, websites, and posts by clinical and advocacy groups. Review of these webpages confirmed that patients were asking about targeted therapy and clinical trial enrollment decisions; however, no patient decision aid for MTC was identified.

Decisional Needs Assessment

Participant Characteristics

The research team invited 106 patients, family members, and providers. A total of 74 individuals responded, and 64 (87%) individuals completed the questionnaire, including 46 (72%) patients, 10 (16%) family members, and 10 (16%) providers. Table 1 summarizes the respondents' characteristics. In addition, 46% (25/54) of patients and family members received surgery and care at both the study site and outside institutions. Notably, the respondents included individuals who had recently undergone a secondary surgery or focal treatment, individuals with indolent disease who may face these decisions in the future, and individuals experiencing an advanced stage of disease treated with at least one systemic therapy agent. Many providers (6/10, 60%) reported being attending physicians who saw 30-50 patients with MTC per year.

The following paragraphs summarize participants' responses to the 3 sections of the questionnaire assessing (1) previous decision-making experiences, (2) decision support needs, and (3) recommendations for designing a decision support tool such as a web-based patient decision aid. To protect individuals' privacy, patient and family member responses have been combined, identifying information has been redacted in the quotes, and results from fewer than 5 patients and family members are reported but not quantified.

Table 1. Participants' characteristics (N=64).

Characteristics	Patients and family members[a] (n=54)	Providers (n=10)
Number of years of treating or being with patients with medullary thyroid carcinoma, median (minimum, maximum)	4.5 (<1, 24)	13 (5, 25)
Location of cancer care or clinical practice, n (%)[b]		
MD Anderson Cancer Center	44 (95)	1 (10)
Another institution	27 (56)	9 (90)
Experience with medullary thyroid carcinoma, n (%)[b]		
Patient with medullary thyroid cancer or survivor	46 (85)	—[c]
Caregiver or family member	10 (19)	—[c]
Medical oncologist	—[c]	5 (50)
Endocrinologist	—[c]	4 (40)
Surgeon	—[c]	1 (10)
Age (years), median (minimum, maximum)	52 (21, 80)	46 (40, 60)
Female sex, n (%)	30 (56)	2 (20)
Race, n (%)[b]		
White	46 (85)	7 (70)
Other	8 (15)	3 (30)
Hispanic or Latino/Latina, n (%)	7 (13)	0 (0)
Education, n (%)		
Some college, associate's or technical degree	14 (26)	—[c]
Bachelor's degree	25 (46)	—[c]
Graduate degree	11 (20)	—[c]
Religion, n (%)[b]		
Atheism or agnosticism	5 (9)	—[c]
Christianity	46 (85)	—[c]
Health insurance, n (%)[b]		
Private insurance	49 (91)	—[c]
Medicare or Medicaid	17 (32)	—[c]
Annual household income (US $), n (%)		
<50,000	12 (22)	—[c]
50,001-100,000	12 (22)	—[c]
>100,000	30 (56)	—[c]

[a]To protect patients' privacy, cells with <5 responses have not been reported; therefore, not all sections total 100%.

[b]Participants could select more than 1 response.

[c]Not assessed in this study group.

Patient and Family Member Perspectives

Of the 54, 20 (37%) of patients and family members reported making decisions about whether to start a new targeted therapy drug, 24 (44%) had deliberated about whether to enroll in a clinical trial, and 9 (16%) had chosen to stop a therapy. *Other* responses included whether to take or increase synthetic thyroid hormone, undergo radiation therapy, or undergo surgery with the possibility of losing their voice. A few patients focused on personal decisions such as when to disclose their diagnosis, discuss cascade genetic testing, or inform their family about progression. One person highlighted the decision to accept that

they had terminal cancer. Others described logistical decisions such as whether to travel for second opinions, treatment, or surgery:

> *Choosing doctors & treatment options to best suit my specific needs is difficult because they're few and far between. There are different types of this rare cancer (inherited and sporadic) and...different gene mutations...which ultimately contribute to compartmentalizing and/or reducing treatment options and adversely impacting [one's] specific needs.* [Patient]

> *Where to get help? Local endocrinologists and surgeons had little to no experience with MTC and even their comments were unsettling. Is there a benefit to traveling for treatment?* [Patient]

Most of the patients (31/44, 72%) reported worry as a primary barrier, including significant concern regarding how each option would affect their family financially, emotionally, and in caregiving burden. Some patients (12/54, 22%) reported feeling rushed or pressured (by their doctor, family, or insurance company) or worried about disappointing their doctor (10/54, 19%). A few patients reported challenges with trust and communication:

> *I had to decide if I wanted to fight my initial endocrinologist about having genetic testing. He told me it was very expensive and since my children were adopted it wasn't critical. When I asked about my siblings, he shrugged.* [Patient]

Both patients and family members (16/54, 30%) focused on the need for help dealing with uncertainty, clarifying risks, and weighing future effects on quality of life. Some participants (12/54, 22%) reported information barriers such as difficulty finding trustworthy information or frustration over finding conflicting information. A few participants noted that they needed time to process information and to connect with survivors to discuss the lived experience. Notably, most patients (45/54, 83%) and family preferred "discussing treatment options and my preferences with my providers, then making the decisions together." Only a few wanted to make the decision themselves (6/54, 11%) or have the doctor make the decisions (3/54, 6%):

> *[We] have small children...[so we] had to weigh in the travel and cost for our family.* [Caregiver or family member]

> *[I] was not allowed time to gain knowledge of MTC. Also, I did not seek a second opinion which would have been valuable.* [Patient]

Table 2 summarizes patients' and family members' ratings of possible features for a decision support tool. Overall, most of the patients and family members recommended using plain language and providing a step-by-step guide, example questions, charts, and a printable summary. *Other* recommendations included providing a glossary, responses to frequently asked questions, question-prompt list, tips for talking with employers, guidelines on how to select a provider, and activities to elicit and clarify what is most important in these decisions (eg, travel costs, financial considerations, and timing):

> *Keep the language simple. The video we watched for [a previous clinical trial] was very informative. We followed it just fine, but my thoughts drifted to those that might not have a high education level, how well would they comprehend?* [Caregiver or family member]

> *Keep a library of historical real Questions & Answers made by people.* [Patient]

> *Mental health information—particularly aimed at grief and how to include children. Explain mortality rates in lay person terms.* [Patient]

Table 2. Patients' and family members' recommendations for a decision support tool (n=54).

Recommendations for a patient decision aid	Patients and family members, n (%)
Explain each treatment option in plain language	44 (82)
A step-by-step guide to walk you through considering the decision	36 (67)
Example questions to ask the doctor	32 (59)
Charts comparing options side by side	30 (56)
Printable summary of your information at the end	28 (52)
Stories from other patients or families about what each option was like	27 (50)
A glossary of the medical terms	27 (50)
Keep it simple	26 (48)
Stories from other patients or families about how they made these decisions	25 (46)
Graphics that illustrate the risks (eg, 8 of 10,000 people)	25 (46)
Activities to help you sort out what is most important to you personally	16 (30)
A place to write down your questions for the doctor	14 (26)
Other	6 (11)

Regarding the amount of information, a slight majority (32/54, 59%) reported wanting "the key facts and lots of details about all of the options," but others preferred "the key facts, plus detail about the options I am interested in" (12/54, 22%) or "the key

facts about each of the treatment options" (10/54, 19%). A few participants commented that they particularly wanted more information for these decisions because of the potential long-term effects on quality of life and on their families. Notably, a few participants requested information comparing clinical trials and information comparing novel therapeutics:

> *A simple pros and cons list for each clinical trial...or, a chart where you can see each drug side-by-side.* [Patient]

Regarding preferred mediums, most of the patients and family members recommended a worksheet that walks them through the decision(s) (39/54, 73%), an interactive website (35/54, 66%), a 1-page printable summary (34/54, 64%), or video (30/54, 57%). Most of the participants recommended multiple delivery routes, including the hospital website (45/54, 83%), personal email (37/54, 57%), smartphone app (25/54, 46%), paper copies at the doctor's office (19/54, 35%), or mail (13/54, 24%). A few individuals recommended sending the worksheet through the patient portal, providing a link in the annual guidelines, or making it available on social media cancer support groups, peer-to-peer support groups, and patient advocacy sites.

Provider Perspectives

Regarding current experiences, all providers reported that their care pathway involves treatment by an endocrinologist until progression occurs, followed by referral to a medical oncologist. In total, 70% (7/10) of providers recommended introducing these decisions early on, including at the initial visit. In total, 20% (2/10) of providers recommended waiting until the patient developed distant disease:

> *[Targeted therapy should be discussed] as soon as distant metastases are identified. If they are small distant mets, then it is a brief mention that systemic therapy options are available in the future. As the mets get bigger or if they are progressing, then more detailed discussions ensue.* [Endocrinologist]

> *At the initial visit, I provide a comprehensive picture of their disease management, the palliative nature of therapy, the role of surveillance, what guides the decision to treat, and what the treatment options are (standard and experimental).* [Medical oncologist]

Regarding clinical trials, the providers reported engaging in discussions at least once a week (3/10, 30%), once a month (4/10, 40%), or a few times a year (2/10, 20%). Most of the providers (7/10, 70%) felt that it was their role to initiate these conversations with patients; others (3/10, 30%) felt that it could be introduced by the study team. In total, 40% (4/10) of providers reported that patients initiated these decisions approximately 50% of the time or more:

> *The best quality discussion happens over several visits...more as a continuing conversation, rather than a sudden surprise discussion that it is time to start systemic therapy tomorrow. This gives patients time to think about the information, involve family members, do their own research, and come prepared with better questions.* [Endocrinologist]

The providers reported moderate satisfaction with these discussions (10-point scale score: mean 7.5, SD 2.1; minimum=2, maximum=10). Their descriptions of the "best outcome of this conversation" were that patients understood the key information (6/10, 60%), including that trials are experimental, and that they interacted or asked questions (6/10, 60%) and stated that the decision aligned with goals of care (4/10, 40%):

> *Success is when a patient and his/her family feel like they have a good understanding of the risks/benefits of their decision and are comfortable with the path we choose together.* [Medical oncologist]

> *Success is they understand that clinical trials are experimental, we don't know if they are better than standard of care, and the risks may not be completely known.* [Endocrinologist]

When discussing targeted therapies, the providers reported needing interventions that address preconceived notions (5/10, 50%), misinformation (4/10, 40%), and time constraints (4/10, 40%). A few described situations in which patients were informed that there is no cure, but they continued to believe that a cure may still be achievable. They also discussed 2 effects of misinformation and preconceived notions: (1) patients assuming that the side effects are negligible and not considering quality of life or (2) patients assuming the degree of side effects to be so harmful that they will not consider a certain therapy. *Other* barriers included lack of visual aids, poor retention, difficulties clarifying goals of care, fear and logistical challenges related to clinic flow, paucity of multidisciplinary approaches, and insurance coverage:

> *[Barriers include] preconceived notions from patients that approved therapies are too toxic and not efficacious; some patients want to dictate the way they should be treated.* [Endocrinologist]

> *The limitations imposed by busy clinics and limited time with patients is the biggest hindrance. These are complicated issues that require time with the patient to have a comprehensive discussion that is well-received with the patient.* [Medical oncologist]

When discussing decisions about clinical trials, most of the providers (9/10, 90%) also described situations in which patients stated unrealistic goals, overly optimistic assumptions, or beliefs that the trial would be curative. However, half of the providers (5/10, 50%) also discussed conversations in which patients distrusted pharmaceutical companies and did not want to be a "guinea pig." *Other* barriers included lack of visual aids, concerns about randomization, worry about the unknown risks of side effects, and potential logistical challenges or costs:

> *[Patients believe] that we are just experimenting on them and that we have no idea whether it will work...there is a general mistrust of drug companies.* [Endocrinologist]

> *[Patients tell me] "I am a guinea pig," or [they are] overly optimistic that the trial drug will help them [and have few side-effects].* [Endocrinologist]

The providers recommended a variety of approaches to designing a web-based patient decision aid. All providers (10/10, 100%) endorsed the need to include both decisions (targeted therapies and clinical trials), and most (7/10, 70%) endorsed having the ability to tailor or separate the decisions. Table 3 summarizes their ratings of the possible formats. *Other* responses included purposefully designing the patient decision aid for repeated discussions over time; face-to-face meetings with a midlevel provider to discuss side effects; and 1-page summaries of the disease, therapies, and trials:

> *Individualization is key.* [Medical oncologist]
>
> *In the absence of a curative systemic therapy, I think I would use a decision aid that incorporates standard of care and clinical trials.* [Endocrinologist]

Table 3. Perceptions regarding potential decision support tools (N=64).

How helpful would the following tools be?	Patients and family members (n=54)	Providers (n=10)
Patient-facing tools, n (%)		
A 1-page comparison chart of the treatment options you can use in consultation	34 (64)	9 (90)
A brochure or video patients can be given before their appointment	30 (57)	8 (80)
A worksheet about preferences and values they complete that you can add to their electronic health record	39 (74)	7 (70)
A page on your institutional website	35 (66)	6 (60)
A face to face meeting with a nurse to talk about side effects	0 (0)	6 (60)
Other	8 (15)	7 (70)
Provider-facing tools, n (%)		
A brief training seminar on the current evidence	—[a]	7 (70)
A brief training seminar on decision coaching as a clinical skill	—[a]	7 (70)
A collaborative meeting between departments to discuss the upstream/downstream impacts of these decisions	—[a]	7 (70)
A study of the patients' reported experience	—[a]	7 (70)
Other	—[a]	0 (0)

[a]Not assessed in this study group.

In terms of the key facts that should be conveyed, most of the providers (7/10, 70%) focused on quality of life and repeating that targeted therapies may not prolong survival. Some also focused on balanced discussion, lack of known probabilities, acknowledging that experimental therapy may be better tolerated, emphasizing that goals of care change over time, and describing co-pays. A few providers cautioned that the decision aid should advise patients to make sure that their expectations, both expressed and implied, are realistic before enrolling in a clinical trial. One provider also recommended explicitly addressing the concept of altruistic volunteering:

> *A tutorial on the role of clinical trials in drug development and patient care to establish general background before a discussion would be helpful.* [Medical oncologist]

The providers recommended introducing clinical trials early on or during the first visit (4/10, 40%), at the same time as standard therapies (3/10, 30%), or at all stages (3/10, 30%). A few providers recommended waiting until standard therapy failed, before surgery, or when a novel therapy has compelling clinical data. Several providers brought up improving the overall decision-making process, including developing better patient education materials (3/10, 30%) and initiating multidisciplinary conversations earlier (3/10, 30%). *Other* recommendations included getting clarity about expectations, verbally encouraging patients to communicate side effects, and planning additional time for these conversations. They also recommended that the conversation be led by a clinician who is experienced in caring for patients with MTC:

> *[We need] better patient education materials aimed toward patients in their language.* [Endocrinologist]
>
> *[We need] to have MTC patients see knowledgeable medical oncologists earlier in the disease course, so it doesn't feel like a defeat when they're referred to us.* [Medical oncologist]

Decision Support Design Guide

Figure 3 illustrates the decision support design guide, with the left column listing the top-reported decision support needs and the right column proposing decision support approaches to address each need. A review of the international standards identified several relevant best practices, including explicitly introducing shared decision making, inviting engagement, balanced presentation of pros and cons, addressing uncertainty, providing cost ranges, and delivering the patient decision aid on the hospital website with optional paper worksheets. To meet provider needs, strategies include seminars on decision coaching, communication, and behavioral therapy skills (to address anxiety, trust, fear, etc); a consultation tool kit of shared

decision-making discussion prompts; responses to frequently asked questions; 1-page summaries of clinical trials; or illustrative material such as icon arrays and side-by-side comparison charts. The advisory panel reviewed and approved the design guide for use in future studies.

Figure 3. Decision support design guide. Left column: top-rated decision support needs from our assessment. Right column: proposed decision support strategies for addressing each need.

Discussion

Principal Findings

Overall, the results indicate that patients with chronic cancer may have significant unmet decision-making needs, and strong support exists for designing decision support tools regarding novel targeted therapies and clinical trial enrollment. Patients and family members report multiple information and decision support needs, such as needing understandable information, examples of the lived experience, help in personalizing the information, strategies to address worry, step-by-step guidance, and opportunities to revisit decision making over time. In addition, the providers emphasized the need to address misinformation, foster realistic expectations, and address mistrust toward clinical trials. The participants supported the development of a web-based tool that can be delivered across multiple platforms (hospital website and email) and that provides a printable personal summary. The providers also requested tools to support shared decision making in consultation. Although no existing patient decision aid could be identified, clinical content regarding targeted therapies is available, and examples of clinical trial tools exist in other clinical contexts. To support clinicians and designers who wish to develop such a tool, the proposed decision support design guide (Figure 3) illustrates the top-priority needs and best practices in decision support to address each need.

Comparison With Previous Work

The results of this needs assessment highlighted several constructs, mechanisms, and behaviors that may affect patient decision aid design. Patients and family members reported heterogeneous information-seeking behaviors and deliberative styles. Some preferred "just the key facts" and may have been overwhelmed by too much detail, whereas others sought highly detailed information and side-by-side comparison charts. Some preferred implicit decision support (introducing the concepts of shared decision making but allowing them to manage their deliberative process internally), whereas others specifically requested explicit decision support (providing step-by-step guidance, interactive websites, or worksheets) [19]. These patterns are consistent with those in other studies [19,27] and may be linked to coping strategies such as monitoring (seeking a sense of control by seeking and attending to information) or blunting (seeking a sense of control by limiting information) [59,60]. Additional research is needed to explore dynamic designs that assess and address each patient's information-seeking and deliberative styles.

Furthermore, these decisions highlight the challenges of shared decision making in the context of chronic or terminal stages of disease. The Ottawa Decision Support Framework focuses on addressing modifiable constructs to decisional conflict, such as feeling uninformed, unclear, and uncertain [16,17]. When discussing novel therapeutics and clinical trial enrollment, the options for providing evidence to foster certainty may be limited. However, the process of helping patients acclimate to the paucity of information, clarify what matters most (including quality of life), develop shared decision-making skills, and communicate with family and providers may provide important benefits that improve long-term decisional regret.

To our knowledge, this is the first study of MTC decision support needs and recommendations for a patient decision aid [13,61]. Previous studies have focused on the quality of patient-facing information. A review of 100 thyroid cancer websites [62,63] reported that most of the websites addressed diagnosis (92/100, 92%) and treatment (94/100, 94%); however, only some (50/100, 50%) were accurate, included source references (53/100, 53%), or were appropriate for a high school education level (2/100, 2%). A similar study in Germany [48] reported similar heterogeneity in the quality and accessibility of information. One study [50] tested web-based, personalized information and support with individuals with neuroendocrine tumors and found no difference in patients' distress or satisfaction. A recent review of websites for the surgical management of low-risk thyroid cancer [64] reported that few (19/60, 32%) of the websites presented all treatment options, and none of the websites discussed the 2015 guidelines [3].

Since the 2017 review of internet-based patient decision aids [19], several studies have been published that may inform the design of web-based tools [65-72]. Overall, these studies continue to report positive ratings of acceptability, usability, and satisfaction as well as improved knowledge, decisional conflict, decision self-efficacy, preparation for decision making, and satisfaction. Baptista et al [73] reported that web-based patient decision aids improved knowledge and decisional conflict compared with usual care and were comparable with paper-based patient decision aids. Related reviews of computerized decision aids [74,75] report positive outcomes and satisfaction, strong correlations with the quality of development, and improved decision making for tools with features such as content control but poorer decision making when tools included tailoring or patient narratives. These topics continue to be emerging areas of research and can be explored in user design studies.

On the basis of the results of this study, the next steps will include continuing with the systematic development of a patient decision aid (Figure 2) for patients and family members with MTC. Once the review and synthesis of the clinical evidence are complete and we develop the initial prototype with the advisory panel, we will re-engage the participants who consented to be recontacted to iteratively review and revise the drafts. In parallel, we will develop and validate a Decision Quality Index, the gold standard measure of the degree to which patients' decisions are informed and values congruent. With these tools, we can begin to simultaneously assess efficacy and effectiveness as well as explore some of the methodological research questions discussed herein. The ultimate long-term goals of this program of research continue to be to help patients with MTC and their families to make well-informed personal health care decisions, while simultaneously learning from patient-reported data about patients' needs, values, cultural considerations, and informed preferences regarding starting and stopping novel therapeutics and clinical trials.

Limitations

Several limitations of this study should be noted. The use of a web-based questionnaire typically limits follow-up; however, respondents are well known in this small and very active community, and most of the patients and family members consented to continued involvement in the iterative design and testing of tools and resources. Most patients received care at a comprehensive care center; however, we included patients across the spectrum of care (newly diagnosed to advanced disease), and responses were received from 19 states. This initial study focused on decisions about therapeutics and clinical trial enrollment; however, needs assessments are needed for the other difficult decisions identified by the respondents.

Conclusions

Patients with chronic progressive cancers and their families face difficult decisions involving high uncertainty, complex topics, and concerns about potential effects on the family. High-quality patient decision aids are needed that provide information in plain language, explain how to make a decision under uncertainty, incorporate quality of life, address potential effects on family members, and can be revisited over time.

Acknowledgments

The authors would like to thank the patients and family members of the Medullary Thyroid Cancer Registry of the University of Texas MD Anderson Cancer Center and the University of California, San Francisco. The authors also acknowledge the Shared Decision-Making Collaborative and the Duncan Family Institute for Cancer Prevention and Risk Assessment. The authors also greatly thank and acknowledge the important insight and guidance provided by their stakeholder advisory panel, both the individuals who were able to participate as authors as well as Anne Brinkman, Jennifer Morgenthaler, Dwight Vicks, Lu Harris, and Shari Harris. Editorial support was provided by Bryan Tutt, Editing Services, Research Medical Library, the University of Texas MD Anderson Cancer Center. Financial support for this study was provided by an institutional research grant from the University of Texas MD Anderson Cancer Center. The funding agreement ensured the authors' independence in designing the study, interpreting the data, and writing and publishing this paper.

Conflicts of Interest

JAS is a member of the Data Monitoring Committee of the Medullary Thyroid Cancer Consortium Registry and is supported by GlaxoSmithKline, Novo Nordisk, Astra Zeneca, and Eli Lilly. She receives institutional research funding from Exelixis and Eli Lilly. MEC is part of the advisory board in Exelixis. All other authors declare that they do not have any real or perceived conflicts of interest.

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Abbreviations

MTC: medullary thyroid carcinoma
REDCap: Research Electronic Data Capture

Edited by G Eysenbach; submitted 26.01.21; peer-reviewed by H Llewellyn-Thomas, M Basile; comments to author 26.03.21; revised version received 08.04.21; accepted 13.04.21; published 16.07.21.

Please cite as:
Shojaie D, Hoffman AS, Amaku R, Cabanillas ME, Sosa JA, Waguespack SG, Zafereo ME, Hu MI, Grubbs EE
Decision Making When Cancer Becomes Chronic: Needs Assessment for a Web-Based Medullary Thyroid Carcinoma Patient Decision Aid
JMIR Form Res 2021;5(7):e27484
URL: https://formative.jmir.org/2021/7/e27484
doi:10.2196/27484
PMID:34269691

Protocol

Development of Automated Reinforcement Management System (ARMS): Protocol for a Phase I Feasibility and Usability Study

Andre Miguel[1*], PhD; Crystal Smith[1*], PhD; Nicole Perea[2], PharmD; Kim Johnson[3], BS; Michael McDonell[1], PhD; Sterling McPherson[1], PhD

[1]Elson S Floyd College of Medicine, Washington State University, Spokane, WA, United States

[2]College of Pharmacy and Pharmaceutical Sciences, Washington State University, Spokane, WA, United States

[3]Managed Health Connections, Spokane, WA, United States

[*]these authors contributed equally

Corresponding Author:
Andre Miguel, PhD
Elson S Floyd College of Medicine
Washington State University
665 N Riverpoint Blvd
Office 406
Spokane, WA, 99202
United States
Phone: 1 5096866896
Email: andre.miguel@wsu.edu

Abstract

Background: Alcohol use is directly related to over 3 million deaths worldwide every year. Contingency management is a cost-effective treatment for substance use disorders; however, few studies have examined its efficacy for alcohol use disorder. Recent technological advances have enabled the combined use of mobile apps and low-cost electronic breathalyzer devices to remotely monitor alcohol use. Leveraging this type of technology, our study group has recently developed an integrated contingency management system that would enable community treatment programs to remotely deliver contingency management to anyone who owns a smartphone.

Objective: In this paper, we present a full description of our integrated contingency management system, Automated Reinforcement Management System (ARMS), and describe a protocol that will evaluate its feasibility and usability.

Methods: Initially, 6 clinicians will participate in a 1-hour focus group where the study staff will navigate through ARMS as it would be used by clinicians and patients. Clinicians will provide feedback on the intervention in general, which will be used to modify ARMS to make it more user friendly, time saving, and relevant to treatment. A second focus group will summarize the changes made following the initial clinician feedback and will provide additional input regarding the potential utilization of ARMS. Thereafter, the clinicians' acceptability of ARMS will be evaluated using the System Usability Scale. Following the clinicians' assessments of ARMS and final modifications, the system will be evaluated in terms of feasibility and patient usability by using an A-B-A within-subject experimental design wherein 20 treatment-seeking individuals with alcohol use disorder will be recruited. The two A phases (control conditions) will each last 2 weeks, and the B phase (contingency management condition) will last 4 weeks. During all phases, participants will be asked to use the ARMS app to submit three breathalyzer samples per day (at 10 AM, 2 PM, and 8 PM). Participants will be prompted by the ARMS app at these predetermined times to record and submit their breathalyzer samples. During the A phases, participants will earn vouchers for every breathalyzer sample submitted, independent of their sample results. During the B phase, vouchers will be provided contingent upon the submission of alcohol-negative breathalyzer samples (breath alcohol content = 0.00). At the end of the A-B-A experiment trial, patients' usability of the ARMS app will be evaluated using the System Usability Scale. Feasibility will be measured based on whether the ARMS app helped significantly increase alcohol abstinence.

Results: Recruitment for this study began in January 2021 and is expected to be completed by December 2021.

Conclusions: This study will provide the baseline capability for the implementation of a remotely monitored contingency management platform. If successful, ARMS has the potential to provide effective treatment for alcohol use disorders to individuals living in remote rural areas.

(JMIR Form Res 2021;5(7):e25796) doi:10.2196/25796

KEYWORDS

alcohol use disorder; contingency management; ecological momentary assessment; treatment

Introduction

Alcohol use is directly related to over 3 million deaths worldwide each year (ie, 5.3% of all deaths reported annually) and is a casual factor of more than 200 diseases, injuries, and conditions [1]. In the United States, the lifetime and past-year prevalence of alcohol use disorder (AUD) are 29.1% and 13.9%, respectively [2], making it the most prevalent substance use disorder in the country [3].

Contingency management is an effective treatment for substance use disorders that consists of providing reinforcement (ie, rewards) after an objective verification of drug abstinence through the submission of a substance-negative biospecimen [4-6]. Although the efficacy of contingency management has been demonstrated for a range of substance use disorders [7-9], fewer studies have examined the efficacy of contingency management for AUD [10-14]. This was primarily due to the lack of biomarkers that could detect alcohol consumption for prolonged periods. Until recent years, the only commercially available biomarker for alcohol use was breath alcohol content (BAC), assessed using breathalyzers that measure the concentration of ethanol in an individual's breath [15,16]. Although accurate, this biomarker can only detect alcohol use for up to 12 hours after consumption; moreover, when used infrequently, it is a tool better used to assess intoxication rather than abstinence [14]. As a result, to accurately assess recent alcohol consumption, contingency management interventions using a breathalyzer require individuals to be physically present at an office or treatment center to submit samples multiple times per day [14], limiting the feasibility of such an approach.

Fortunately, recent technological advances have enabled the combined use of mobile apps and low-cost consumer electronic breathalyzer devices to remotely monitor alcohol use [17,18]. Studies wherein smartphone apps and remote breathalyzers were used to provide contingency management for AUD have found them to be effective in promoting alcohol abstinence [17,19,20]. Although other technologies, such as prescription digital therapeutics (eg, reSET and reSET-O by Pear Therapeutics), have been approved by the US Food and Drug Administration (FDA) for substance use disorders, they have not directly targeted substance abstinence. As a result, to date, app-based contingency management technologies for alcohol use have yet to be integrated into AUD treatment programs and evaluated in community treatment settings.

To further advance research on the use of technology to address AUD and to enable the development of more effective treatment strategies, our research group has partnered with Managed Health Connections [21] to develop an integrated, end-to-end contingency management system that would enable community treatment programs to deliver contingency management remotely to anyone who owns a smartphone and seeks to reduce their alcohol consumption. In this methods paper, we present a full description of an integrated contingency management system, termed Automated Reinforcement Management System (ARMS), and describe the protocol that will evaluate its feasibility and usability.

Methods

Participants

This study will be conducted within the community and with community clinic partners in Spokane, WA, USA, under the auspices of the Washington State University Program of Excellence in Addictions Research at the Analytics and PsychoPharmacology Laboratory. In this phase 1 study, a total of 6 clinicians and 20 patients will be recruited. Patients of either biological sex who are 18 years of age or older and have an Alcohol Use Disorders Identification Test (AUDIT) [22] score of 8 or higher will be eligible to enroll in the study. Participants must read and speak English and have the ability to provide written informed consent. Patients with severe AUD or a co-occurring psychotic disorder according to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) [23], with significant risk of dangerous alcohol withdrawal (defined as a history of alcohol detoxification or seizure in the last 12 months and expression of concern by the individual about dangerous withdrawal), or with a lifetime suicide attempt or suicidality in the past year will not be eligible for enrollment in the study.

Study Design

To evaluate the feasibility and usability of ARMS delivered in treatment settings, our research team has designed a three-step study where ARMS will be evaluated by both treatment providers and patients. Initially, 6 clinicians will participate in a 1-hour-long interview or focus group (depending on their availability) that will describe and provide visuals of the contingency management intervention and introduce patient- and provider-facing apps. Study staff will navigate through the program in ways consistent with both clinician and patient users. Clinicians will also participate in a semistructured interview where they will be asked to provide information on their standard protocol when working with patients who have AUD, such as how they currently track progress and communicate with patients. Furthermore, they will be asked to provide feedback on the intervention in general, including why they would or would not use the app, suggestions for improvement, app usability, potential obstacles that may be encountered with the use of the app, preferences for accessing the data generated by the app, and preferences on which data they would prefer to have highlighted briefly.

The information provided by the clinicians in this first focus group will then be used to modify ARMS to make it more user friendly, time saving, and relevant to treatment (possibly by incorporating new features that may assist treatment). A second focus group will then summarize the changes made following

the clinician feedback and provide deidentified user data allowing clinicians to navigate through the system and provide additional feedback regarding the potential utilization of patient data.

Once the modifications are made in response to the second wave of clinician feedback, ARMS will be evaluated primarily for efficacy but also for feasibility and patient usability through an A-B-A (or, "return-to-baseline") completely within-subject experimental design. Following similar single subject-design studies conducted by our group [20,24], the two A phases will each last 2 weeks and the B phase will last 4 weeks, for a total study duration of 8 weeks. During all phases, participants will be asked to use the ARMS app to submit breathalyzer samples at 10 AM, 2 PM, and 8 PM each day. Submission of each sample should take less than 5 minutes. Participants will be prompted by their ARMS app to record and submit their breathalyzer samples at these predetermined times and will have a half-hour window following the prompt to submit each sample. During the A phases (control conditions), participants will earn US $2 in vouchers for every breathalyzer sample submitted during the predetermined period, independent of their sample results. Notably, this reward system will be in effect for both the first and second A phases. During the B phase (contingency management condition), vouchers will be provided contingent upon the submission of alcohol-negative breathalyzer samples—that is, breath alcohol content (BAC) = 0.00. Participants will begin by receiving vouchers worth US $2 per alcohol-negative breath sample submitted, with the value escalating by US $0.25 per alcohol-negative sample submission to a maximum value of US $3.50 per submission. Vouchers will be reset to US $2 per sample if a participant does not submit a sample in the predetermined period, if an alcohol-positive breath sample is submitted, or if the participant cannot be identified from the facial recognition photo (see details below).

At the end of the A-B-A experiment trial, the patients' acceptability of ARMS will be evaluated with the System Usability Scale (SUS).

Assessments

Assessments collected in this study will include sociodemographic and medical or treatment history data, the Mini-International Neuropsychiatric Interview [25], Addiction Severity Index-Lite (ASI) [26], Brief Symptom Inventory (BSI) [27], DSM-V [23], Fagerström Test for Nicotine Dependence [28], AUDIT [22], Alcohol Urge Questionnaire (AUQ) [29], and 15D Health-Related Quality of Life (HRQoL) [30]. Alcohol use will be measured using the Alcohol Timeline Follow Back (ATFB) method [31], and BAC results will be collected via the ARMS app. Both the providers' and patients' acceptability toward ARMS will be evaluated using the SUS [32]. For the assessment schedule, see Table 1.

Table 1. Assessment schedule for the A-B-A design experimental trial.

Content	Baseline	A-B-A							
	Week 0	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
Informed consent	✓								
Sociodemographic	✓								
Medical/treatment history	✓								
DSM-V[a]	✓								
Mini-International Neuropsychiatric Interview	✓								
Addiction Severity Index: ASI-Lite	✓		✓		✓		✓		✓
15D Health-Related Quality of Life	✓		✓		✓		✓		✓
Alcohol Urge Questionnaire	✓	✓	✓	✓	✓	✓	✓	✓	✓
Fagerström Test for Nicotine Dependence	✓		✓		✓		✓		✓
Alcohol Use Disorders Identification Test (AUDIT)	✓	✓	✓	✓	✓	✓	✓	✓	✓
Brief Symptom Inventory (BSI)	✓		✓		✓		✓		✓
Alcohol use (biochemical BAC[b])	✓	3 times per day							
Alcohol Timeline Follow Back (self-report)	✓	✓	✓	✓	✓	✓	✓	✓	✓
Patient acceptability: System Usability Scale		✓	✓	✓	✓	✓	✓	✓	✓

[a]DSM-V: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition.

[b]BAC: blood alcohol content.

ARMS Mobile App Intervention

ARMS is a hybrid mobile/IOS web-based app for contingency management designed to integrate with the electronic medical record of treatment programs, providing clinicians with an adjunctive treatment modality to (1) administer contingency management treatment to patients with AUD remotely, (2) access updated patient information that can be critical to the

clinical management of AUD, and (3) communicate safely and directly with patients through the ARMS app. ARMS includes two separate interfaces: (1) a mobile/IOS interface to be used by patients and (2) a web-based application to be used by treatment providers.

Patient Interface and Dashboard

The patient interface includes five features: (1) recording and submitting breathalyzer samples, (2) recording and submitting ecological momentary assessments (EMAs) on moods and executive function that may be pertinent to treatment, (3) reminders and messages, (4) redemption of rewards, and (5) a patient dashboard (see below for more details). To comply with the Health Insurance Portability and Accountability Act requirements, ARMS uses a user-protected login for access.

Breathalyzer Sample Recording and Submission

A critical aspect of the contingency management component involves providing rewards contingent upon the objective verification of alcohol abstinence. In ARMS, the patient mobile interface syncs via Bluetooth with a BACtrack breathalyzer device, enabling the recording and submission of breathalyzer sample results from the BACtrack device to the ARMS app. The app prompts users, instructing them to place their face in the center of a square displayed on their phone screen while blowing into the breathalyzer. A photo is then captured to allow for facial recognition of the patient submitting the sample (ie, a full-face image is required to conduct the facial recognition). Immediately after the breathalyzer result is captured, the ARMS app presents both the breathalyzer result and the facial image and provides the patient the option to submit the breathalyzer result to their provider. If the patient agrees with the breathalyzer result and believes that the captured image will allow them to be identified, they can click on “submit” and the breathalyzer result will be uploaded onto a secure server accessible only by their treatment providers and the study researchers. If the patient does not agree with the breathalyzer result or believes that the photo will not allow for facial recognition, the option to submit another sample can be chosen.

Ecological Momentary Assessment

After the submission of the breathalyzer result, ARMS will prompt the patient to respond to 3 to 5 questions about moods and states that might be pertinent to the patient’s recovery. As shown in Table 2, the ecological momentary assessment (EMA) questions include options that were created based on the Addiction Neuroclinical Assessment (ANA) framework developed by Kwako et al [33,34], which postulates that three domains defined as poor executive functioning (ie, working memory and impulsivity), negative emotionality (eg, depression, anxiety, and symptoms of withdrawal), and incentive salience (eg, thinking about and/or craving alcohol) are the primary factors that cause and maintain addictions [33-37]. Kwako and colleagues [33] propose that ANA domains, assessed by self-reports and cognitive testing, as well as genetic analysis and, eventually, neuroimaging, can be used to identify groups of patients who do not respond to existing treatments. The ANA also provides a framework to guide treatment adaptations to improve outcomes for specific groups (ie, nonresponders or more severe disease groups). Furthermore, it can be used to match individuals to specific interventions based on their ANA characteristics. Thus, the ANA may provide an ideal structure for developing a personalized medicine approach to integrated treatment for AUD.

Table 2. Description of the ecological momentary assessment (EMA) questions.

EMA question	Type of response	ANA[a] domain
Since your last assessment, how much have you craved alcohol?	5-point Likert scale	Reward salience
I want to drink so bad I can almost taste it.	5-point Likert scale	Reward salience
How happy do you feel right now?	5-point Likert scale	Negative emotionality
How sad do you feel right now?	5-point Likert scale	Negative emotionality
How relaxed do you feel right now?	5-point Likert scale	Negative emotionality
How Stressed do you feel right now?	5-point Likert scale	Negative emotionality
How bored do you feel right now?	5-point Likert scale	Negative emotionality
How irritable do you feel right now?	5-point Likert scale	Negative emotionality
In the last two hours have you been doing things without thinking?	5-point Likert scale	Executive functioning
In the last two hours have you been acting on impulse?	5-point Likert scale	Executive functioning
In the last two hours have you felt self-controlled?	5-point Likert scale	Executive functioning

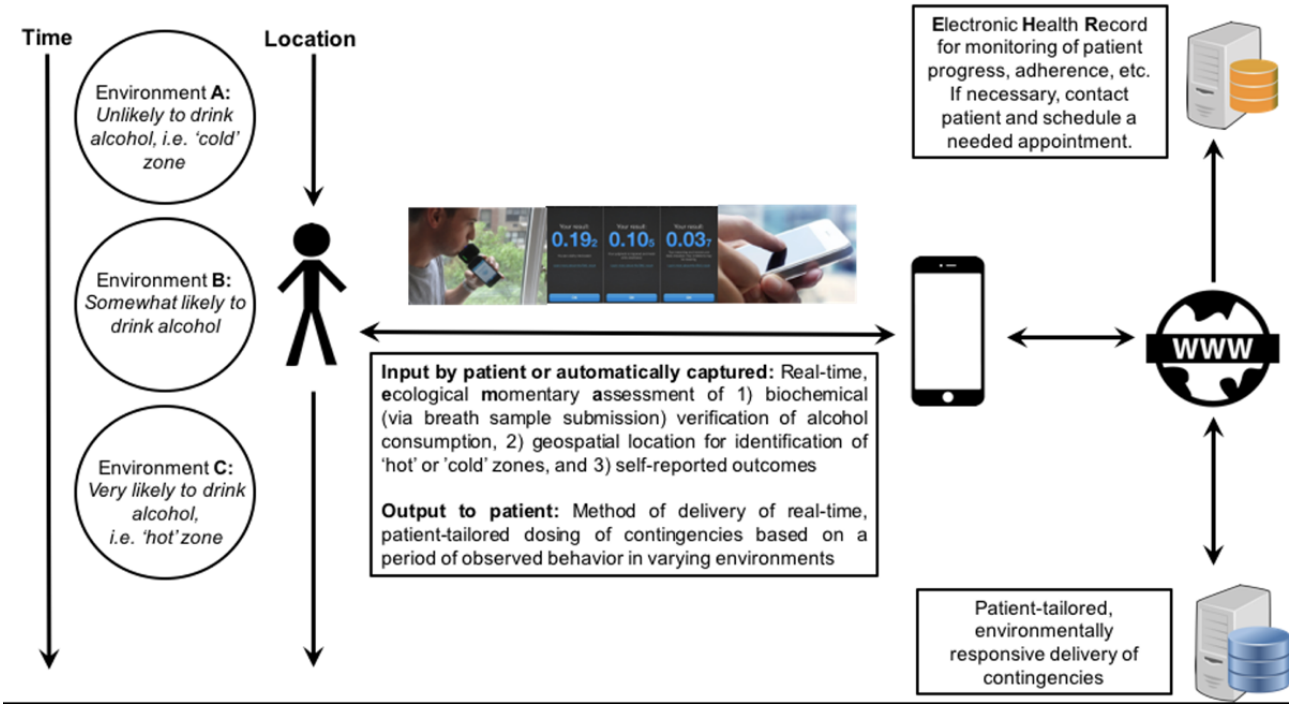
[a]ANA: Addiction Neuroclinical Assessment.

The EMA questions in ARMS will provide clinicians and researchers with relevant real-time information about their patients’ states and moods specific to the three ANA domains. This information may serve multiple purposes. First, comparing the EMA answers and breathalyzer results of the general patient population may assist clinicians in identifying specific traits and states associated with positive or negative treatment outcomes, possibly enabling them to identify, at the beginning of treatment, whether a participant may benefit from more intensive care. Second, and perhaps more important, by comparing the EMA answers and breathalyzer results of a specific patient, clinicians may be able to identify specific cognitions and moods associated with risks of future relapse, enabling them to intervene before relapse occurs.

Reminders and Messages

To promote compliance and recovery, the ARMS app will send reminders when it is time to submit the breathalyzer samples and EMA responses. It will also send an alert when patients fail to submit a sample. To further enhance treatment response, ARMS will also send reinforcing messages. These messages range from congratulating patients when they reach a certain milestone (eg, "Three straight days of alcohol abstinence, keep up the good work!") to encouraging them after relapse (eg, "Treatment success is not about falling but how quickly we pick ourselves up" and "Tomorrow you get another chance to do what's right by you!"). Patients will also receive messages confirming their breathalyzer sample submissions and facial image validations, as well as messages informing them about the number of rewards earned in the contingency management intervention. Figure 1 presents an overall schematic of how ARMS functions.

Figure 1. Data capture and participant flow.



Redeeming Rewards

Patients will be able to use the ARMS app to redeem the credit earned immediately after the breathalyzer sample is validated. Patients can choose to redeem any specific amount in the form of a digital gift card sent to a preregistered email address. The gift card information will also be stored in both the patient's and provider's ARMS interfaces.

Provider Interface

All data collected in the patient's mobile ARMS app will be stored securely in a database that can be accessed by providers from the provider dashboard. This web-based console allows providers to register new patients, access and evaluate patient performance, and validate the authenticity of the breathalyzer samples submitted. Furthermore, the provider dashboard provides an easy way for providers to identify patients that may need more personalized care by displaying a summary of the status of all patients enrolled in the system, with nonadherent patients or patients failing to achieve their goals being placed at the top of the list. The ARMS provider interface was also created to integrate directly into electronic medical record systems using standard health information exchange formats, such as Health Level Seven (HL7; a specific method for the exchange, integration, sharing, and retrieval of electronic health information) and Clinical Core Document (which offers updates to previous efforts by HL7), thereby enabling clinicians to receive progress alerts based on nonadherence and overall status. These provider alerts are customizable to accommodate variations in workflow.

ARMS Contingency Management Intervention

Contingency management interventions involve providing reinforcement (ie, rewards or incentives) after a targeted behavior is exhibited. In the field of substance use disorder treatment, contingency management usually consists of providing vouchers of monetary value after a specific period of substance abstinence is verified through the submission of a negative drug screening sample. The combination of features present in ARMS and the BACtrack breathalyzer device enables the provision of contingency management remotely to any patient that owns a smartphone. To provide more personalized care, the ARMS contingency management intervention is flexible, allowing providers to modify and adjust several components of the intervention. This flexibility allows providers to mold the contingency management intervention to best suit the patient's specific needs as well as to adapt it to the daily clinic routine.

To initiate the contingency management intervention with ARMS, treatment providers will select the type of response that will be targeted in that intervention (eg, alcohol abstinence and

low levels of alcohol use), the schedule of reinforcement (ie, the number of samples to be submitted daily), and the duration of the intervention. After these parameters are set, patients will be prompted by their ARMS app to record and submit their breathalyzer samples at the predetermined times. To reduce the burden or other inconveniences related to sample submission, patients will have a half-hour window to submit each sample following the prompt. After a sample is submitted, patients will receive a message stating that the sample was received and is currently awaiting verification. A research staff member will then have 24 hours to confirm the patient's identity (based on the facial image captured at the time of sample collection). The research staff member will be presented with a recommendation for approval or rejection based on facial recognition verification. This process will be evaluated for the potential to automate verification. After providers verify the authenticity of the sample, patients will be immediately informed that the sample was verified and, when the target response is achieved (ie, confirmed alcohol abstinence), patients will be notified of the number of rewards earned. If the sample is deemed invalid or the target behavioral response is not accomplished, patients will be notified of the reason they did not earn the reward.

Buildout Options

There are additional features that are either in progress or are planned for future iterations. One such feature is to enable the selection of different target responses such as abstinence (ie, BAC=0.00) or reduction of heavy drinking (ie, BAC=0.08). We also plan to enable the selection of different options related to specific components of the contingency management intervention; for example, setting the expected number of sample submissions to be fewer than 3 submissions per day, scheduling sample requests at different times of day, or using artificial intelligence to conduct immediate facial recognition after the BAC sample is submitted**.** We also intend to make reminders multimodal so that they can reach users through different means based on their preferences. Users would thus be able set up their reminders as local alarms on their smartphone device or receive them via push, SMS text messages, or automated voice calls.

Another feature that is in progress but will not be active during this phase 1 study is defining patient-specific "hot zones" (and "cold zones") using a type of geolocation "fence" in an effort to provide patients with feedback and alert them when they are entering a physical area or location where they have not achieved their stated drinking goals (Figure 1). Finally, we plan to develop additional dashboard features, including the ability for patients to see which EMA responses are correlated with alcohol outcomes over time and which factors are most likely associated with craving and alcohol use, to promote additional awareness of executive function and moods associated with relapse.

Outcomes

Patient usability will be evaluated using the SUS [32] collected at the end of the A-B-A experimental trial. The use of SUS has been recently recommended by the FDA, and it has been used to evaluate the usability of similar technologies. For this study, a nominal SUS score of 68 or higher will be considered as our target score. The feasibility of ARMS will be measured by whether ARMS could significantly increase alcohol abstinence. Other outcomes will include patient adherence to and compliance with the ARMS app considering (1) the proportion of participants that complete the experiment, (2) the proportion of breathalyzer samples submitted, and (3) the proportion of EMA questions answered during the trial. Additional secondary outcomes will include the efficacy of ARMS considering (1) self-reported alcohol use (ATFB), (2) levels of alcohol craving (AUQ), and (3) overall life-functioning (ASI, BSI, and HRQoL). Finally, we will explore whether and how the ANA framework responses collected thrice daily with EMA correlate with alcohol use or abstinence. For instance, we expect that the information captured with the EMA and breathalyzer results will allow the identification of specific mood and state traits that may predict future relapse and, thus, enable the development of personalized relapse prevention strategies.

Results

Recruitment for this study began in January 2021. Data collection will be finalized by December 2021, and we expect to publish our results by the second semester of 2022.

Discussion

Principal Findings

There currently exists a gap in our knowledge of how to best treat people who wish to reduce their alcohol use, especially in a real-time manner and among those dwelling in areas where access to in-person treatment may be challenging. It is well understood that contingency management is one of the most effective interventions for substance use disorders; however, contingency management has not been widely applied in the field of AUD treatment, in part, because of the difficulty of detecting alcohol abstinence using standard breath alcohol test procedures [15,38]. Our study capitalizes on recent technological advances and clear collaboration potential between academia and start-up companies to partner and develop a smart phone-based contingency management application enabling remote delivery adjunctive treatment for individuals seeking outpatient treatment for AUD.

This phase 1 project will provide baseline capability for the implementation of a remotely monitored contingency management platform. The clinician and user feedback will provide insight into enhancements that can increase utilization and effectiveness. Future capabilities may include (1) adaptation of report-back thresholds to address heavy drinking in addition to abstinence, (2) customization of report-back windows to accommodate user schedules, (3) multimodal reminders (SMS, email, etc) for users and trusted caregivers, (4) geolocation-related alcohol use reporting, and (5) enhanced feedback based on correlations of multiple data points with alcohol use. After completion of this study, we plan to have the necessary information to develop a phase-2 effectiveness trial.

Limitations

This study has some potential limitations that should be noted. First, in this current stage, ARMS was developed to be used in iOS only. Although this decision was decided strictly due to

our budget, we intend to build ARMS for Android as part of our phase 2 trial. Second, this study did not include formal focus groups with the participating patients to evaluate the acceptability and suggestions for improvements by participants. We intend to incorporate such focus groups as part of our phase 2 trial.

Acknowledgments

We would like to thank Amy Sullivan at Obrizus Communications for editing the manuscript.

Conflicts of Interest

This work was performed under a grant from the National Institute for Alcohol Abuse and Alcoholism under the Small Business Innovation Research and Small Business Technology Transfer Research (SBIR/STTR) program. KJ is the Managing Member of Managed Health Connections, LLC, the developer of the software programs implementing the methods.

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Abbreviations

ANA: addiction neuroclinical assessment
ARMS: Automated Reinforcement Management System
ASI: Addiction Severity Index-Lite
ATFB: Alcohol Timeline Follow Back
AUD: alcohol use disorder
AUDIT: Alcohol Use Disorders Identification Test
AUQ: Alcohol Urge Questionnaire
BAC: blood alcohol content
BSI: Brief Symptom Inventory
DSM-V: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition
EMA: ecological momentary assessment
FDA: Food and Drug Administration
HL7: Health Level Seven
HRQoL: 15D Health-Related Quality of Life
SUS: System Usability Scale

Edited by G Eysenbach; submitted 16.11.20; peer-reviewed by M Koffarnus, M Sobolev, B Raiff, H Mehdizadeh; comments to author 24.12.20; revised version received 12.04.21; accepted 31.05.21; published 19.07.21.

Please cite as:
Miguel A, Smith C, Perea N, Johnson K, McDonell M, McPherson S
Development of Automated Reinforcement Management System (ARMS): Protocol for a Phase I Feasibility and Usability Study
JMIR Form Res 2021;5(7):e25796
URL: https://formative.jmir.org/2021/7/e25796
doi:10.2196/25796
PMID:34279238

Original Paper

Design, Development, and Evaluation of a Telemedicine Platform for Patients With Sleep Apnea (Ognomy): Design Science Research Approach

Pavankumar Mulgund[1], PhD; Raj Sharman[1], PhD; Daniel Rifkin[2], MD; Sam Marrazzo[3], MBA

[1]State University of New York at Buffalo, Buffalo, NY, United States

[2]Sleep Centers of Western New York, Buffalo, NY, United States

[3]Buffalo Niagara Medical Campus, Inc, Buffalo, NY, United States

Corresponding Author:
Pavankumar Mulgund, PhD
State University of New York at Buffalo
333 Jacobs Management Center
UB North Campus
Buffalo, NY, 14260
United States
Phone: 1 7166453271
Email: pmulgund@buffalo.edu

Abstract

Background: With an aging population and the escalating cost of care, telemedicine has become a societal imperative. Telemedicine alternatives are especially relevant to patients seeking care for sleep apnea, with its prevalence approaching one billion cases worldwide. Increasing awareness has led to a surge in demand for sleep apnea care; however, there is a shortage of the resources and expertise necessary to cater to the rising demand.

Objective: The aim of this study is to design, develop, and evaluate a telemedicine platform, called Ognomy, for the consultation, diagnosis, and treatment of patients with sleep apnea.

Methods: Using the design science research methodology, we developed a telemedicine platform for patients with sleep apnea. To explore the problem, in the analysis phase, we conducted two brainstorming workshops and structured interviews with 6 subject matter experts to gather requirements. Following that, we conducted three design and architectural review sessions to define and evaluate the system architecture. Subsequently, we conducted 14 formative usability assessments to improve the user interface of the system. In addition, 3 trained test engineers performed end-to-end system testing to comprehensively evaluate the platform.

Results: Patient registration and data collection, physician appointments, video consultation, and patient progress tracking have emerged as critical functional requirements. A telemedicine platform comprising four artifacts—a mobile app for patients, a web app for providers, a dashboard for reporting, and an artificial intelligence–based chatbot for customer onboarding and support—was developed to meet these requirements. Design reviews emphasized the need for a highly cohesive but loosely coupled interaction among the platform's components, which was achieved through a *layered modular* architecture using third-party application programming interfaces. In contrast, critical findings from formative usability assessments focused on the need for a more straightforward onboarding process for patients, better status indicators during patient registration, and reorganization of the appointment calendar. Feedback from the design reviews and usability assessments was translated into technical improvements and design enhancements that were implemented in subsequent iterations.

Conclusions: Sleep apnea is an underdiagnosed and undertreated condition. However, with increasing awareness, the demand for quality sleep apnea care is likely to surge, and creative alternatives are needed. The results of this study demonstrate the successful application of a framework using a design science research paradigm to design, develop, and evaluate a telemedicine platform for patients with sleep apnea and their providers.

(JMIR Form Res 2021;5(7):e26059) doi:10.2196/26059

KEYWORDS

design science research; telemedicine platform; sleep apnea care; mHealth; telemedicine; sleep apnea; mobile health; web application; mobile phone

Introduction

Background

The National Sleep Foundation defines obstructive sleep apnea (OSA) as a chronic condition characterized by involuntary breathing cessation while the patient is asleep. It is a common disorder that affects more than 22 million Americans [1]. A previous study estimated that OSA affects 26% of adults aged between 30 and 70 years [2]. Gender, age, family history, obesity, smoking, and alcohol use often make patients more vulnerable to OSA. Furthermore, OSA is increasingly recognized as a risk factor for medical conditions, such as hypertension, cardiovascular diseases, and stroke [3]. Therefore, it is important to diagnose and treat OSA early. Continuous positive airway pressure (CPAP) remains the gold standard for treatment [4]. For patients who do not respond to CPAP, other treatment options may be prescribed based on the severity of the condition. Increasing awareness coupled with better prognosis from timely interventions has led to an exponential surge in the demand for evaluation and treatment services, but there has not been a commensurate increase in resources to deal with this increasing demand. The diagnosis and treatment of OSA are particularly challenging from an operational perspective because of the limited number of sleep clinics [5]. To compound this problem, there is also an acute shortage of clinical expertise for delivering these services, with the ratio of general population to certified sleep specialists being as high as 43,000:1 [6]. The situation is further exacerbated by their inequitable distribution, with most specialists serving in urban areas. Therefore, there is a need to explore other approaches for diagnosing and treating patients with sleep apnea. Telemedicine is a potentially viable alternative.

In this study, we explore this alternative by developing and evaluating a telemedicine platform for the diagnosis and treatment of OSA. Specifically, we addressed the following two research questions:

- How can we conceptualize and design a patient-first telemedicine platform to provide high-quality sleep care to patients from the comfort of their homes?
- How can we evaluate the artifact's design quality and its potential in reducing access barriers and operational bottlenecks in the diagnosis and treatment of sleep apnea?

Following the design science research (DSR) framework [7,8], we developed a telemedicine platform called *Ognomy* (North American Sleep Management Inc), where the data collection, consultation with physicians, patient education, and monitoring occur using a mobile app. Access to nursing staff, sleep technicians, and physicians is available through video consultation. Artificial intelligence (AI)–based chatbots for self-help and helpline contacts are provided to assist care seekers in using the app effectively. Such a platform is expected to reduce costs and increase access to care while maintaining quality expectations.

Telemedicine Background

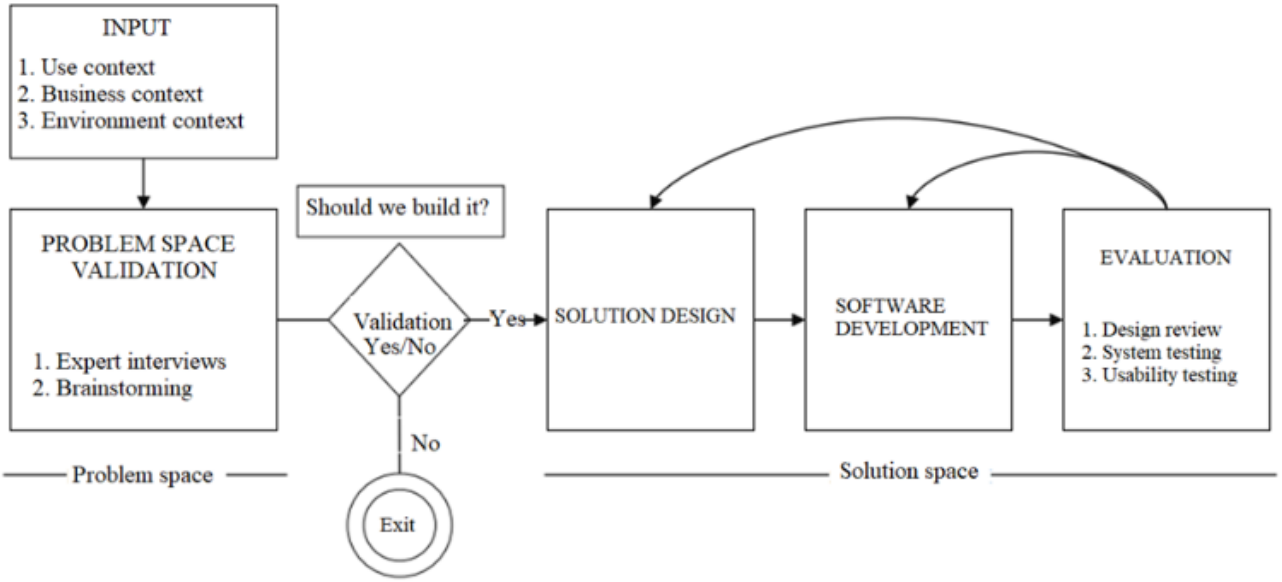
The World Health Organization defines telemedicine as "the use of information and communication technologies in the delivery of health care services, the diagnosis of a condition, prevention of diseases and injuries, treatment, research, and evaluation of patients at a distance" [9]. Owing to its advantages, the development, deployment, and use of telemedicine have surged in the United States [10] and other developed nations [11]. Recent studies have shown that telemedicine interventions effectively improve clinical outcomes [12], decrease costs by reducing expensive inpatient service utilization [13], and provide a superior patient experience [14], particularly in the areas of chronic disease management, such as diabetes [15], chronic heart diseases [16], thyroid disorders [17], varicose veins [18], stroke [19], mental and emotional health issues [20], and sexually transmitted diseases [21]. Previous research has also discussed the benefits, drawbacks, and barriers to the adoption of telemedicine. Some common barriers include patients' poor perception of its efficacy [22], nonacceptance by insurance companies [23], and technology hurdles [24]. However, with the growing maturity of technology platforms and increasing patient acceptance, telemedicine interventions have begun to overcome these barriers. A study by Watson et al [25] found that monitoring patients via telemedicine is as effective as traditional medical processes. Furthermore, some studies [26,27] have explored the use of telemedicine to monitor compliance with CPAP therapy. However, the design of telemedicine interventions that focus on testing and diagnosing patients with OSA has not been well addressed in previous research. Our study addresses this gap by developing a comprehensive telemedicine platform that caters to all stakeholders involved in seeking and providing OSA care.

Methods

Overview

Overall, we follow a DSR approach, a principal research methodology that has evolved within the information systems (ISs) discipline. It is defined as the development of a system by an iterative process of developing and evaluating artifacts [28]. The primary goal of this study is to define and develop a telemedicine platform that caters to all stakeholders involved in diagnosing, treating, and managing sleep apnea. Previous research has discussed the process of conducting and evaluating design science [29]. We used the framework suggested by Horvath [30]. Our research approach is illustrated in Figure 1.

Figure 1. Design science research approach.



Furthermore, this framework divides DSR into three phases: (1) exploring the problem, the context, and the activities using activity theory; (2) designing and developing solutions; and (3) evaluating solutions and generalizing design principles.

We present the details of the abovementioned three phases in the following sections.

Exploration of the Problem, Context, and Activities Using Activity Theory

We used activity theory to guide our understanding of the end user and business context. According to activity theory, an activity is a basic unit of analysis [31], which includes six components: (1) subjects or people involved in the activity, (2) object or intended goal of the activity, (3) tools that mediate the activity, (4) rules imposed by the business environment, (5) division of labor among various stakeholders in the organization, and (6) the community impacted by the activity. Activity theory was an apt choice for our study because it emphasizes developing a comprehensive understanding of the environment in which the system operates (which includes participants and subsystems), including all the complexity that manifests from the interactions of various actors in the real world rather than from the limited viewpoint of a single actor [32]. Furthermore, activity theory allows us to develop flexible systems that dynamically cater to various users' specific workflows, such as patients, providers, office administrators, and information technology (IT) staff. Contemporary activity theory focuses on the interaction of several systems of activities to investigate a complex social phenomenon. In doing so, it brings to the fore some of the deeply embedded contextual issues associated with the research topic [33].

At the outset, we identified the key stakeholders (subjects) involved in the process of seeking and providing care for sleep apnea, including patients, providers, referring physicians, administrative staff such as billers and coders, and back-office personnel. To develop a deeper understanding of their roles in seeking and providing care, the resources they require, and the challenges they face, we conducted six structured interviews with each of these stakeholders and two brainstorming workshops. Details of interview participants and interview questions are presented in Multimedia Appendix 1. The dimensions of activity theory guided the questions and the line of inquiry. On the basis of interviews and brainstorming sessions, we identified Health Information Portability and Accountability Act (HIPAA) application forms, health forms, information about the diagnosis, and treatment protocols as critical resources. Enrollment, consultation, and monitoring emerged as crucial processes. In the interviews, patients expressed a strong preference for a mobile app for consultation, whereas providers favored a web portal for documentation, reporting, and integration with an electronic medical record (EMR) system. During the interviews, the collection of patient information, such as personal and contact details, HIPAA consent, insurance information, and prior health history, emerged as a crucial design challenge. The crux of the problem was to collect all relevant data from patients without overwhelming them. Owing to their limited interactivity, traditional data entry forms are not very effective in engaging users, especially when a large amount of information is collected. Guided by prior research on the effectiveness of chatbots in improving patient engagement [34,35] and care experience [36], we decided to develop a rule-based AI chatbot for enhanced engagement and better patient interaction.

In addition, stakeholders pointed out several business rules and constraints that emerged from the business context. These rules are subsequently coded into the system to develop a patient-first, state-of-the-art telemedicine platform for patients with OSA. The contextual details are presented in Table 1 along the dimensions of activity, subject, instrument, object, division of labor, community, and rules.

Table 1. Medical activity system mapped to technical activity system.

Activity theory construct	End user context	System construct
Subject	• Patient with sleep apnea • Providers • Admin staff • Sleep technicians • Billing and patient support	• Built-in customizable user interface to sign-in users • Adaptive authentication
Rules	• Referrals or self-referrals rules • Rules of patient health status tracking • Previous health or surgical history of the patient • Health Information Portability and Accountability Act rules • Positive air pressure compliance rules • App terms and conditions	• Multiple patient workflows • Multiple compliance program rules • Managing patient progress • Maintenance of health care database records
Division of labor	• Doctors: provide treatment • Sleep technicians: monitor sleep laboratory • Admin staff: process billing and offer patient support • Insurance: review and pay claims • Vendors: manufacture and ship device	• Integration with reusable business services such as payment, video consultation, and role-based access control • Dashboards for multiple users (physicians, patients, administrators, and technicians)
Community forum	• Patients • Primary care physicians • Sleep specialists • Administrators • Management • Information technology service providers • CPAP[a] vendors	• Social and enterprise identity federation • Integration with Facebook and Instagram • Offering support services • Access control for AWS[b] resources
Instrument	• Frontline • Mobile app for patient • Web app for doctors • Virtual assistants for patient onboarding and support • Dashboard to track patient progress • Enabler • HST[c] device • CPAP device • Infrastructure AWS (cloud)	• Artificial intelligence–based responsive chatbot • Order management • CPAP tracking • HST tracking
Object	• Objective: provide a telemedicine platform for the diagnosis, treatment, and management of sleep apnea • Outcome: seek to improve the condition of patients with sleep apnea	• N/A[d]

[a]CPAP: continuous positive airway pressure.

[b]AWS: Amazon Web Services.

[c]HST: home sleep test.

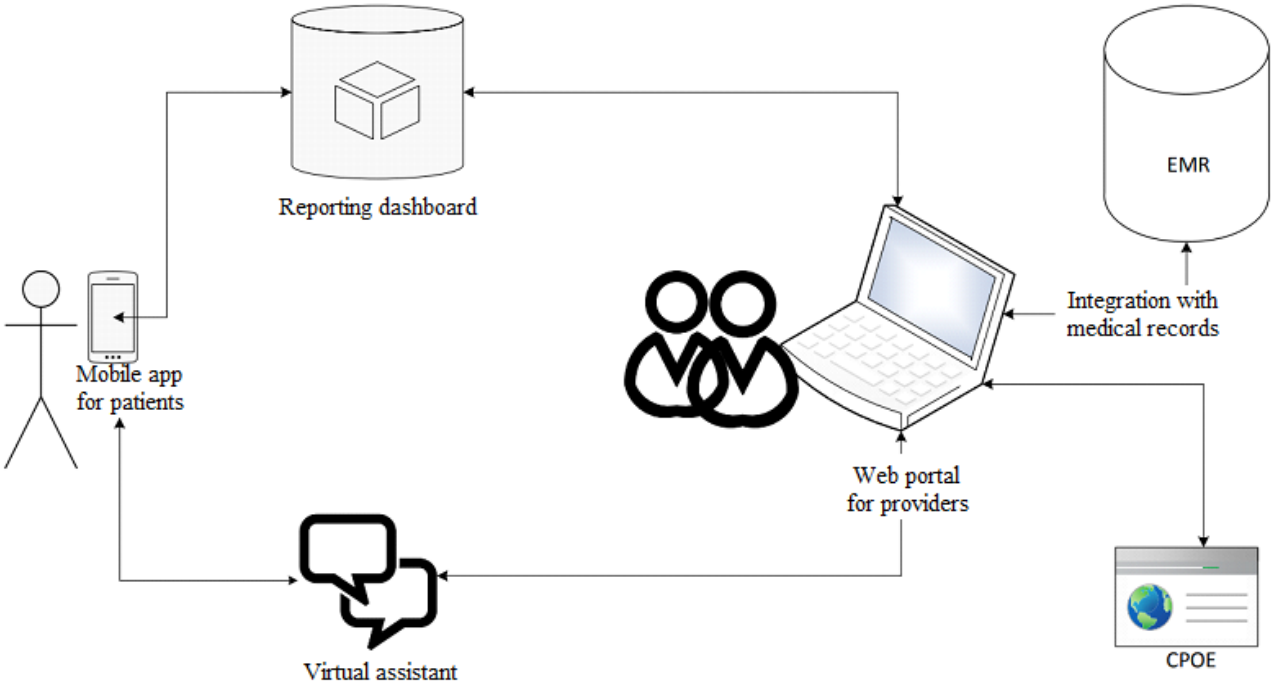
[d]N/A: not applicable.

System Design and Development

Product Concept

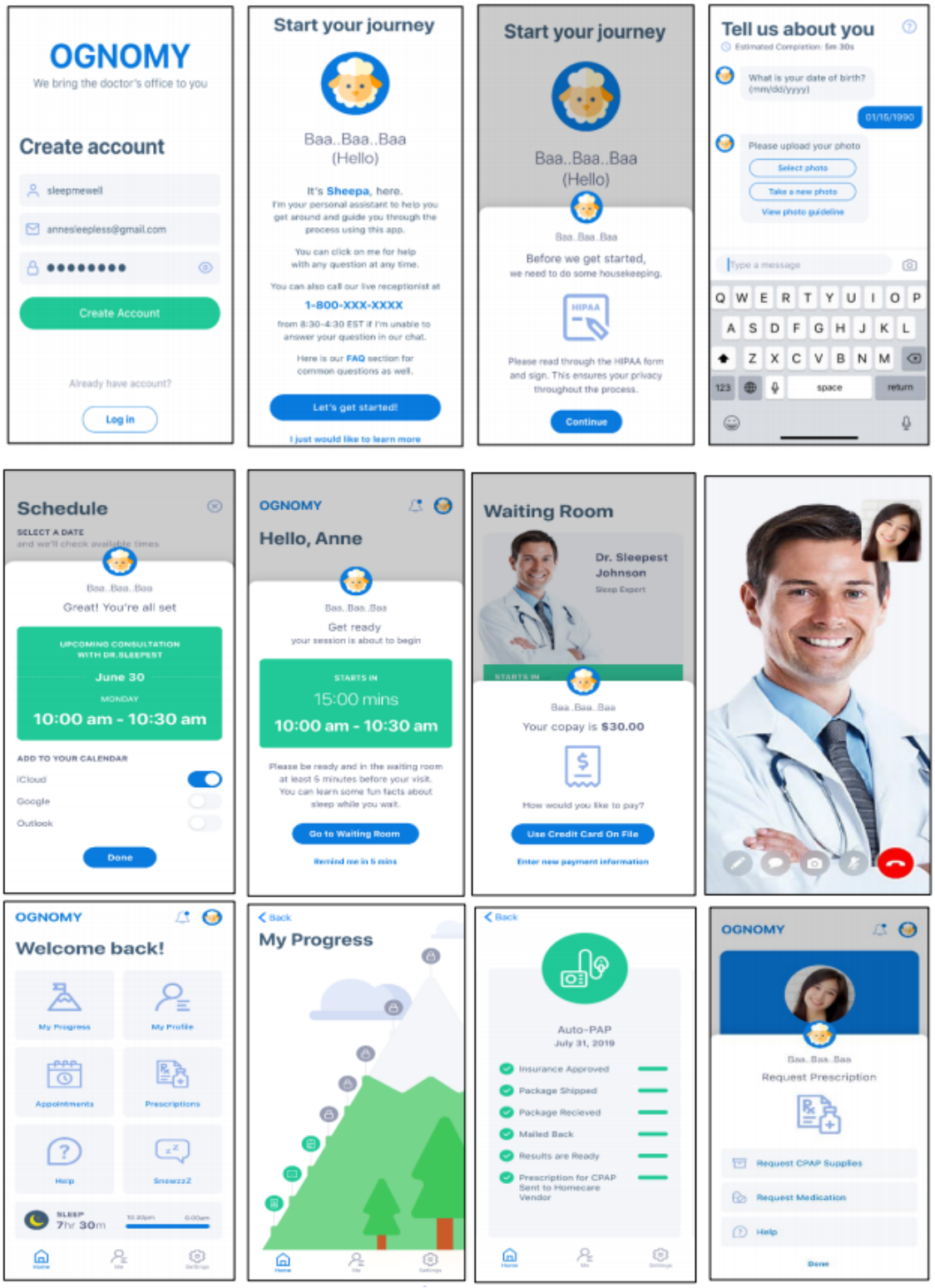
In this section, we describe the development of the four specific artifacts that support the needs of all stakeholders involved in seeking and providing care. These artifacts include (1) a mobile app for patients, (2) a web app for providers, (3) a dashboard for reporting, and (4) an AI-based chatbot for patient onboarding and support. This telemedicine platform is an example of a design science approach. The ecosystem of the telemedicine platform is shown in Figure 2. Our final platform, which involves four artifacts working together, offers access to high-quality care for patients with sleep apnea.

Figure 2. Telemedicine platform for sleep apnea. CPOE: computerized physician order entry; EMR: electronic medical records.



To develop the product concept, we used iterative prototyping with varying levels of fidelity. In early iterations, the team developed paper prototypes and wireframes using the mock-up Marvel to seek early and continuous feedback from end users to improve the product concept. In the later iterations, the team finalized the mock-up screens of the product, as shown in Figure 3. Individuals intending to seek care for sleep apnea can download *Ognomy* from the Apple App Store or Google Play Store. Patients can create their accounts using email IDs and passwords. Subsequently, they can interact with our platform through an AI-based chatbot and furnish demographic, insurance, and medical information, as highlighted in screens 1-4. Thereafter, as presented in screens 5-8, patients can schedule an appointment with sleep specialists and will receive reminders 15 minutes before the appointment. Patients can then meet the sleep specialists virtually through video consultation, order a sleep test, review the results with their providers, and seek further treatment. At the other end, providers and sleep technicians used the web portal to offer their services. The dashboard provides sleep specialists and other providers with the opportunity to review patient data and monitor progress, as presented in screens 9-12. The platform is also integrated with EMRs and computerized physician order entry systems to enable seamless interaction among care providers and administrative staff.

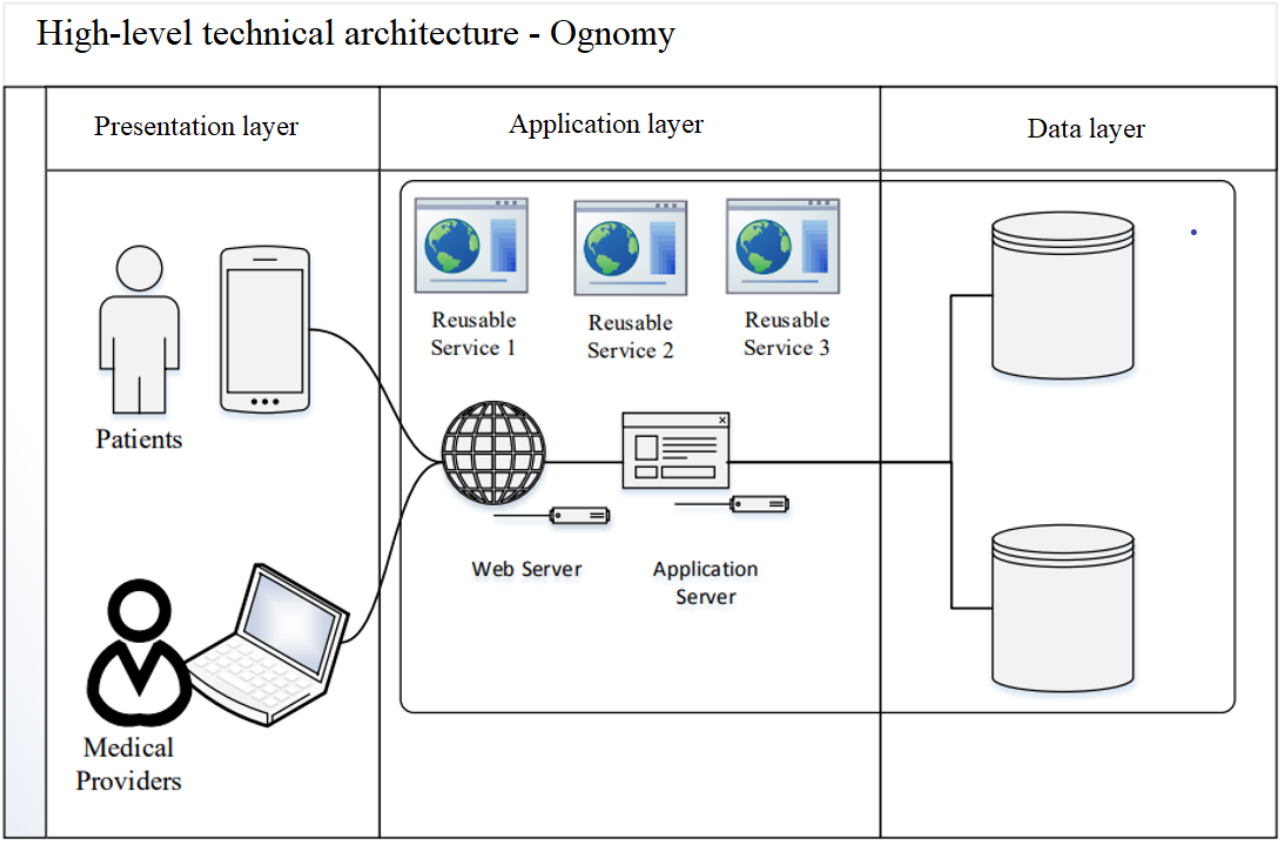
Figure 3. Mockup screens of the telemedicine platform.



Overall Technical Architecture

We used a *layered modular architecture* that uses the software as a service app hosted in the cloud environment. This architecture leverages the capabilities of the best-of-breed apps to build a platform for a fee instead of developing them from scratch. For instance, to process out-of-pocket payments from patients, we can integrate with application programming interfaces offered by market leaders, such as Square, instead of developing our own payment processing apps. In addition to being robust [37], these services considerably reduce the software development time [38] and do not require a large upfront investment [39]. Given the high expectations in terms of interface quality and time to market, such an architecture was especially relevant for Ognomy. Figure 4 shows the high-level technical architecture used in this study. We used several third-party application programming interfaces, including AWS Cognito, and the latest technologies, such as React JS.

Figure 4. The technical architecture of the telemedicine platform.



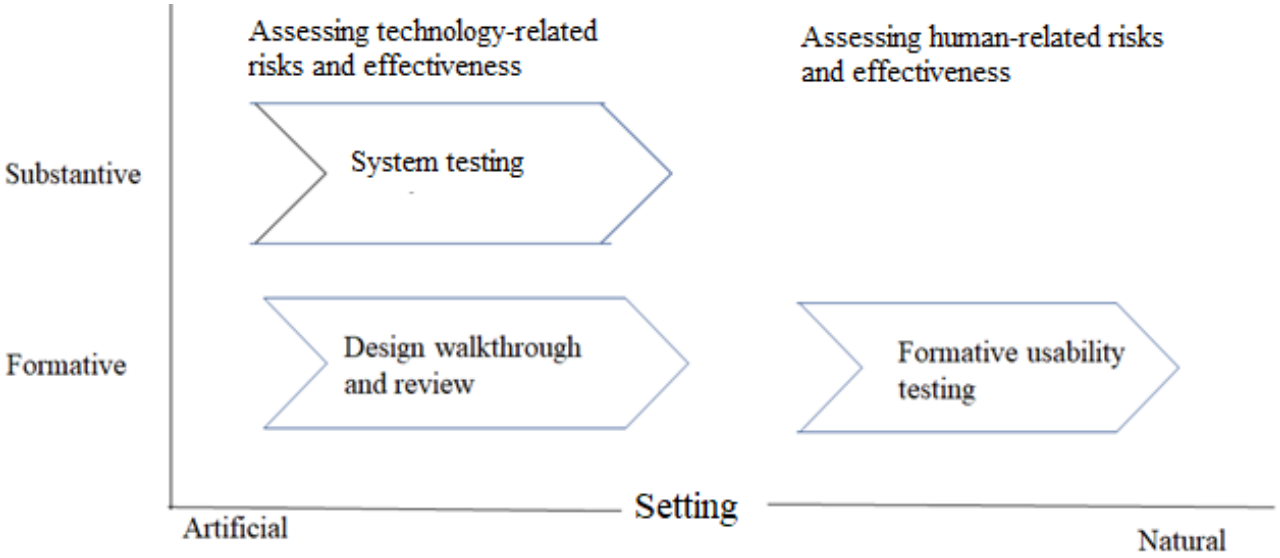
The clinical team, digital innovation consultants, and development team were dispersed across different geographies. The initial meeting to discuss the prospects of a digital sleep medicine platform occurred in June 2019. Ognomy was successfully deployed in the second quarter of 2020. The platform has been downloaded more than 4000 times and has received excellent reviews and ratings on Android and iPhone app stores. The platform has also been successfully deployed at two sleep centers, one in western New York and the other in Georgia. The sleep centers offer a full range of sleep apnea care and have diagnosed and treated more than 100,000 patients exclusive of those on the Ognomy platform.

Evaluating Solutions and Generalizing Design Principles

Evaluation Strategy

Rigorous evaluation is a crucial activity in DSR that ensures the utility, quality, and impact of the resulting design artifacts. We followed the guidelines stipulated by the framework for evaluation in DSR [40] to evaluate the design artifact. We performed a formative evaluation by conducting an expert review of the technical design and system architecture to reduce technical risks. Furthermore, we assessed the platform summatively by performing end-to-end system testing to ensure the robustness of the artifact. We also assessed the platform's effectiveness from a human perspective through formative field-based usability testing by the end users to identify and reduce user-related risks or concerns. We provide the details of our evaluation in Figure 5.

Figure 5. Evaluation approach.



Design Review and Walkthrough

The evaluation of the design against the requirements was performed to ensure that the underlying system design was robust enough to support the product features. The review process is a preliminary activity that takes place before the development of the product begins. In their study, Tang and Lau [41] provided elaborate procedures for reviewing software architectures. In this study, we followed their approach to conducting a design review. The initial design was reviewed by 3 expert solution architects with more than 10 years of experience in data and system architectures. The details of the profiles are provided in Multimedia Appendix 2. The design was reviewed to ensure that there were no conflicts between (1) use context and design, (2) requirements and design, (3) design and development, and (4) design choice as compared with alternatives.

Furthermore, software design was reviewed against several technological aspects, such as service orientation, interface requirements, the platform's core technology stack, environment details, security, backup, and performance best practices. The checklist used to perform the design review is provided in Multimedia Appendix 3. The findings of the design review were finalized by triangulating the reviews of the experts.

System Testing

To ensure a robust formative assessment of the product in an artificial setting, we conducted a system test on our platform. A test team of 3 expert software test professionals with an average software engineering experience of 4.35 years performed system testing. The team developed system test scenarios and test cases based on the requirements and design of the platform. Throughout the implementation phase, we followed an agile method of system testing where defects were identified and fixed on an iterative basis with regular product demonstrations on a weekly basis for 2 months. Given that the app was deployed in the production environment, all features were extensively tested. All the user interface screens, forms, actions, integrations, and end-to-end features, including positive and negative scenarios, were tested to ensure maximum test coverage. We also performed several compatibility tests with different handsets from iPhone and Android phones to ensure that the mobile app was consistent across the different devices.

Furthermore, we conducted several regression tests to ensure that the new code from the defect fixes did not introduce new defects inadvertently. Several defects were logged and fixed on an ongoing basis. Sample test cases and example defects are provided for reference in Multimedia Appendix 4. The system test phase concluded when critical patient-facing portions of the app, such as video consultation, appointment management, and reporting, were robust, with no critical or significant defects. However, addressing defects and issues in other parts of the apps was deferred for future releases.

Formative Field-Based Usability Testing

Overview

We conducted formative laboratory-based usability testing [42] on the fully functional mobile phone app prototype Ognomy to identify usability problems and obtain usability measures. Formative evaluations involve identifying and diagnosing problems, making and implementing recommendations, and then reevaluating the product, often iteratively, to detect and eliminate usability problems. In this study, we used the think-aloud approach to facilitate this process. After the participants provided consent to participate in the study, they were asked to complete a demographics form. Then, the participants were introduced to the think-aloud approach using a short video [43]. In this approach, the participants verbalized their thoughts and experiences as they moved through the app.

Subject Recruitment

We adopted a purposive sampling approach to select candidates for usability testing. We invited participants representing different stakeholder groups, including providers, patients, and hospital administrators. On the basis of their consent, the potential participants were invited to the testing center. Participants testing patient-facing apps were chosen depending on their risk profile, age, gender, education, and access to a mobile device. In this first version of the app, we intended to

focus on the feedback from the critical segment of the target audience to ensure that our priorities, trade-offs, and design considerations were guided by the realities of individuals most likely to seek care for sleep apnea. Therefore, we decided to choose patients from the high-risk category. A total of 8 participants aged between 20 and 60 years who had access to a mobile device were included in the final sample.

Furthermore, to evaluate the apps' physician-facing and administrative features, we adopted a convenient sampling approach. A total of 3 physicians and 3 hospital administrators with more than 10 years of experience in sleep and primary care were chosen to perform the evaluation. The details of the participants are provided in Multimedia Appendix 5.

Evaluation Design

After inviting the participants to the sleep laboratory, the subjects were introduced to the mobile or web app's user interface design. The facilitator briefed the participants on the mobile or web app and informed them that they were evaluating the app and that the facilitator was not evaluating them. The participants signed an informed consent form acknowledging that participation was voluntary and that they could quit the study at any time. Although the sessions were audiotaped, the participants' data privacy was ensured.

The facilitator instructed the participants to *think aloud* to obtain a verbal record of their interaction with the app. A mobile device and laptop with the web app and supporting software were used in a controlled environment. Each participant's interaction with the app was monitored by a facilitator seated in the same office. The notetakers monitored the sessions. After all task scenarios were attempted, the participants completed the posttest satisfaction questionnaire regarding ease of use and satisfaction. These questionnaires were followed up with a debriefing at the end of the session.

Scenarios for the Patient

The participants went through typical scenarios on the app. The scenarios for would-be patient participants are listed in Textbox 1, and the scenarios for doctors and administrators are listed in Textbox 2.

Textbox 1. Scenarios for the patient.

1. Create an account with your email address and answer all the questions asked by the artificial intelligence bot.
2. Schedule a consultation, follow through with the entire process, and then reschedule an appointment for another day. Schedule the appointment from the account created in task 1 and receive a reminder for the consultation. Then, reschedule the appointment.
3. Consult with a doctor on a video call: attend the consultation using a video call and validate the various options, including notes, messages, with the camera on or off, decrease or increase volume, and mute.
4. Postconsultation comments and order a home sleep test: review the doctor's comments and select from the given choices to order a home sleep test and perform the test.
5. Refer a patient and provide the patient's information. Provide a friend's information as the referring patient.

Textbox 2. Scenarios for doctors and administrators.

- Check your appointments: see the upcoming appointments this week or month and review recent sessions.
- Review the to-do list: check or add reminders and tasks, make notes, and see new messages from patients, secretary, or office.
- Consult with a doctor on a video call: attend the consultation using a video call and check the notes and messages, explore camera options, decrease or increase volume, mute, and turn the camera off.
- Study the current treatments of the patients: bring up the details of the treatment provided to the patients, including the notes which they made about it, and update the information.

Posttest Questions

To further understand the perceptions of the users, we conducted posttest interviews following the best practices suggested by usability testing guides and exemplars [44,45]. The questions are listed in Textbox 3.

Textbox 3. Posttest questions.

1. How would you describe the app to someone?
2. What was your favorite aspect of the app?
3. What was the most confusing part of the app?
4. Would you continue using this product? If so, why?
5. Would you recommend this product to a friend or colleague?

Results

Participants in the usability studies highlighted several interesting issues and classified them as critical or noncritical. The compiled list of issues, along with the steps taken for their resolution, are presented in Tables 2 and 3.

Overall, we received positive feedback from all types of participants on visual design aspects, such as color choices, esthetic appeal, the contrast ratio between font and the background, and the information architecture of the product. However, patients and administrative users highlighted some issues with the onboarding workflow and patient profiles. The crux of the problem was the large volume of information, including personal information, medical information, insurance information, and payment information, that patients had to furnish before setting up an appointment with a physician. They also suggested several enhancements to the onboarding workflow, such as adding a progress bar, providing a guided tour, and moving some of the information uploads to postappointment screens. Physician users, on the other hand, were mainly concerned about calendar design and notification issues.

We addressed all critical and noncritical feedback in the patient-facing parts of the app before launching the product. Several prior studies have emphasized the importance of patient-centered design as a prerequisite for the adoption and eventual success of mobile health apps [46]. Therefore, we deliberately prioritized patient-specific issues to develop a patient-first platform. Except for showstopper defects, the issues and concerns of other users, including administrators and providers, were deprioritized for the current version and deferred for later releases.

Table 2. Critical issues from usability tests.

ID	Stakeholder	Critical issues	Steps taken for their resolution
1	Patient or admin	Simpler customer onboarding process	Two important changes were made as part of the onboarding process. First, registration process was simplified to include only basic fields, such as name, email, and password. Second, chatbot-based interaction during data collection was enhanced to include optical character recognition capability to simplify data entry for patients.
2	Patient	Unavailability of user profile: there is no option that allows the user to access their profile page and edit the details in just a single click. This is especially important when the users provide incorrect information to the bot by mistake.	A patient dashboard and account home page were developed to resolve this concern.
3	Patient	Status indicator: several studies have highlighted that users are more motivated to complete the tasks as they get closer to the end. A progress bar that indicates the status would better engage the users.	The issue was resolved through front-end code changes.
4	Patient	Option to exit from the app: users should have an option to exit from any screen in the app if they so choose. For instance, if a user opts to book an appointment later, the user should have the ability to do so.	User interface–related code changes were made to provide users an exit option from any screen. At the backend, information provided by the users during each session would be stored.

Table 3. Noncritical issues from usability tests.

ID	Stakeholder	Noncritical issues	Steps taken for their resolution
1	Admin	Guided tour: the app does not have an initial tour guide. Having a tour guide would ease the user into onboarding, facilitate smarter user training, and reduce support queries with interactive walkthroughs.	A context-specific support is integrated with the artificial intelligence bot to facilitate user training and reduce support cost.
2	Physician or admin	UI[a] calendar's click: the app does not allow users to navigate dates with minimal clicks. One must click multiple times to reach dates after a few months or years.	Two resolutions were provided. First, the navigation across dates was made easy by providing users month and year pickers in addition to the day. Second, a provision to type in the date was provided to the users.
3	Admin	Rewording referral functionality: currently, the functionality of referring a friend is labeled as "Patient Referral," which is confusing. It should be labeled "Refer a Friend."	We intend to fix the label with code changes in the UI programs; however, the issue has been deferred to a future version.

[a]UI: user interface.

Discussion

Theoretical Implications

This design science study makes several notable contributions to both theory and practice. We make several theoretical contributions of this study. Although ISs research in the health care field has been ripe with development [47], there have not been many interventions developed for patients seeking sleep apnea care [48]. Furthermore, extant DSR has mostly emphasized the design, development, and evaluation of IT solution artifacts [49]. Exploring and validating the problem space have been insufficiently pursued. In this study, we took advantage of the design knowledge model [50] to bifurcate the design space into problem and solution spaces. Problem space validation establishes the relevance of the research product, whereas solution space addresses technical feasibility and product usability.

This study also informs the ISs research community on how telemedicine interventions can be implemented using the activity theory framework for building and evaluating artifacts. Activity theory in DSR has been used to design data models [51] and mobile apps in an educational context [52]. In this study, we enhanced activity theory by mapping the business activity system to a problem space and the technical activity system to a solution space. Furthermore, we argue that any IT artifact embodies the social and technical aspects of system development. The success of an artifact depends on the interactions between business and technical activity systems.

Practical Implication

From a practice perspective, we designed and developed a telemedicine platform and demonstrated the potential for such an intervention. We also showed how novel methods for managing products and developing digital architecture can quickly and effectively scale digital interventions. This study generated transferable insights into the most effective practices in conceptualizing and developing digital health products. A total of four core themes of generalizable guidelines emerged:

- learning from diverse end user perspectives is critical
- the use of frugal engineering methods to foster cost savings and reduce the time to market can be highly effective
- the commoditization of software through layered modular architecture and cloud-based infrastructure is the new norm
- access to software development talent

We have provided an elaborate discussion on these themes in the following sections.

Learning From Diverse End User Perspectives Is Critical

As highlighted in several prior studies, software development organizations may be tempted to quickly cruise through the conceptualization and design phases without validating the problem space from an end user perspective [53]. However, such practices usually lead to the development of products that are not grounded in their customers' needs. Researchers frequently use co-design workshops and structured interviews with different stakeholders to overcome this challenge [54].

In this study, we note that the diversity of opinions early on is especially important, as it provides a good platform for all ideas to emerge. It facilitates the holistic development of an app that is relevant, usable, and valuable to all stakeholders, including patients and clinicians, thus overcoming potential barriers to successful adoption and continued use. This implication is particularly relevant for complex business domains, such as health care, where several subject matter experts, such as medical providers (doctors and nurses), administrators (billing, coders, and operation managers), and sleep technicians, interact with end users (patients).

The Use of Frugal Engineering Methods to Foster Cost Savings and Reduce the Time to Market Can Be Highly Effective

Extant literature has emphasized that weeding out feature ideas without potential quickly and economically can be a critical success factor in the development of digital platforms [55,56]. To accomplish this goal, development organizations must leverage a combination of novel frugal engineering methods to save time and money. For instance, in our study, we used iterative prototyping with varying fidelity levels to understand the potential problems before building the final product.

The Commoditization of Software Through Layered Modular Architecture and Cloud-Based Infrastructure Is the New Norm

The team used layered modular architecture using the software as a service app hosted on the cloud environment. Such architecture helps borrow capabilities from other apps for a fee instead of developing them from scratch. In addition to being robust, these services reduce the development time considerably and do not require a large upfront investment. Furthermore, the app was hosted on the AWS cloud environment, which complied with all technology-related HIPAA requirements. The team also used tools such as EC2 (Elastic Compute Cloud), S3 (Simple Storage Service), and ELB (Elastic Load Balancer) to enhance the ease of deployment and migration and to meet on-demand scaling.

Access to Software Development Talent

Prior research has highlighted the shortage of software development talent [57]. This challenge is pronounced in nontechnology hubs. Although many universities offer courses in software engineering and several boot camps and training centers have arisen to fill the talent gap, the availability of solid software development talent, especially in the latest technologies such as React JS and dev-ops automation that can deliver apps quickly in short time frames, remains a significant bottleneck.

Limitations

This study had several limitations. We conducted formative usability tests with only a limited number of end users, including 8 patients, 3 providers, and 3 sleep clinic administrators. As a result, the issues identified in the usability tests may not be generalizable to other settings. Furthermore, all the participants of the usability tests were from the northeastern United States, and hence, the sample of participants may not be nationally representative. However, our focus was not on the

generalizability of our findings but on gathering practical insights about the challenges faced by the end users of the app.

Although the participants testing the patient-facing apps exhibited diversity in age, gender, and educational accomplishments, they all had access to smartphones and were reasonably comfortable using them. Our findings might have been significantly different if we had focused our attention on individuals who lacked technology proficiency or who had cognitive or physical challenges. However, given the ubiquity of mobile devices and the large number of smartphone users, we deliberately focused on this market segment.

Another limitation is that not all the issues identified during the design review, system test, and formative usability tests were addressed in the current version of the app. We refined the design artifact based on the priority of the concerns raised, as we were constrained by time and budget. All the critical issues and errors associated with the patient-facing features, such as appointment management and video consultation, were addressed. However, issues associated with EMRs and computerized physician order entry integration; physician reports; and administrative features, such as insurance card verification, were deferred for future releases.

Conclusions

Against the backdrop of a surge in demand for sleep apnea care, the telemedicine platform offers a scalable and economical alternative. With an aging population and the escalating cost of care, telemedicine alternatives have become increasingly imperative. This is especially true for patients seeking care for sleep apnea because of its increasing prevalence. This paper discusses the design, development, and evaluation of a telemedicine intervention that aids providers and care seekers in virtual consultation, conducts tests, and prescribes treatment virtually. Such a telemedicine platform breaks access barriers while ensuring high-quality care. During the evaluation phase, we noted that this platform is economically viable, technically feasible, and highly usable by all stakeholder groups. Future research can extend this line of inquiry by developing artifact instances for other sleep-related issues, such as insomnia. An interesting contribution would be to demonstrate how telemedicine interventions are accepted across different cultures and geographies, especially where there is a lack of awareness about sleep issues. Future work could also address related issues of e-consent and explore the legal and ethical guidelines for using such platforms.

Conflicts of Interest

DR has a majority financial interest in the company North American Sleep Management Inc, which is the sole owner of the Ognomy platform. The remaining authors declare no conflict of interest.

Multimedia Appendix 1
Questionnaire for requirements gathering interviews.
[DOCX File , 15 KB - formative_v5i7e26059_app1.docx]

Multimedia Appendix 2
Expert profiles for design and architectural review.
[DOCX File , 15 KB - formative_v5i7e26059_app2.docx]

Multimedia Appendix 3
Checklist for design and architectural review.
[DOC File , 751 KB - formative_v5i7e26059_app3.doc]

Multimedia Appendix 4
Sample defects found during system testing.
[DOCX File , 14 KB - formative_v5i7e26059_app4.docx]

Multimedia Appendix 5
Participant profiles.
[DOCX File , 16 KB - formative_v5i7e26059_app5.docx]

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Abbreviations

AI: artificial intelligence
CPAP: continuous positive airway pressure
DSR: design science research
EC2: Elastic Compute Cloud
ELB: Elastic Load Balancer
EMR: electronic medical record
HIPAA: Health Information Portability and Accountability Act
IS: information system
IT: information technology
OSA: obstructive sleep apnea
S3: Simple Storage Service

Edited by G Eysenbach; submitted 03.12.20; peer-reviewed by E Kasaeyan Naeini, I Bouloukaki, M Mueller; comments to author 08.01.21; revised version received 30.03.21; accepted 11.06.21; published 19.07.21.

Please cite as:
Mulgund P, Sharman R, Rifkin D, Marrazzo S
Design, Development, and Evaluation of a Telemedicine Platform for Patients With Sleep Apnea (Ognomy): Design Science Research Approach
JMIR Form Res 2021;5(7):e26059
URL: https://formative.jmir.org/2021/7/e26059
doi:10.2196/26059
PMID:34279237

Original Paper

Mobile Ecological Momentary Assessment and Intervention and Health Behavior Change Among Adults in Rakai, Uganda: Pilot Randomized Controlled Trial

Laura K Beres[1*], MPH, PhD; Ismail Mbabali[2*], MPH; Aggrey Anok[2], BSc; Charles Katabalwa[2], BBA; Jeremiah Mulamba[2], DMHN; Alvin G Thomas[3,4], MSPH; Eva Bugos[5,6,7], MSPH, MD; Gertrude Nakigozi[2], MPH; Mary K Grabowski[2,8], PhD; Larry W Chang[1,2,9], MD, MPH

[1]Department of International Health, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, United States

[2]Rakai Health Sciences Program, Entebbe, Uganda

[3]Department of Epidemiology, University of North Carolina, Chapel Hill, Chapel Hill, NC, United States

[4]Department of Surgery, Johns Hopkins University, Baltimore, MD, United States

[5]University of Chicago Pritzker School of Medicine, Chicago, IL, United States

[6]Department of Population, Family and Reproductive Health, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, United States

[7]Department of Internal Medicine, University of Pittsburgh Medical Center, Pittsburgh, PA, United States

[8]Department of Pathology, Johns Hopkins University School of Medicine, Baltimore, MD, United States

[9]Division of Infectious Diseases, Department of Medicine, Johns Hopkins University School of Medicine, Baltimore, MD, United States

[*]these authors contributed equally

Corresponding Author:
Laura K Beres, MPH, PhD
Department of International Health
Johns Hopkins Bloomberg School of Public Health
615 N. Wolfe Street, E5031
Baltimore, MD, 21205
United States
Phone: 1 410 955 7159
Email: laura.beres@jhu.edu

Abstract

Background: An extraordinary increase in mobile phone ownership has revolutionized the opportunities to use mobile health approaches in lower- and middle-income countries (LMICs). Ecological momentary assessment and intervention (EMAI) uses mobile technology to gather data and deliver timely, personalized behavior change interventions in an individual's natural setting. To our knowledge, there have been no previous trials of EMAI in sub-Saharan Africa.

Objective: To advance the evidence base for mobile health (mHealth) interventions in LMICs, we conduct a pilot randomized trial to assess the feasibility of EMAI and establish estimates of the potential effect of EMAI on a range of health-related behaviors in Rakai, Uganda.

Methods: This prospective, parallel-group, randomized pilot trial compared health behaviors between adult participants submitting ecological momentary assessment (EMA) data and receiving behaviorally responsive interventional health messaging (EMAI) with those submitting EMA data alone. Using a fully automated mobile phone app, participants submitted daily reports on 5 different health behaviors (fruit consumption, vegetable consumption, alcohol intake, cigarette smoking, and condomless sex with a non–long-term partner) during a 30-day period before randomization (P1). Participants were then block randomized to the control arm, continuing EMA reporting through exit, or the intervention arm, EMA reporting and behavioral health messaging receipt. Participants exited after 90 days of follow-up, divided into study periods 2 (P2: randomization + 29 days) and 3 (P3: 30 days postrandomization to exit). We used descriptive statistics to assess the feasibility of EMAI through the completeness of data and differences in reported behaviors between periods and study arms.

Results: The study included 48 participants (24 per arm; 23/48, 48% women; median age 31 years). EMA data collection was feasible, with 85.5% (3777/4418) of the combined days reporting behavioral data. There was a decrease in the mean proportion of days when alcohol was consumed in both arms over time (control: P1, 9.6% of days to P2, 4.3% of days; intervention: P1,

7.2% of days to P3, 2.4% of days). Decreases in sex with a non–long-term partner without a condom were also reported in both arms (P1 to P3 control: 1.9% of days to 1% of days; intervention: 6.6% of days to 1.3% of days). An increase in vegetable consumption was found in the intervention (vegetable: 65.6% of days to 76.6% of days) but not in the control arm. Between arms, there was a significant difference in the change in reported vegetable consumption between P1 and P3 (control: 8% decrease in the mean proportion of days vegetables consumed; intervention: 11.1% increase; *P*=.01).

Conclusions: Preliminary estimates suggest that EMAI may be a promising strategy for promoting behavior change across a range of behaviors. Larger trials examining the effectiveness of EMAI in LMICs are warranted.

Trial Registration: ClinicalTrials.gov NCT04375423; https://www.clinicaltrials.gov/ct2/show/NCT04375423

(JMIR Form Res 2021;5(7):e22693) doi:10.2196/22693

KEYWORDS

ecological momentary assessment; ecological momentary intervention; mHealth; digital health; smartphone; mobile phone; randomized trial; Uganda; Africa

Introduction

Background

To date, behavior change strategies in lower- and middle-income countries (LMICs) have failed to fully leverage the potential of mobile technology to promote optimal health outcomes. Although this may be partially because of historically limited technology access in these settings, an extraordinary increase in mobile technology ownership and use, facilitated by advances in lower-cost smartphones, has revolutionized the opportunities to use mobile health approaches in LMICs [1].

Ecological momentary assessment and intervention (EMAI) uses mobile technology to gather individual-level behavioral data and deliver timely, personalized behavior change interventions in an individual's natural setting [2]. These strengths can promote a range of health objectives. Compared with traditional, in-person assessments and interventions, EMAI may offer more user-driven, cost-effective, and ecologically and temporally relevant strategies [2,3] and may generate more accurate data than traditional retrospective questionnaires, which are subject to recall bias [4]. Rapid and repeated individual-level behavioral measurement and feedback may be particularly effective in supporting changes to semiconscious behaviors or habits that are difficult to accurately recall and benefit from interruptions in routine to alter [5,6]. Remote data collection and intervention strategies may be critical for hard-to-reach populations, and because of infection-related concerns such as COVID-19, this may help to fill the more widespread need for remote or contactless intervention options.

However, there is limited extant literature on the effectiveness of EMAI, particularly in LMICs. Several studies in high-income settings have demonstrated the preliminary effectiveness of EMAI using targeted, remote messages to improve mental health outcomes [3,7,8], fruit and vegetable consumption [9], and smoking-related behaviors [10]. A qualitative study in the United States demonstrated that young women responded positively to the development of an EMAI approach for sexual risk reduction, identifying the potential for future intervention trials [11]. There are several recently published protocols on the use of mobile ecological momentary intervention across behaviors, including alcohol and drug use, healthy food consumption and coping [12-16], and a consistently identified need for more research into the effectiveness of EMAI with mobile technologies [17-19]. To date, we are not aware of any previous EMAI trials in sub-Saharan Africa.

Objectives

To advance the evidence base for mobile health interventions in LMICs, we conducted a pilot randomized trial to establish estimates of the potential effect of EMAI on a broad range of health-related behaviors in Rakai, Uganda. On the basis of extant EMAI literature, theory, and evidence [20] that targeted nudges, including behavioral messaging, can alter behavior, we hypothesized that participants submitting ecological momentary assessment (EMA) reports and receiving intervention messaging (EMAI) would have improved self-reported health behaviors compared with those submitting EMA reports only. As the first study, to our knowledge, to trial EMAI in sub-Saharan Africa, we sought to generate preliminary data to guide future investigations on the feasibility and effectiveness of EMAI in LMICs.

Methods

Study Design and Population

The study was a prospective, parallel-group, randomized pilot trial in Rakai, Uganda. It sought to establish a preliminary estimate of the effect of EMAI on health behaviors between participants submitting EMA data and receiving behaviorally responsive interventional health messaging compared with those submitting EMA data alone.

The study sampled adult participants (aged 18-49 years) from the Rakai Community Cohort Study (RCCS), an open, population-based cohort running since 1994 [21,22]. Rakai District, Uganda, is approximately 150 km southwest of the capital, Kampala, bordered by Tanzania and Lake Victoria. It includes agrarian, trading, and fishing communities [22]. Participants were eligible if they were current RCCS participants who had provided a telephone number during the last survey and had at least a secondary-level education. The lists of potential participants who met the eligibility criteria according to the RCCS survey data were generated from the RCCS database. Participants were purposively recruited via the telephone. Study staff members sought variation in participant age, sex, and occupation, aiming to include a minimum of 20%

traders and 20% farmers in the sample, to enable researchers to assess possible differential EMAI acceptability and feasibility by participant characteristics in this pilot trial.

In addition to the primary study outcome, the preliminary estimate of the effect of EMAI, as a pilot study, the secondary aim was to assess the feasibility of the data collection and intervention approach. To do so, we examined the indicators of data collection success by the study arm. All outcomes were assessed after the closure of the study.

Procedures

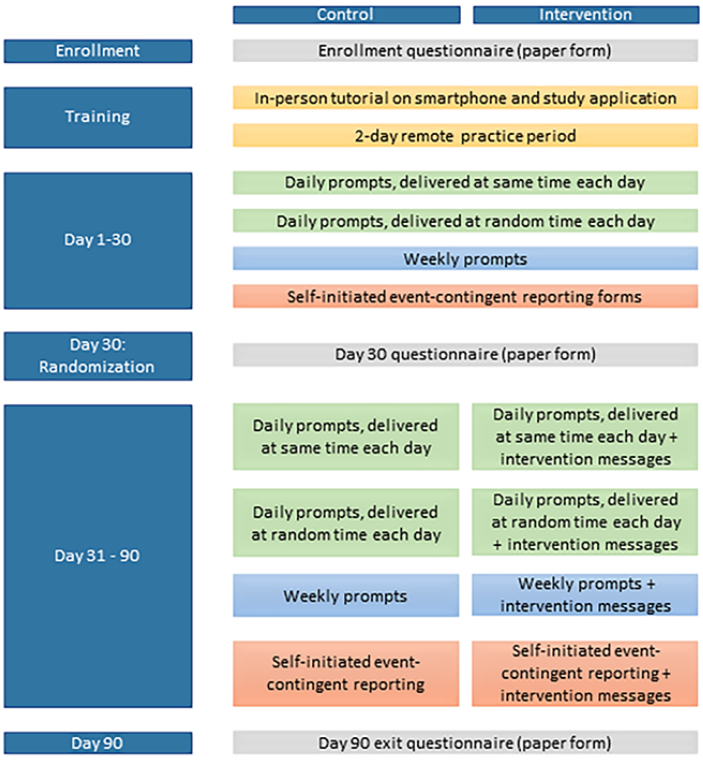
Interested participants attended an in-person visit at the study office, enrolling on completion of voluntary, written informed consent at the first in-person study visit. At the first study visit, participants were issued a password-protected smartphone programmed with the EMAI study app (emocha Health Inc), a phone charger, and a portable power bank. Participants were trained on the use of the smartphone and a fully automated study app and completed a paper-based enrollment questionnaire collecting participant demographic and behavioral data, recalling the 30 days before enrollment.

Communicating in Luganda, the primary language spoken in the region, the app collected EMA data on 5 behaviors of interest: fruit consumption, vegetable consumption, alcohol intake, cigarette smoking, and sex with a nonmarital or non–long-term partner without a condom. EMA behavioral data were submitted by the participant through the app (1) in response to a text message prompt twice per day, once at a random time and once at a fixed time asking about each of the behaviors since the last prompt-based report, (2) in response to a text message prompt sent each week, recalling behaviors throughout the week, and (3) through a participant-generated report sent within approximately 1 hour of engaging in any of the study behaviors of interest (an *event-contingent* report). Participants were asked to reply “yes=1” or “no=0” to sequential questions about each behavior. If they replied “yes,” they were asked for the associated numeric quantity (eg, number of cigarettes smoked and number of vegetables eaten).

For the first 30 days of the study, all participants sent EMA data, after which they were randomized to control or intervention conditions. Participants in the control arm continued to submit EMA data throughout the remainder of the study period. From randomization to study exit, intervention arm participants received health-related messages responsive to the behavioral data submitted in addition to continuing EMA data submissions. The messages, developed using participatory formative research including free-listing and sorting of proposed messages with a convenience sample of 8 Rakai residents to enhance appropriateness and relevance, provided positive reinforcement for reported healthy behaviors (eg, Living alcohol-free today is a step to a healthier future! Alcohol contributes to heart disease and liver cancer.) and encouragement to change in response to reported risk behaviors (eg, Alcohol abuse increases your risk of heart disease. Protect your heart, and stick to water or juice tomorrow). The participants received messages that were directly relevant to the responses they submitted. The specific message a participant received from the bank of possible messages (Multimedia Appendix 1) related to the reported behavior was randomly selected each time. Participants exited after study day 90 (Figure 1). Up to 10 participants were enrolled simultaneously throughout the study period. Behavioral data were stored on the phone and sent to the remote study database for analysis.

Participants were compensated for their time (UGX 10,000; approximately US $3) and reimbursed for travel costs (UGX 5000-40,000; US $1.50-12) for each in-person study visit. Participants were given funds equivalent to 525 MBs of data monthly throughout the study and an incentive totaling UGX 100,000 (approximately US $30) in 3 increments at 30, 60, and 90 days for responding to ≥50% of data collection prompts. The study was approved by the Ugandan Virus Research Institute Research and Ethics Committee and the Johns Hopkins School of Medicine Institutional Review Board.

Figure 1. Study design.



Randomization

Participants were assigned to the control or intervention study arm using block randomization with randomly varying block sizes of 4, 6, and 8 through blockr R package by Greg Snow. The study arm assignments were enclosed within opaque, consecutively numbered envelopes. At the day 30 visit, the study coordinator allocated the randomization assignment enclosed in the next consecutive envelope to each participant, activating the appropriate EMAI smartphone module. The assignments were not masked to the study participants or staff.

Study Measurements and Outcomes

Participant characteristics and behaviors at enrollment were collected on the paper-based enrollment questionnaire. Occupation was measured using the last RCCS survey round. The exposure of interest, receiving intervention messages, was measured as a dichotomous variable, with all participants assigned to the intervention arm counted as exposed and all control arm participants as unexposed. The outcomes were examined separately for each of the 5 study behaviors of interest: (1) fruit consumption, (2) vegetable consumption, (3) alcohol use, (4) cigarette smoking, and (5) sex with a nonmarital or non–long-term partner without a condom.

Participants were assigned a *yes* or *no* for each behavior for each day of the study follow-up. A participant was counted as engaging in a behavior if the participant reported having practiced the behavior on at least one of the twice-daily prompt response forms or any event-contingent form submitted on that day. They were counted as not engaging in the behavior if none of the submitted forms reported the behavior on that day. If no data forms were submitted, the participant had missing data for that day. Sex with a nonmarital or non–long-term partner without a condom was determined by 2 questions: first, asking if the participant had a sexual encounter with such a partner and then asking if a condom was used in that encounter. Participants were counted as engaging in the behavior if they reported both *yes* to sex with a nonmarital or non–long-term partner and *no* to condom use in that encounter.

The total number of days in the study was counted from enrollment to the exit date. The number of event-contingent reports and prompt-driven behavioral report responses submitted was counted using the total number of database entries (submitted by the smartphone and received by the database) for each type of report mechanism. Each report included the behavioral information reported and the time and date it was submitted. A day was counted as missing behavioral data for a participant if there were no reports recorded in the database on a date between study enrollment and exit. The study follow-up was divided into 3 study periods: period 1 (baseline; P1: enrollment to the day before randomization), period 2 (P2: the day of randomization to 29 days postrandomization), and period 3 (P3: 30 days postrandomization to study exit).

Analysis

Given the pilot nature of the study, we primarily used a descriptive approach to examine the study outcomes. Descriptive statistics were used to compare participant characteristics and data collection between the 2 study arms. We examined the comparability of participant characteristics by arm at baseline using chi-square and two-tailed Student *t* tests. We estimated the effect sizes for differences in data collection between the 2 arms using Cohen *d* with bootstrapped CIs to account for the small sample size and nonnormal data distribution. We

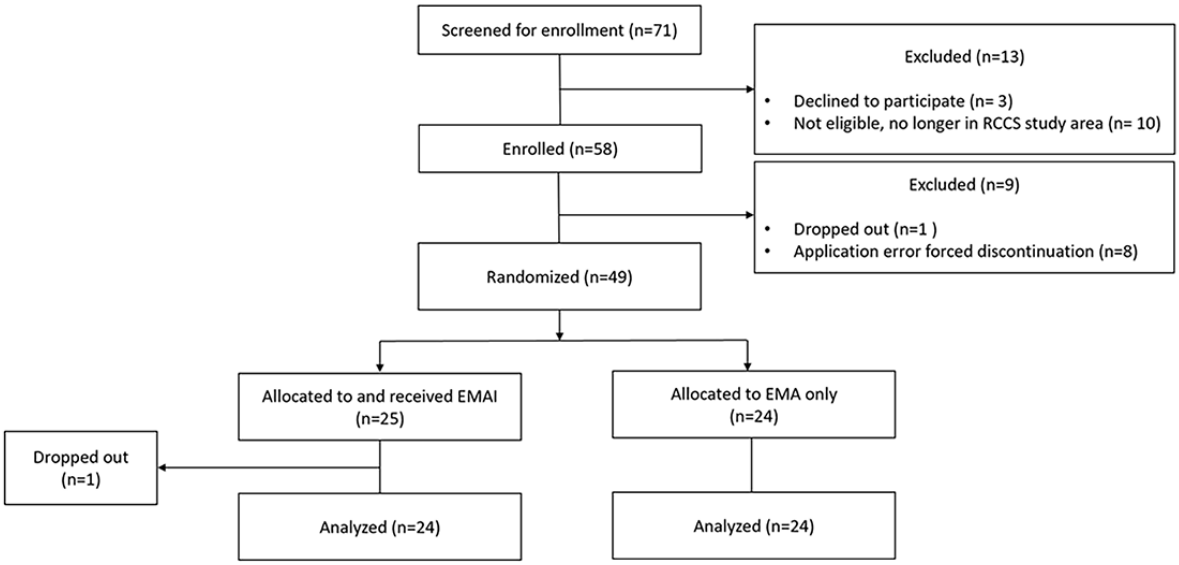
determined the proportion of study days when a behavior was practiced by taking the total number of days the participant engaged in the behavior over the total days with behavioral data reported for each participant for each study period. We excluded missing data (days without behavioral reports). We calculated bootstrapped 95% CIs to identify differences in the mean proportion of days when participants reported each behavior between P1 and P2, P2 and P3, and P1 and P3 within each study arm. We present visual plots of the proportion of days when behaviors are reported for each participant by study arm and study period. To compare changes between study arms, we calculated the mean difference in the proportion of days each participant reported each behavior between periods by subtracting the later period's mean proportion of days when the behavior was practiced from the earlier period's mean. We then took the overall mean difference across all participants for each study arm and calculated the difference within the differences by subtracting the control arm from the intervention arm. We used two-sample *t* tests with two-sided *P* values to assess if the mean differences between each period were the same in the 2 study arms. The analyses were conducted using Stata 15.1 IC (StataCorp, 2018).

Results

Overview and Flow

Between June 10, 2016, and March 1, 2017, 71 participants were screened for enrollment, of whom 58 were enrolled. Of 58 participants, 8 were excluded because of early failure of the study application and 2 dropped out at 15 and 79 days after enrollment. The complete analysis data set included 48 participants (Figure 2).

Figure 2. Participant flow diagram. EMA: ecological momentary assessment; EMAI: ecological momentary assessment and intervention.



Of the 48 participants, 23 (48%) were female, with a median age of 31 (IQR 25-38) years. Less than one-third of the participants worked in agriculture (14/48, 29%), with 17% (8/48) working in trade, 23% (11/48) teachers, and 31% (15/48) in other occupations. In the 30 days before study enrollment, nearly all participants (47/48, 98%) reported eating a vegetable on at least one day, 90% (43/48) consumed fruit, whereas 35% (17/48) consumed alcohol, 17% (8/48) reported sex with a nonmarital or non–long-term partner, and 13% (3/48) smoked a cigarette. There were no significant differences in participant characteristics or behaviors at enrollment between the study arms (Table 1).

Table 1. Participant characteristics at enrollment by study arm.

Participant characteristics	Control (n=24)	Intervention (n=24)	Total (N=48)	*P* value[a]
Female, n (%)	12 (50)	11 (46)	23 (48)	.77
Age at enrollment (years), mean (SD)	32.7 (7.1)	30.1 (6.7)	31.4 (7.0)	.10
Education completed , n (%)				.94
Some secondary	7 (29)	8 (33)	15 (31)	
Secondary	10 (42)	9 (38)	19 (40)	
University, technical or vocational	7 (29)	7 (29)	14 (29)	
Yes, owns a cell phone, n (%)	24 (100)	24 (100)	48 (100)	N/A[b]
Yes, feels comfortable using a phone to send text messages, n (%)	24 (100)	22 (92)	46 (96)	.15
Yes, ever used a smartphone app, n (%)	14 (58)	12 (50)	26 (54)	.56
Occupation , n (%)				.53
Agrarian	6 (25)	8 (33)	14 (29)	
Trader	5 (20)	3 (12)	8 (16)	
Teacher	4 (17)	7 (29)	11 (23)	
Other	9 (38)	6 (25)	15 (31)	
Health behaviors, past 30 days				
Smoked cigarette at least one day, n (%)	3 (13)	0 (0)	3 (13)	.07
Among smokers, days smoked at least one cigarette, mean (SD)	20 (13.1)	N/A	N/A	N/A
Drank alcoholic beverage at least one day, n (%)	8 (33)	9 (38)	17 (35)	.76
Among drinkers, days drank at least one alcoholic beverage, mean (SD)	2.1 (1.3)	1.6 (0.7)	N/A	.29
Ate vegetables at least one day, n (%)	22 (92)	21 (88)	43 (90)	.64
Among those who ate vegetables, days ate at least one vegetable, mean (SD)	7.2 (5.4)	6.7 (7.9)	N/A	.80
Ate fruit at least one day, n (%)	23 (96)	24 (100)	47 (98)	.31
Among those who ate fruit, days ate at least one fruit, mean (SD)	13.6 (9.0)	12.5 (8.2)	N/A	.67
Had sex with nonmarital or non–long-term partner without using a condom at least once, n (%)	5 (21)	3 (13)	8 (17)	.44
Times had sex with a nonmarital or non–long-term partner without a condom, among those reporting sex, mean (SD)	2.4 (1.9)	2.3 (0.6)	N/A	.96

[a]Two-sided *P* value calculated using chi-square tests for categorical variables and Student *t* test for continuous variables.

[b]N/A: not applicable.

Data Collection

The mean total number of days of follow-up was 92 (minimum 90 and maximum 94). Comparing study arms, there were no significant differences in time in study, data submission types (event-contingent or prompt-based responses), or proportion of study days without data submitted (Table 2). There were also no significant differences in study arm in behaviors reported during the prerandomization P1 baseline period (Table 2). Overall, 85.5% (3777/4418) of the total study days had behavioral data reported.

Over the study periods, the reported engagement in any of the behaviors varied. All 48 participants reported eating fruits and vegetables on at least one day during each of the 3 study periods, except for 1 participant who did not report eating vegetables on any day during study period 2. Ever consuming alcohol was reported by approximately half of the participants or fewer across the periods (control arm period 1: 13 participants, period 2: 9 participants, and period 3: 8 participants; intervention arm periods 1 and 2: 12 participants, period 3: 7 participants). Far fewer participants reported ever having sex with a non–long-term partner without a condom (control arm period 1: 4 participants, periods 2 and 3: 2 participants; intervention arm periods 1 and 2: 4 participants and period 3: 5 participants) or ever smoking cigarettes (control arm period 1: 7 participants, period 2: 3 participants, and period 3: 4 participants; intervention arm period 1: 3 participants, period 2: 1 participant, and period 3: 0 participants).

Table 2. Study data collection indicators by study arm.

Data indicator	Control	Intervention	*t* test[a] (*df*)	*P* value[a]	Effect size[b] (95% CI)
Total study days, mean (range)	92.0 (90-94)	92.1 (90-94)	−0.28 (46)	.78	−0.08 (−0.66 to 0.50)
Days in study period, mean (range)					
Period 1: baseline (study day 1 to day before randomization)	30.6 (29-33)	30.8 (29-33)	−0.57 (46)	.57	−0.16 (−0.71 to 0.38)
Period 2 (randomization to 29 days postrandomization)	30 (30-30)	30 (30-30)	N/A[c]	N/A	N/A
Period 3 (30 days postrandomization to final study day)	31.4 (28-33)	31.3 (28-33)	0.23 (46)	.82	0.07 (−0.48 to 0.61)
Total event-contingent reports, mean (SD)	108.6 (67.5)	99.8 (46.4)	0.53 (46)	.60	0.15 (−0.44 to 0.75)
Event-contingent reports by period, mean (SD)					
Period 1: baseline (study day 1 to day before randomization)	47.5 (35.0)	43.3 (26.7)	0.47 (46)	.63	0.14 (−0.45 to 0.72)
Period 2 (randomization to 30 days after randomization)	30.0 (22.4)	27.9 (14.7)	0.38 (46)	.71	0.11 (−0.54 to 0.76)
Period 3 (30 days after randomization to final study day)	31.1 (23.0)	28.9 (13.8)	0.46 (46)	.65	0.13 (−0.48 to 0.75)
Total responses submitted to prompts, mean (SD)	92.2 (28.6)	96.9 (23.2)	−0.63 (46)	.53	−0.18 (−0.78 to 0.42)
Responses submitted to prompts by period, mean (SD)					
Period 1: baseline (study day 1 to day before randomization)	20.4 (6.9)	21.5 (5.0)	−0.62 (46)	.54	−0.18 (−0.78 to 0.42)
Period 2 (randomization to 30 days after randomization)	35.4 (14.5)	38.3 (9.0)	−0.85 (46)	.40	−0.24 (−0.82 to 0.33)
Period 3 (30 days after randomization to final study day)	36.4 (12.8)	37.1 (12.2)	−0.18 (46)	.85	−0.05 (−0.64 to 0.53)
Total days without behavior reported, mean (SD)	14.2 (10.7)	12.4 (9.3)	0.62 (46)	.54	0.18 (−0.45 to 0.81)
Days without behavior reported by period, mean (SD)					
Period 1 (study day 1 to day before randomization)	3.1 (2.6)	3.4 (2.9)	−0.36 (46)	.72	−0.10 (−0.70 to 0.49)
Period 2 (randomization to 30 days after randomization)	3.7 (3.2)	3.0 (3.1)	0.73 (46)	.47	0.21 (−0.44 to 0.86)
Period 3 (30 days after randomization to final study day)	7.4 (7.1)	6.0 (6.2)	0.74 (46)	.47	0.21 (−0.40 to 0.82)
Proportion of study days without behavior report (%), mean (SD)	15.4 (11.5)	13.5 (10.1)	0.61 (46)	.54	0.18 (−0.45 to 0.81)
Proportion of study days participants report behaviors in first study period: P1 baseline (prerandomization; %), mean (SD)					
Fruit	79.0 (0.2)	78.6 (0.2)	0.06 (46)	.95	0.02 (−0.61 to 0.65)
Vegetable	57.8 (0.2)	65.6 (0.3)	−0.99 (46)	.33	−0.28 (−0.93 to 0.36)
Alcohol	9.6 (0.2)	7.2 (0.1)	0.51 (46)	.61	0.15 (−0.44 to 0.73)
Sex with non–long-term partner without a condom	1.9 (0.04)	6.6 (0.1)	−1.74 (46)	.09	−0.50 (−0.96 to −0.05)
Smoking	6.5 (0.2)	1.4 (0.03)	1.26 (46)	.22	0.36 (−0.14 to 0.86)

[a]Two-sided *P* value calculated using Student *t* test for continuous variables.

[b]Cohen *d*.

[c]N/A: not applicable.

Within-Arm Change Over Time

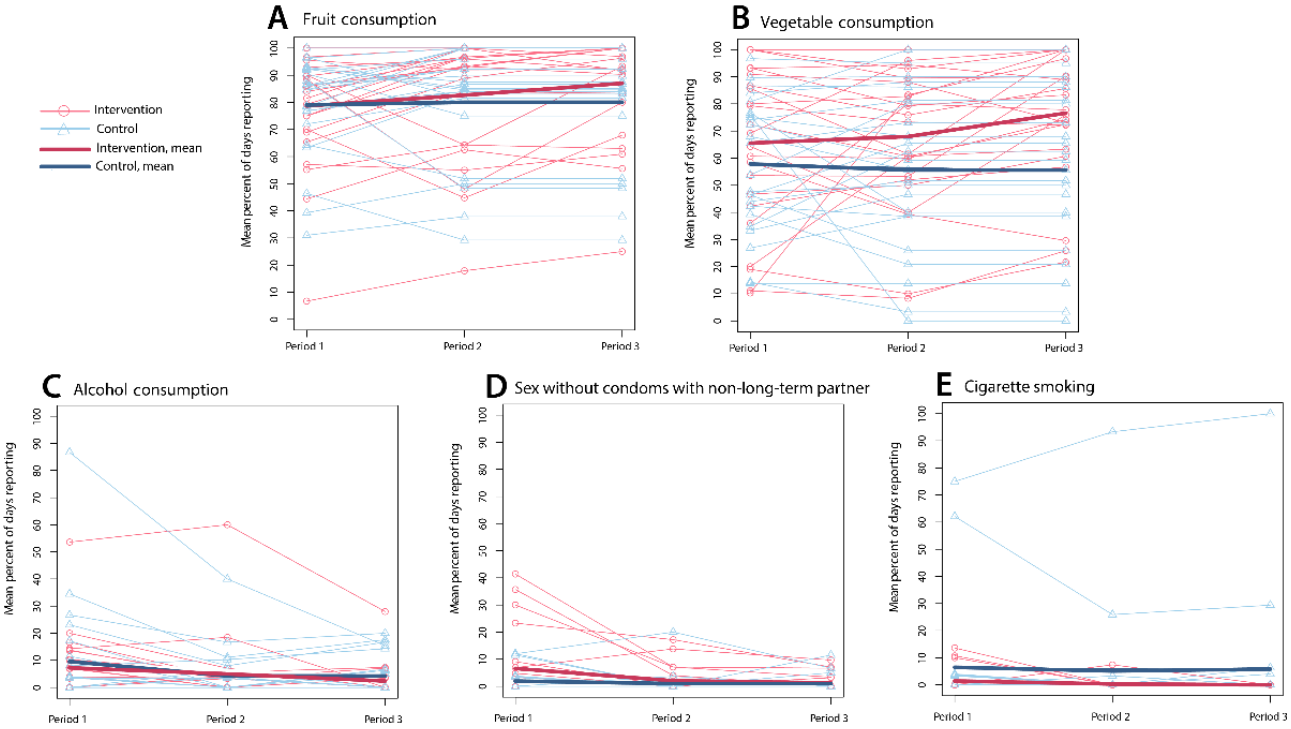
There was a decrease in the mean proportion of days when alcohol was consumed in both the control and intervention arms. In the control arm, a decrease was observed between periods 1 and 2 (9.6% of days to 4.3% of days), whereas it was observed between periods 1 and 3 in the intervention arm (7.2% of days to 2.4% of days; Table 3). Similarly, both arms showed a decrease in the mean proportion of days when participants reported having sex with a nonmarital or non–long-term partner without a condom between periods 1 and 3 (control: 1.9% of days to 1% of days and intervention: 6.6% of days to 1.3% of days) and an increase in fruit consumption (control: 79% of days to 82% of days and intervention: 78.6% of days to 87% of days; Table 3). In the intervention arm only, there was an increase in the mean proportion of days when vegetables were reported to be consumed between periods 1 and 3 (vegetable: 65.6% of days to 76.6% of days) and periods 2 and 3 (vegetable: 68% of days to 76.6% of days; Table 3; Figure 3).

Table 3. Mean proportion of days participants report behaviors by study period and arm (n=24 per arm).

Reported behavior	Control (%), mean (95% CI)			Intervention (%), mean (95% CI)		
	Period 1	Period 2	Period 3	Period 1	Period 2	Period 3
Fruit	79 (71.9 to 86)	80 (71.3 to 88.8)	82 (73.7 to 90.3)	78.6 (70.2 to 87.1)	82.6 (73.5 to 91.8)	87.0 (79.3 to 94.7)
Vegetable	57.8 (48.2 to 67.5)	55.6 (44.2 to 66.9)	49.9 (37.7 to 62)	65.6 (54.1 to 77)	68 (57.3 to 78.6)	76.6 (67 to 86.2)
Alcohol	9.6 (1.3 to 17.8)	4.3 (1 to 7.6)	4.2 (1.6 to 6.8)	7.2 (2.9 to 11.6)	5 (−0.1 to 10.1)	2.4 (−0.2 to 4.9)
Sex with non–long-term partner without a condom	1.9 (0.5 to 3.3)	1 (−0.7 to 2.7)	1 (−0.1 to 2.1)	6.6 (1.8 to 11.4)	2.1 (0.3 to 3.8)	1.3 (0.2 to 2.3)
Smoking	6.5 (−0.9 to 13.9)	5.1 (−2.6 to 12.8)	5.8 (−2.7 to 14.3)	1.4 (−0.1 to 3)	0.3 (−0.3 to 1)	0[a]

[a]95% CI values are not applicable.

Figure 3. Mean proportion of days on which behavior occurred by participant according to study arm and period (n=24 per arm).



Between-Arm Comparison

The comparison of study arms showed a significant difference in the change in reported vegetable consumption between periods 1 and 3 (control: 8% decrease in the mean proportion of days vegetables were consumed; intervention: 11.1% increase in the mean proportion of days vegetables were consumed; *P*=.01) and periods 2 and 3 (control: 5.7% decrease in the mean proportion of days vegetables were consumed; intervention: 8.6% increase in the mean proportion of days vegetables were consumed; *P*=.002). There were no other significant differences in the change in behavior over time between the intervention and control groups (Table 4).

Table 4. Mean difference in proportion of days participants reported behavior between periods (later period minus earlier period, positive number indicates increase in behavior over time, and negative number indicates decrease in behavior over time; n=24 per arm).

Reported behavior	Control (%)	Intervention (%)	Difference of differences (intervention−control; %)	*P* value[a]
Period 1 to period 2				
Fruit	1.01	3.99	2.98	.49
Vegetable	−2.28	2.41	4.69	.47
Alcohol	−5.28	−2.24	3.04	.24
Sex with non–long-term partner without a condom	−0.94	−4.53	−3.59	.12
Smoking	−1.36	−1.12	0.24	.90
Period 2 to period 3				
Fruit	1.98	4.38	2.4	.52
Vegetable	−5.71	8.64	14.35	.002
Alcohol	−0.05	−2.61	−2.56	.21
Sex with non–long-term partner without a condom	−0.02	−0.8	−0.78	.42
Smoking	0.71	−0.31	−1.02	.07
Period 1 to period 3				
Fruit	2.99	8.37	5.38	.18
Vegetable	−7.99	11.05	19.04	.01
Alcohol	−5.33	−4.86	0.47	.89
Sex with non–long-term partner without a condom	−0.96	−5.33	−4.37	.07
Smoking	−0.65	−1.43	−0.78	.69

[a]Two-sided *P* values calculated using two-sample *t* test.

Discussion

Principal Findings

This pilot study found that EMAI was feasible and may influence a range of participant behaviors. EMA alone may also affect the reported behaviors. To our knowledge, this is the first study of EMAI in sub-Saharan Africa. It provides a foundation on which further research on EMAI in transferable settings can be framed.

The feasibility of EMAI in a pilot study context in Rakai, Uganda, was supported in this study through high participant retention in both arms, yielding comparable study groups without adjustment and consistent submission of EMA data. The 85.5% (3777/4418) of the combined study follow-up days with behavioral data in this study is consistent with or better than data collection feasibility in other studies in high-income settings [3,23-26]. Compared with study periods 1 and 2, study period 3 saw an increase in days without behavioral reports in both study arms, indicating that more support may be needed to maintain EMA reports over time. Other EMAI studies have discussed the need for a careful examination of the participant population and study procedure burden to determine necessary and appropriate support for successful EMAI implementation [26,27].

Remote data collection and messaging may have some effect on behavior over a relatively short period. Descriptive comparisons of daily behavioral reports between the approximately 30-day study periods within arms suggest that alcohol consumption, sex with a non–long-term partner without a condom, fruit consumption, and smoking may be influenced by EMA or EMAI and that vegetable consumption may be influenced by EMAI. Although the study expected behavior change to be associated with intervention messaging, we hypothesize that daily reporting increased participant awareness of health risk behaviors, which may have changed their practices or reporting. This is consistent with theoretical and interventional extant self-monitoring literature, supporting that reactivity associated with improved self-awareness, particularly for routinized behaviors, can lead to behavior change [28,29].

Future research should not only expand beyond a pilot context to determine more robust estimates of the EMAI effect but should also examine differential pathways of change in raising awareness of risk behaviors compared with provision of feedback on positive, routinized behaviors to better understand the potential of both EMA and EMAI, beyond measurement. Although behavioral change may be rapid with EMAI, it is also necessary to examine the sustainability of change beyond the study's relatively short 90-day follow-up. Although our study used smartphones to allow for geospatial data collection in addition to behavioral data exchange, any phone with SMS or

Unstructured Supplementary Service Data capabilities could support the key elements of the study monitoring and intervention. Research examining the effect of EMAI using more basic phones could broaden the reach of future EMAI work by allowing interventions to operate on any type of phone currently owned by members of the population of interest.

Throughout the study period, the direction of the intervention arm trends in the mean proportion of days when behaviors were reported was consistent: increasing for fruit and vegetable consumption and decreasing for alcohol consumption, cigarette smoking, and sex with a nonmarital or non–long-term partner without a condom. There was more variation in the trends in the control arm. Although only vegetable consumption showed significant differences in change over time between arms, the direction and, with the exception of alcohol, the magnitude of the change in behaviors between study arms are consistent with the study hypotheses. This supports that remote intervention messaging warrants further study to promote behavioral change. Remote data collection and intervention may be particularly important in LMIC contexts such as Rakia, Uganda, where regular follow-up of people is difficult because of high population mobility and poor infrastructure. Similarly, in the era of COVID-19, human interaction carries risks that may exceed small to moderate, but otherwise important, behavior change benefits. Research to further establish the effectiveness of EMAI in these settings may be of critical importance.

Limitations

The findings of this pilot trial were not designed to be generalizable beyond the study's target population, including participants with at least a secondary level of education or a 90-day follow-up period. However, as preliminary estimates, they offer insight into the potential of EMAI and warrant further exploration. Behaviors were self-reported. It is not possible to differentiate actual changes in behavior from changes in reported behaviors influenced by social desirability bias, potentially reinforced by intervention messages, or other facts. However, although at different magnitudes, changes were observed in both the control and intervention arms of the trial. Furthermore, for sensitive behaviors such as condom use, self-report is the best available standard, with questions asking about recent experiences considered to be more valid and reliable than longer recall periods [30]. We did not collect the servings of fruits and vegetables consumed, precluding our ability to examine a dose-response relationship, which would be of interest in future, larger trials.

The study enrolled current RCCS participants who are accustomed to participating in trials. They may respond differently to interventions than research-naïve participants. Given the pilot nature of the study, explanations for reported behavioral changes other than the effect of intervention messaging cannot be ruled out. Particularly given block randomization and the study limit of 10 simultaneous active participants, seasonality in vegetable access, for example, could have influenced the decrease observed in vegetable consumption in the control arm.

Conclusions

Preliminary estimates from this pilot trial suggest that EMAI may be an effective strategy to promote behavior change across a range of behaviors. Larger trials examining the effectiveness of EMA alone and EMAI with responsive messaging in LMICs are warranted. Cost-effectiveness work is also recommended to establish the comparative potential of EMAI with more traditional approaches, leveraging increasingly accessible mobile technology in low-resource settings.

Acknowledgments

The study was funded by the Johns Hopkins Center for Global Health and the National Institutes of Health NIAID R01 AI143333. AGT was supported by the National Institutes of Health, NHLBI T32HL007055.

Authors' Contributions

LWC, IM, and MKG conceptualized and designed the study. The study procedures and data collection were implemented by IM, AA, CK, JM, AGT, EB, and GN. Study analyses were completed by LKB, MKG, AA, and LWC. LKB wrote the manuscript. All other authors have reviewed and substantively contributed to the manuscript revisions.

Conflicts of Interest

emocha Mobile Health Inc developed the application used in this study. LWC is entitled to royalties on certain nonresearch revenues generated by this company and owns company equity. Specific to this study, LWC received no royalties or compensation from emocha Mobile Health Inc. This arrangement has been reviewed and approved by Johns Hopkins University in accordance with its conflict of interest policies. None of the other study team members had known competing interests.

Multimedia Appendix 1
Bank of possible messages sent in response to reported behaviors (English translations).
[DOCX File , 15 KB - formative_v5i7e22693_app1.docx]

Multimedia Appendix 2
CONSORT-eHEALTH checklist V1.6.1.
[PDF File (Adobe PDF File), 1636 KB - formative_v5i7e22693_app2.pdf]

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Abbreviations

EMA: ecological momentary assessment
EMAI: ecological momentary assessment and intervention
LMIC: lower- and middle-income country
RCCS: Rakai Community Cohort Study

Edited by G Eysenbach; submitted 21.07.20; peer-reviewed by J Sekandi, L König; comments to author 12.09.20; revised version received 12.11.20; accepted 31.05.21; published 20.07.21.

Please cite as:
Beres LK, Mbabali I, Anok A, Katabalwa C, Mulamba J, Thomas AG, Bugos E, Nakigozi G, Grabowski MK, Chang LW
Mobile Ecological Momentary Assessment and Intervention and Health Behavior Change Among Adults in Rakai, Uganda: Pilot Randomized Controlled Trial
JMIR Form Res 2021;5(7):e22693
URL: https://formative.jmir.org/2021/7/e22693
doi:10.2196/22693
PMID:34283027

Original Paper

Exploring the Constituent Elements of a Successful Mobile Health Intervention for Prediabetic Patients in King Saud University Medical City Hospitals in Saudi Arabia: Cross-sectional Study

Fayz Alshehri[1], MSc, MPH; Fahdah Alshaikh[2], BSc, MPH, PhD

[1]Executive Department of Information Technology, King Saud University Medical City, King Saud University, Riyadh, Saudi Arabia

[2]Community Health Department, Applied Medical Sciences, King Saud University, Riyadh, Saudi Arabia

Corresponding Author:
Fayz Alshehri, MSc, MPH
Executive Department of Information Technology
King Saud University Medical City
King Saud University
King Abdulaziz University Hospital, Building 4, Level 3
King Abdulaziz Road
Riyadh, 12629
Saudi Arabia
Phone: 966 118067119
Email: afayz@ksu.edu.sa

Abstract

Background: Self-management of prediabetic patients is crucial since they are at high risk of developing type 2 diabetes. Mobile health (mHealth) apps could contribute to potentially reducing the burden of diabetes by supporting the self-management of prediabetic patients.

Objective: This study aimed to explore the constituent elements of a successful mHealth intervention for prediabetic patients in King Saud University Medical City (KSUMC) hospitals in Saudi Arabia using the Centre for eHealth Research (CeHRes) roadmap.

Methods: This study used the CeHRes roadmap as a developmental guideline for proposing mHealth app features for self-management of prediabetic patients and was performed in 3 phases with one round in each phase. First, a contextual inquiry was conducted via an online self-administered questionnaire for both health care providers and patients. Second, the value specification phase elaborated on the outcomes from the contextual inquiry phase. Finally, prototype user design was performed in cocreation with end users. The design phase was also conducted via an online self-administered questionnaire to evaluate the proposed features of mHealth apps by prediabetic patients.

Results: A total of 20 health care providers participated in the study. The results revealed that the most powerful intervention for prediabetes was a combination of medication, physical activity, and healthy diet plans (12/20, 60%). Furthermore, the most common challenge faced by prediabetes patients was patient adherence to healthy diet and physical activity recommendations (10/20, 50%). Almost all patients believed that mHealth apps would be useful for prediabetic patients. A total of 48 prediabetic patients participated in the study. The results indicated that the most powerful intervention for prediabetic patients is a combination of healthy diet and physical activity plans (21/48, 44%), and the most frequent challenge that may lead the patients to discontinue the current intervention was the commitment to a physical activity plan (35/48, 75%). Furthermore, 15% (17/48) of patients use well-being and health apps to manage their current health status. The most common difficulties faced by the patients were navigating app features (mean 2.02 [SD 1.7]) followed by the app language (mean 1.88 [SD 2.0]); these difficulties occurred at a significantly higher rate among those with secondary or lower educational levels as compared to undergraduate and postgraduate levels (P<.05). Finally, the features proposed in the prototype design scored more than 2.5 points higher and indicate the need for these features to be included in the mHealth app.

Conclusions: This study aimed to provide real-world insights into the development of an mHealth app for a diabetes prevention intervention by involving both health care providers and prediabetic patients in KSUMC hospitals. Therefore, the proposed app, which comprises all necessary features, may aid patients with prediabetes in self-management and making changes in their lifestyle.

(JMIR Form Res 2021;5(7):e22968) doi:10.2196/22968

KEYWORDS

prediabetes; mHealth; CeHRes roadmap; Saudi Arabia

Introduction

Background

Diabetes mellitus (DM) is one of the fastest growing health problems worldwide, and it has been associated with adverse health outcomes such as rising obesity, reduced physical activity, and mortality [1,2]. According to the International Diabetes Federation, the number of adults (aged 20 to 79 years) with diabetes worldwide was 463 million in 2019; by 2045, this number will increase to 700 million [3,4]. Furthermore, the worldwide prevalence of underdiagnosed diabetes (prediabetes) was estimated as 50.1% in 2019 [3,4]. Compared to overseas countries, Saudi Arabia has a high prevalence of DM, and the World Health Organization has ranked it as the seventh highest country for the prevalence of DM [5]. Approximately 4.3 million adults have diabetes in 2019; by 2045, this will increase to about 7.9 million, and the estimated age-adjusted comparative prevalence of DM was 15.8% in 2019, which will rise to 17.8% by 2045 as reported by the International Diabetes Federation [4]. In the meantime, the number of patients with prediabetes was approximately 1.7 million in 2019 in Saudi Arabia with a prevalence of 39% [4]. Prediabetes refers to a person who a higher than normal blood sugar level that is not high enough to be considered diabetic yet. However, without lifestyle changes, individuals with prediabetes are more likely to develop the disease. This indicates that prediabetic patients are at relatively high risk for developing diabetes in the future [6].

It is believed that self-management of prediabetes might play a vital role in preventing or delaying the development of the disease and its adverse effects. Components of self-management include diabetes education, healthy eating, physical activity, medication, and device use [7]. For instance, any increase from a low level of physical activity can reduce the incidence of developing diabetes [8]. One popular lifestyle change program directed toward prediabetic patients is the one modeled after the Diabetes Prevention Program research study [9,10].

Recent years have seen a growing trend in the availability and use of well-being and health apps. Mobile health (mHealth), "the use of mobile communications for health information and services" [11], can play a significant role in adjusting and improving health promotion lifestyle, prevention of disease, and disease self-management [12-16]. That is, mHealth is characterized by the mobile technology's mobility, which facilitates instantaneous access and direct communication allowing for faster transfer of health information, which in turn supports medical and public health practices [17]. In the diabetes context, mHealth is a promising technology that supports patient engagement in their health care since most people own and regularly use a mobile phone and may use functions like text and voice messaging with health care professionals, connections to external devices (eg, heart rate measurement and monitoring of blood glucose or blood pressure), medication support, tracking physical activity (eg, lifestyle tracking using pedometer technologies to track one's steps and calories), and monitoring healthy diet behavior via mHealth apps [18-22]. A systematic review assessed the efficacy, usability, and features of commercially available mHealth apps for self-management of diabetes and showed that none of the reviewed studies exhibited significant patient improvements in quality of life, BMI, and blood pressure.

There is extensive literature on the adoption of mHealth apps to illustrate influences on the adoption decision [23-35]. Some studies were based on the technology acceptance model [23-29]. Other studies relied on the unified theory of acceptance and use of technology [30-32]. Little research took into account the appropriation and implementation perspective on the use of mHealth apps; these studies mostly focusing on continued use and failed to consider the integration of multifaceted everyday life patterns [28,33,34]. A study by Rossmann et al [35] used the mobile appropriation model to investigate how diabetes patients use mHealth apps for self-management and showed that patients are heterogeneous in evaluating such mHealth apps. Some studies relied on the Centre for eHealth Research (CeHRes) roadmap [22,23]. According to the framework by Klasnja and Pratt [22], there are 5 behavioral intervention strategies enabled by smartphones. These include tracking health information (eg, setting goals for targeted behavior, monitoring, tracking, reminders, and progress visualization), involving the health care team (eg, sharing health information with health care providers), leveraging social influence (eg, social networking), increasing the accessibility of health information (eg, access to didactic curriculum, coaching), and using entertainment (eg, reward-based games). Thus, most existing frameworks were found to rely more on a conceptual approach instead of practical guidelines and lack of participatory approach that ensure the eHealth technologies are stakeholder-driven [23]. Furthermore, studies were largely heterogeneous and had to some extent methodological issues including inconsistency in randomization reporting, masking, and allocation and low quality that hurt interpretation of the results [20,21,23]. Therefore, to avoid failure of making an impact with these eHealth technologies, eHealth developers and researchers should adopt a reliable approach in the early stage of development. The behavioral change intervention strategy was also used and showed it was an effective tool for developing mHealth apps [36,37].

The preliminary research in the literature shows that there is a lack of evidence on the use of mHealth technologies in the prevention of type 2 diabetes in Saudi Arabia [38]. Therefore, this study aims to provide an initial step toward building an mHealth technology that could support the current prediabetes self-management intervention. More specifically, this study is devoted to determining the requirements and specifications needed to design an mHealth intervention for prediabetic patients in King Saud University Medical City hospitals. This study should contribute to the overall vision of Saudi Arabia's

Ministry of Health in reducing the burden of type 2 diabetes [39].

Centre for eHealth Research Roadmap

Van Gemert-Pijnen et al [23] proposed a holistic framework for the development of eHealth technologies which are the outcomes of a systematic review of existing frameworks and from empirical research and progressive insights about the framework obtained from experts at eHealth conferences. The framework is also referred to as the CeHRes roadmap. It serves as an evidence-based roadmap to the research and developmental activities involved in developing eHealth technologies from concept definition through development to summative evaluation [40]. This roadmap aims to ensure the developed eHealth technologies are human-centered, tailored to stakeholder needs, and capable of altering user behaviors, thus increasing the uptake and impact of eHealth technologies. The CeHRes roadmap takes an iterative approach through 5 phases of development: contextual inquiry, value specification, design, operationalization, and summative evaluation to ensure an iterative, flexible, and dynamic process resulting in concepts of the technology (from ideation to product) [23].

Identifying user values is one key task in developing eHealth technologies, which are a key aspect of the CeHRes roadmap. Despite well-established literature on consumer needs, it is often not clear what needs to be addressed [41]. Studies that used the CeHRes roadmap reported that they benefit from the iterative approach provided by the framework which allows them to use it as a checklist tool afterward [42]. This also allows creating outcome benchmarks meaning that if the design requirement does not meet the targeted goals of the eHealth technology, one can return to different points within the CeHRes phases to make adjustments [41].

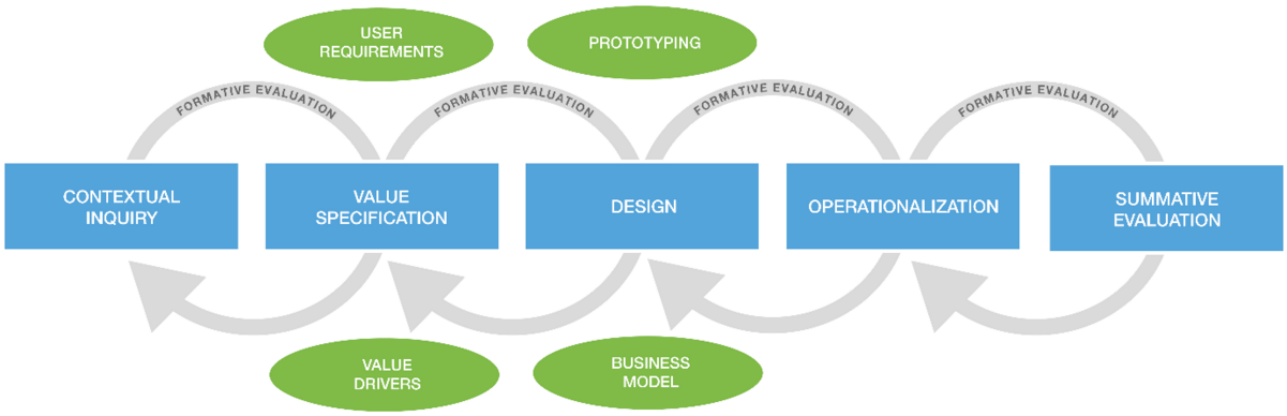
By 2017, the use of the CeHRes roadmap in the development of eHealth technologies was apparent in 26 studies but also recognized and referenced in hundreds of studies. The app of the CeHRes roadmap was mostly for the control of infectious diseases, management of cancer, treatment of mental health, and management of diabetes [43].

Methods

Overview

This is a cross-sectional study using self-administered questionnaires as the main tools for collecting data and the CeHRes roadmap as a guide. For this study, the first 3 phases were conducted: contextual inquiry, value specification, and design phases. According to the CeHRes roadmap, the operationalization and summative evaluation phases are concerned with the introduction, adoption, and employment of the technology in practice and evaluating how it is being used and its effects. Therefore, they are beyond the scope of this study, which is limited to designing a low fidelity prototype that reflects the requirements and specifications for the mHealth intervention for prediabetic patients in KSUMC hospitals (Figure 1).

Figure 1. The CeHRes roadmap.



Methodological Framework

The first phase of the CeHRes roadmap is the contextual inquiry. This phase aims to understand the current issues, how the technology can contribute to resolving these issues, and who might benefit from the technology. This can be realized by investigating 3 subphases: stakeholder identification, stakeholder analysis, and describing the current situation [44]. In this study, we initially identified and analyzed key stakeholders such as physicians, dietitians, health educators, and prediabetic patients before we explored the current situation for the prediabetes intervention in KSUMC hospitals. The current situation then was explored using self-administrated questionnaires sent to health care providers and prediabetic patients.

The second phase of the CeHRes roadmap is value specification which elaborates on the outcomes from the contextual inquiry. The value specification has two main outcomes: a value map that contains the values that mHealth should address and a list of requirements [45]. These requirements are needed to develop the technology, which is in our case is the mHealth app for a prediabetes intervention. In this phase, the key stakeholder values and requirements were realized and ranked based on the importance and need using descriptive statistics. The findings helped us to understand the added value that the proposed mHealth features would provide for prediabetic patients.

The outcomes of the contextual inquiry and value specification phases were then translated into a blueprint for our proposed mHealth technology, which was developed in the design phase. According to the CeHRes roadmap, the design of any eHealth

technology should consist of 3 subphases: develop low-fidelity and high-fidelity prototypes, conduct usability tests, and add persuasive elements [46]. For this study, a low-fidelity prototype was developed that addressed the values and requirements from the previous phases. Table 1 describes how the proposed mHealth features were guided by Klansja and Pratt's framework of 5 behavioral intervention strategies enabled by smartphones as well as the key components of a lifestyle change program in preventing type 2 diabetes [9,22]. These proposed mHealth features were then translated into a prototype of user interfaces. The prototype was then tested by 2 mobile app developers on the design level.

Table 1. Proposed mHealth features guided by lifestyle change plan of Kirley & Sachdev and Klansja and Pratt's framework.

Kirley & Sachdev lifestyle change plan to prevent diabetes	Klansj and Pratt's framework	Proposed mHealth features
Self-monitoring of diet and physical activity	Tracking health information	• Weight management • Step counting • Blood glucose calculator • List of healthy food • Notifications
Didactic curriculum and coaching	Involving health team	• Phone call • Text messaging
Peer support	Leveraging social media	• Peer and group communication
Individual skills development and problem solving	Accessibility of health information	• Pop-up quizzes • Frequently asked questions
Motivation	Using entertainment	• Users collecting points for the following features • Weight measurement (reaching goal) • Step counting (reaching goal) • Pop-up quizzes (questions answered)

The end users for our proposed mHealth app are prediabetic patients. Therefore, the prototype user interfaces were sent to patients using an online form to evaluate them one by one on a 5-point Likert-type scale from "I strongly need it" to "I do not need it at all." The design of the prototype has considered the need for persuasive elements in the proposed mHealth features, which are introduced as motivation features such as collecting points and getting badges when a certain goal was achieved.

Participants

The populations of this study comprised health care providers from both KSUMC hospitals and prediabetic patients. The health care providers were eligible if they are involved in the management of prediabetic patients. A total of 40 health care providers working in the primary care departments in the KSUMC hospitals were eligible: physicians (28/40), dietitians (8/40), health educators (4/40). The prediabetic patient population inclusive criteria were patients diagnosed with prediabetes, Arabic speakers, age group from 20 to 65 years, and receiving intervention for prediabetes. The age range used is the frequent age of onset of diabetes [1], and 1040 prediabetic patients were found eligible for this study in the hospitals' electronic health records.

The sample size for health care providers population was 38 and for prediabetic patients it was 281. A convenience sampling technique was used for health care providers and simple random sampling was performed on the prediabetic patients list.

Data Collection Tools

Two self-administrated questionnaires were used in this study; one for health care providers and one for prediabetic patients. The first questionnaire was sent to health care providers in paper-based form to explore the current situation from the health care provider side. The second questionnaire was an online questionnaire that was sent by text message to patient phones, and it aimed to explore the current situation from the prediabetic patient side. Both questionnaires were developed using the information gathered during the stakeholder identification and analysis subphases in the contextual inquiry phase. This information was collected by interviewing 3 health care providers, a physician, dietitian, and health educator from the primary care departments in KSUMC hospitals. For the prediabetic patient questionnaire, 3 prediabetic patients were interviewed (male aged 58 years, male aged 32 years, and female aged 31 years). All questionnaires were then piloted for clarity of questions (Multimedia Appendix 1 and 2).

Moreover, the prototype of user interfaces was also reviewed by the same group of patients for clarity of the presentation of user interfaces of the proposed mHealth features (Multimedia Appendix 3). The instruments were sent to participants for a duration of 1 week and with a reminder 2 days before the closing time of the online form.

Data Analysis

The data were analyzed using SPSS (version 25, IBM Corp) software. Descriptive statistics were presented as means and standard deviations for continuous variables and as frequencies and percentages for categorical variables. Independent sample *t* tests and 1-way analysis of variance tests were performed to test for differences in mean scores as appropriate. Statistical significance was sought at values lower than 5%.

Ethical Consideration

This study has received the ethical approval number E-19-4118 from the Institute of Review Board at College of Medicine in King Saud University (Multimedia Appendix 4).

Results

Health Care Provider Questionnaire

A total of 20 questionnaires were completed and received: 10 physicians (50%), 6 dietitians (30%), and 4 health educators (20%). The majority of respondents were females (16/20, 80%) and aged 30 to 39 years (8/20, 40%). One-half of them worked at King Khalid University Hospital (KKUH) (10/20, 50%). Most respondents stated that the most impactful intervention technique for prediabetes was a combination of medication with both healthy diet and physical exercise plans. About 65% (13/20) of participants had communicated with patients in terms of phone call (8/20, 62%), text messages (4/20, 31%), and emails (1/20, 8%). The majority of participants believed that mHealth apps would help prediabetes patients (17/20, 85%; Table 2).

Furthermore, health care providers were asked about the challenges and barriers using open questions. The health care provider answers were then analyzed using quantitative text analysis to categorize the barriers and challenges facing the current interventions for prediabetic patients in KSUMC hospitals. The results showed 5 common reported barriers and challenges to the current intervention. The lack of adherence to a healthy diet and physical activity plans was the most common barrier (10/20, 50%). This is followed by the lack of awareness (8/20, 40%). Accordingly, lack of awareness was described frequently as the patients denying the fact that they had a high blood sugar level or not taking the medical diagnosis seriously. Furthermore, loss of follow-up (7/20, 35%) and lack of motivation (5/20, 25%) were found among the barriers faced by patients. Finally, the participants also reported that there were cultural barriers facing patients to adhere to medical recommendations (4/20, 20%; Table 2).

Table 2. Descriptive statistics of health care providers questionnaire (n-20).

Characteristics	Value, n (%)
Occupation	
Dietitian	10 (50)
Physician	6 (30)
Health educator	4 (20)
Gender	
Male	6 (30)
Female	14 (70)
Age group (years)	
20-29	4 (20)
30-39	6 (30)
40-49	8 (40)
50-59	2 (10)
Hospital	
King Khalid University Hospital	10 (50)
King Abdulaziz University Hospital	10 (50)
What are the most impactful intervention techniques you used in your clinic for patients with prediabetes?	
Medication and healthy diet plan	1 (5)
Medication, healthy diet plan, and physical exercise plan	12 (60)
Healthy diet plan and physical exercise plan	7 (35)
Do you or any of your team members communicate with patients remotely? If so, by what means?	
No	7 (35)
Yes	13 (65)
Phone call	8 (62)
Text messages	4 (31)
Emails	1 (8)
Health care provider perceptions of mobile health technologies	
No, I do not believe it can help them	0 (0)
Not sure if it can help them	3 (15)
Yes, I believe it can help them	17 (85)
Barriers or challenges facing the current interventions for prediabetic patients to prevent diabetes	
Adherence to healthy diet and physical activity plans	10 (50)
Lack of awareness	8 (40)
Loss of follow-up	7 (35)
Lack of motivation	5 (25)
Cultural barriers	4 (20)

Prediabetic Patient Questionnaire

A total of 48 participants responded to the questionnaire (Table 3). Two-thirds of participants were males (32/48, 67%). One-half of them were aged 50 years or above (24/48) and 46% (22/48) had undergraduate educational level. One-third (16/48) of respondents were diagnosed with prediabetes more than five years ago. The majority (37/48, 77%) of patients who participated in this questionnaire were from KKUH.

The majority (21/48, 44%) of participants were engaged with lifestyle change programs including a healthy diet plan and physical activity plan as an intervention strategy for diabetes. Meanwhile, the less frequent intervention strategy was the combined one of medication, healthy diet, and physical activity plans (7/48, 15%).

The majority (35/48, 75%) of participants reported that the most frequent challenges and barriers leading prediabetic patients to discontinue the current intervention were the commitment to physical activity plan. This is followed by commitment to healthy dietary plan (25/48, 52%), commitment to constantly following up in clinic (12/48, 25%), and lack of self-motivation (11/48, 23%). However, the less frequent challenge and the barrier was the commitment to take medication on time (7/48, 15%).

The results also revealed that most (31/48, 65%) respondents stated that they did not use mHealth apps to manage their status of health. On the other hand, 15% (17/48) of respondents stated they use mHealth apps either usually or sometimes to manage their current status of health, and some of them mentioned some apps including iHealth, VitaDock, Fitbit, Nike Run, Samsung Health, and Apple Health and others mentioned they use apps for Zumba training for fitness and weight loss. Most participants reported that they used websites using search engines (30/48, 63%) while social media platforms such as Facebook, Twitter (20/48, 42%), and YouTube (23/48, 48%) had been used sometimes. The majority (36/48, 75%) of respondents exhibited their willingness and readiness to use mHealth apps while 25% (12/48) of them stated that they may use these apps, but none of them stated that they will not use such apps (Table 3).

Moreover, the results indicate that the most downside and difficulty of using such mHealth apps was navigating the features in mHealth apps whereby it scored a mean of 2.02 (SD 1.7) points. The mean score of app language difficulty was 1.88 (SD 2.0) points, 1.81 (SD 1.6) points for self-motivation to use the mHealth apps, 1.77 (SD 1.7) points for understanding the goal of mHealth apps, and 1.71 (SD 1.7) points for learning how to use these apps (Table 4). Nevertheless, these average scores were less than the average score of 2.5 points (ie, 15/6) indicating that these difficulties were mild. The results also revealed that there were no statistically significant differences in average scores of these difficulties by gender, age, and educational levels. Males were more likely to have difficulty in self-motivation than female counterparts ($P<.05$). However, the only differences found to be statistically significant were self-motivation by gender ($P<.05$) and app language by educational levels ($P<.05$). That is, the average score of self-motivation of males was higher than that for female counterparts. Moreover, the average score of language difficulty for participants with secondary or lower education was higher than those with undergraduate and postgraduate educational levels (Table 5).

Table 3. Descriptive statistics of the sample (n=48).

Item characteristics	Value, n (%)
Gender	
Male	32 (67)
Female	16 (33)
Age group (years)	
20-29	2 (4)
30-39	9 (19)
40-49	13 (27)
50 and above	24 (50)
Educational levels	
Secondary or lower	12 (25)
Undergraduate	22 (46)
Postgraduate	14 (29)
History of diagnosis	
Less than 1 year	11 (23)
1-2 years	9 (19)
2-3 year	9 (19)
3-5 years	3 (6)
More than 5 years	16 (33)
Hospital	
King Khalid University Hospital	37 (77)
King Abdulaziz University Hospital	11 (23)
Intervention strategy for prediabetes	
Only medication	10 (21)
Medication + healthy diet plan	10 (21)
Medication + healthy diet plan + physical activity plan	7 (15)
Healthy diet plan + physical activity plan	21 (44)
Challenges and barriers	
Commitment to physical activity plan	35 (73)
Commitment to a healthy dietary plan	25 (52)
Commitment to constantly following up in the clinic	12 (25)
Lack of self-motivation	11 (23)
Commitment to take medication on time	7 (15)
Frequent use of mHealth Apps	
Always	7 (15)
Sometimes	10 (21)
No	31 (65)
Frequent use of platforms	
Websites using the search engine	
Always	30 (63)
Sometimes	12 (25)
Never	6 (13)
Social media (ie, Twitter, Facebook, WhatsApp, telegram)	

Item characteristics	Value, n (%)
Always	14 (29)
Sometimes	20 (42)
Never	14 (29)
YouTube	
Always	11 (23)
Sometimes	23 (48)
Never	14 (29)
Readiness to use mHealth app among prediabetic patients	
Yes	36 (75)
No	0 (0)
Maybe	12 (25)

Table 4. Downside and difficulty faced by participants while using mHealth apps.

Type of difficulties	Mean (SD)
App language (eg, app does not support the Arabic language)	1.88 (2.0)
Learning how to use the mHealth app	1.71 (1.6)
Understand the goal of the mHealth app	1.77 (1.7)
Navigating the features in the mHealth app	2.02 (1.7)
Self-motivation to use mHealth app	1.81 (1.6)

Table 5. Mean scores of each difficulty by gender, age groups, and educational levels.

Type of difficulties	App language	App learning	App understanding	App navigation	Self-motivation
Gender					
Male	2.09 (1.9)	2.0 (1.6)	2.09 (1.7)	2.25 (1.6)	2.16 (1.6)[a]
Female	1.44 (2.4)	1.13 (1.4)	1.13 (1.5)	1.56 (1.7)	1.13 (1.2)
Age groups					
20-29	0.0 (0)	2.0 (1.4)	1.50 (0.7)	3.50 (2.1)	2.50 (2.1)
30-39	3.22 (2.0)	1.89 (1.4)	2.11 (1.6)	2.22 (1.5)	2.56 (1.3)
40-49	1.92 (1.9)	1.69 (1.7)	1.62 (1.8)	1.62 (1.3)	1.38 (1.6)
50 years and above	1.5 (1.9)	1.63 (1.7)	1.75 (1.8)	2.04 (1.9)	1.71 (1.6)
Educational levels					
Secondary or lower	3.33[a] (1.9)	2.42 (1.7)	2.33 (1.7)	2.08 (1.7)	1.83 (1.4)
Undergraduate	1.41 (1.7)	1.32 (1.4)	1.32 (1.6)	1.82 (1.9)	1.59 (1.8)
Postgraduate	1.36 (1.8)	1.71 (1.7)	2.00 (1.8)	2.29 (1.4)	2.14 (1.4)

[a]Significant at 5% level of significance.

Prediabetic Patient Evaluation of the Prototype User Interfaces

Table 6 presents the average score given for each feature along with their corresponding lifestyle change program components and the 5 smartphone behavioral intervention strategies by Klansja and Pratt as well as the key components of lifestyle change program in preventing type 2 diabetes [9,22]. The findings indicate that the mean score of tracking health information items (ie, self-monitoring of diet, physical activity, and weight component) ranged from 3.88 (SD 0.7) to 4.54 (SD 1.4) points. Furthermore, respondents scored average scores of 4.15 (SD 0.9) and 4.37 (SD 0.9) for involving health teams in terms of the phone call and text messages features, respectively. The mean scores of accessibility of health information (ie, individual skills development and problem solving) were 4.15 (SD 1.0) for pop-up quizzes and 4.37 (SD 0.8) for frequently asked questions about the prevention of diabetes. The

entertainment utility (ie, motivation, collecting points, and getting badges when a certain goal was achieved in such features) had mean scores ranged from 3.92 to 4.15 (SD 1). That is, features like getting points and badges when completing daily steps and walking time needed weekly received an average score of 4.15 (SD 1.0) points, getting points and badges when achieving 5% loss of body weight had a mean score of 4.13 (SD 1.0) points, and getting points and badges by answering the pop-up quizzes correctly had an average score of 3.92 (SD 1.0) points. However, the social communication features had the lowest scores reported by respondents for both peer support (mean 3.58 [SD 1.0]) and group support (mean 3.62 [SD 1.0]). Generally speaking, the prediabetic patients response scores of these features were moderate and indicate the need for these features to be available in mHealth apps.

Table 6. Average scores of each feature along with their correspondents lifestyle change program components and the 5 smartphone behavioral intervention strategies by Klansja and Pratt [9,22].

Feature and component	Value, mean (SD)
Tracking health information (self-monitoring of diet, physical activity, and weight)	
Step count	4.54 (0.7)
Blood glucose calculator	3.88 (1.4)
List of daily healthy diet options	4.54 (0.7)
Notifications	4.37 (0.9)
Weight and body mass management	4.46 (0.9)
Involving health team	
Phone call communication	4.15 (0.9)
Text messages communication	4.37 (0.9)
Accessibility of health information (individual skills development and problem solving)	
Pop-up quizzes	4.15 (1.0)
Frequent asked questions about the prevention of diabetes	4.37 (0.8)
Using entertainment (motivation; collecting points and getting badges when a certain goal was achieved in the following features)	
Weight and body mass management (when achieving 5% body weight loss)	4.13 (1.0)
Step count (completing daily steps & walking time needed weekly)	4.15 (1.0)
Pop-up quizzes (when correctly answering the quizzes)	3.92 (1.0)
Leveraging social media	
Group support	3.58 (1.0)
Peer support	3.62 (1.0)

The results also indicate that there were no statistically significant differences in mean scores of these proposed features by gender, age groups, and educational levels (P<.05) (Tables 7, 8, and 9). That is, participants have the same perceptions toward these features regardless of their gender, age, and educational levels.

Table 7. Average scores of each feature by gender.

Feature and component	Male, mean (SD)	Female, mean (SD)	*P* value
Tracking health information (self-monitoring of diet, physical activity, and weight)			
Step count	4.55 (0.6)	4.53 (0.8)	.95
Blood glucose calculator	3.59 (1.4)	4.10 (1.3)	.18
List of daily healthy diet options	4.50 (0.6)	4.57 (0.7)	.73
Notifications	4.27 (0.9)	4.23 (0.9)	.54
Weight and body mass management	4.64 (0.7)	4.33 (1.0)	.24
Involving health team			
Phone call communication	4.18 (1.0)	4.13 (0.9)	.06
Text messages communication	4.41 (1.0)	4.33 (0.9)	.08
Pop ups quizzes	4.32 (0.8)	4.03 (1.0)	.31
Accessibility of health information (individual skills development and problem solving)			
Frequent asked questions about the prevention of diabetes	4.59 (0.7)	4.20 (0.9)	.10
Using entertainment (motivation; collecting points and getting badges when certain goal was achieved in the following features)			
Weight and body mass management (when achieving 5% body weight loss)	4.41 (0.9)	3.93 (1.0)	.10
Steps count (completing daily steps & walking time needed weekly)	4.27 (0.8)	4.07 (1.1)	.21
Pop-up quizzes (when correctly answering the quizzes)	4.09 (1.0)	3.80 (1.1)	.29
Leveraging social media			
Group support	3.59 (1.0)	3.57 (1.1)	.94
Peer support	3.77 (1.0)	3.50 (1.1)	.37

Table 8. Average scores of each feature by age group.

Feature, component, and age group (years)	Value, mean (SD)	*P* value
Tracking health information (Self-monitoring of diet, physical activity, and weight)		
Step count		.12
20-29	5.00 (0.0)	—[a]
30-39	4.83 (0.4)	—
40-49	4.80 (0.4)	—
50 and above	4.36 (0.8)	—
Blood glucose calculator		.75
20-29	3.67 (2.3)	—
30-39	3.33 (1.9)	—
40-49	4.00 (1.4)	—
50 and above	3.97 (1.1)	—
List of daily healthy diet options		.23
20-29	4.67 (0.6)	—
30-39	4.83 (0.4)	—
40-49	4.80 (0.4)	—
50 and above	4.39 (0.7)	—
Notifications		.09
20-29	5.00 (0.0)	—
30-39	4.83 (0.4)	—
40-49	4.70 (0.7)	—
50 and above	4.12 (1.0)	—
Weight and body mass management		.07
20-29	5.00 (0.0)	—
30-39	5.00 (0.0)	—
40-49	4.80 (0.6)	—
50 and above	4.21 (1.0)	—
Involving health team		
Phone call communication		.78
20-29	4.67 (0.6)	—
30-39	4.17 (0.7)	—
40-49	4.00 (1.2)	—
50 and above	4.15 (0.9)	—
Text messages communication		.16
20-29	5.00 (0.0)	—
30-39	5.00 (0.0)	—
40-49	4.30 (0.9)	—
50 and above	4.21 (0.9)	—
Accessibility of health information (individual skills development and problem solving)		
Pop-up quizzes		.39
20-29	4.00 (1.0)	—
30-39	4.67 (0.5)	—
40-49	4.40 (0.7)	—

Feature, component, and age group (years)	Value, mean (SD)	*P* value
50 and above	4.00 (1.1)	—
Frequent asked questions about the prevention of diabetes		.08
20-29	5.00 (0.0)	—
30-39	4.83 (0.4)	—
40-49	3.90 (1.1)	—
50 and above	4.36 (0.8)	—
Using entertainment (motivation; collecting points and getting badges when a certain goal was achieved in the following features)		
Weight and body mass management (when achieving 5% body weight loss)		.06
20-29	5.00 (0.0)	—
30-39	4.83 (0.4)	—
40-49	4.40 (0.9)	—
50 and above	3.85 (1.0)	—
Step count (completing daily steps & walking time needed weekly)		.46
20-29	4.00 (1.0)	—
30-39	4.50 (0.8)	—
40-49	4.50 (0.7)	—
50 and above	4.00 (1.1)	—
Pop-up quizzes (when correctly answering the quizzes)		.53
20-29	3.67 (1.2)	—
30-39	4.33 (0.8)	—
40-49	4.20 (0.9)	—
50 and above	3.79 (1.1)	—
Leveraging social media		
Group support		.22
20-29	4.00 (1.0)	—
30-39	4.33 (0.5)	—
40-49	3.40 (1.2)	—
50 and above	3.45 (1.0)	—
Peer support		.55
20-29	3.67 (1.2)	—
30-39	4.17 (0.4)	—
40-49	3.70 (1.2)	—
50 and above	3.48 (1.1)	—

[a]Not applicable.

Table 9. Average scores of each feature by educational levels.

Feature, component, and education level	Value, mean (SD)	*P* value
Tracking health information (Self-monitoring of diet, physical activity, and weight)		
Step count		.51
Secondary or lower	4.33 (0.9)	—[a]
Undergraduate	4.59 (0.7)	—
Postgraduate	4.64 (0.5)	—
Blood glucose calculator		.21
Secondary or lower	4.25 (1.0)	—
Undergraduate	3.50 (1.5)	—
Postgraduate	4.36 (1.1)	—
List of daily healthy diet options		.24
Secondary or lower	4.75 (0.6)	—
Undergraduate	4.36 (0.7)	—
Postgraduate	4.64 (0.6)	—
Notifications		.68
Secondary or lower	4.25 (1.2)	—
Undergraduate	4.41 (0.8)	—
Postgraduate	4.57 (0.9)	—
Weight and body mass management		.59
Secondary or lower	4.50 (0.8)	—
Undergraduate	4.32 (1.1)	—
Postgraduate	4.64 (0.6)	—
Involving health team		
Phone call communication		.48
Secondary or lower	4.08 (1.0)	—
Undergraduate	4.09 (0.9)	—
Postgraduate	4.43 (0.8)	—
Text messages communication		.65
Secondary or lower	4.25 (1.1)	—
Undergraduate	4.45 (0.9)	—
Postgraduate	4.57 (0.8)	—
Accessibility of health information (individual skills development and problem solving)		
Pop-up quizzes		.74
Secondary or lower	4.25 (1.1)	—
Undergraduate	4.00 (1.0)	—
Postgraduate	4.21 (0.9)	—
Frequent asked questions about the prevention of diabetes		.47
Secondary or lower	4.17 (1.0)	—
Undergraduate	4.50 (0.7)	—
Postgraduate	4.21 (0.9)	—
Using entertainment (motivation; collecting points and getting badges when certain goal was achieved in the following features)		
Weight and body mass management (when achieving 5% body weight loss)		.51
Secondary or lower	4.17 (1.1)	—

Feature, component, and education level	Value, mean (SD)	*P* value
Undergraduate	3.95 (1.1)	—
Postgraduate	4.36 (0.7)	—
Steps count (completing daily steps & walking time needed weekly)		.08
Secondary or lower	4.08 (1.4)	—
Undergraduate	3.86 (0.9)	—
Postgraduate	4.64 (0.6)	—
Pop-up quizzes (when correctly answering the quizzes)		.12
Secondary or lower	4.08 (1.3)	—
Undergraduate	3.59 (0.9)	—
Postgraduate	4.29 (0.9)	—
Leveraging social media		
Group support		.38
Secondary or lower	3.58 (1.2)	—
Undergraduate	3.36 (0.9)	—
Postgraduate	3.86 (1.0)	—
Peer support		.07
Secondary or lower	3.42 (1.3)	—
Undergraduate	3.36 (0.9)	—
Postgraduate	4.21 (0.9)	—

[a]Not applicable.

Discussion

Principal Findings

This study is an initial development of an mHealth app for self-management of prediabetic patients in KSUMC hospitals in Saudi Arabia using a theoretically driven approach based on the CeHRes roadmap [22,23]. The main objective of this study was to determine the most important features that should be available in successful mHealth apps for self-management of prediabetes based on the CeHRes roadmap guided by the Klansja and Pratt framework and components of the lifestyle change program by Kirley and Sachdev [9,22], which is the first attempt to the best of the authors' knowledge. Accordingly, this study builds on the perceptions of both health care providers and prediabetic patients toward the use of mHealth apps for self-management of prediabetes. From the health care provider point of view, the findings indicate that the most powerful intervention procedure for prediabetes is a combination of medication with both healthy diet and physical exercise plans. From the prediabetic patient point of view, the most powerful intervention procedure for prediabetes is a combination of both healthy diet and physical exercise plans, confirmed with the Diabetes Prevention Program goals [47]. Some studies indicated that physical activity is a key tool for the prevention and management of DM [48,49].

The majority of health care providers, as part of their management of prediabetic patients, reported that they communicated with patients via either a phone call or text messages. This is confirmed with prediabetic patients whereby most of them reported they did not use such mHealth apps while a few reported using social media platforms and websites. Communicating with patients remotely using text messaging was a common approach in delivering the curriculum of various diabetes prevention programs [47]. A recent study indicated that diabetes-related apps accounted for about 16% of the total number of available Health apps [50]. Furthermore, these diabetes-related apps differed in their functions such as tracking blood glucose measurements, physical activity, weight tracking, sharing data with clinicians or peers, social support and messaging, and nutrition database and carbohydrate tracking [51]. Veazie et al [21] indicated that even though many apps for diabetes self-management are available for commercial purposes, their study demonstrated that only 11 apps have had an impact on patient health.

In Saudi Arabia, evidence showed that the major risk factors for developing type 2 diabetes were obesity, lack of physical activity, unhealthy diet, smoking, and aging in addition to more complex factors such as lack of education, poor social support, and unhealthy environment [52]. Health education counseling by physicians was considered one of the most powerful practices in endorsing lifestyle modification such as healthy diet and physical activity as an important factor for weight management control and reduce the risk of developing diabetes [53,54]. Lifestyle modification such as increasing physical activity has the potential to not only raise glycemic control but also boost a patient's insulin sensitivity and repair some of the damage caused by diabetes-associated complications, such as impaired cardiovascular health, one of the most common complications

[55]. Lifestyle modification is also a cornerstone of any prediabetes intervention management. Evidence showed that individuals with prediabetes involved in prediabetes intervention programs have a 40% to 70% relative risk reduction of diabetes [56].

Concerning the perceived challenges and barriers of using mHealth apps in the context of prediabetes, the results revealed that the most significant challenge and barriers faced by patients reported by health care providers were the lack of adherence to a healthy diet and physical activity plans, the lack of awareness, loss of follow-up, lack of motivation, and cultural barriers facing patients to adhere to medical recommendations. On the other hand, prediabetic patients reported that the most common challenges and barriers that may lead them to discontinue the current intervention were the commitment to physical activity plan, commitment to a healthy dietary plan, commitment to constantly following up in the clinic, and lack of self-motivation. However, the commitment to take medication on time received less attention. Prediabetic patients who indicated that they have used such mHealth apps had faced difficulty in navigating the features in apps because of language barriers, self-motivation, understanding the goal, and learning how to use these apps but the levels of these difficulties were mild. The self-motivation difficulty of males was higher than their female counterparts. Moreover, prediabetic patients with lower educational levels faced app language difficulty. A recent study showed that general barriers to use of mHealth apps were evident, including financial, technical, and temporal barriers [35]. The results indicated that both health care providers and prediabetic patients believed that mHealth intervention would help them in self-management and almost all prediabetic patients exhibited their intention to use mHealth apps.

From contextual inquiry and value specification phases, it seems that patients' insights regarding the use, barriers to use, and preferred mHealth features are essential in understanding the role and usefulness of mobile health technology [57]. Therefore, we have elicited key intervention elements that were deemed important by both health care providers and prediabetic patients in KSUMC hospitals. Health care provider values and insights about the most impactful intervention strategies currently used in the practice have shaped the overall idea of the proposed design features of our mHealth app. Challenges and barriers as well as patient insights about their current use of well-being and health apps for the sake of their current health condition have helped us to define the key features of the proposed mHealth app. Given that the management of chronic diseases such as prediabetes has mostly relied on patient compliance to recommendations that occur outside the health care setting, the constant use of mHealth still represents a major challenge [58]. This study builds on Klansja and Pratt's framework of 5 behavioral intervention strategies enabled by smartphones and the key components of lifestyle change programs in preventing type 2 diabetes [9,22]. Consequently, a low fidelity prototype was developed to present the proposed mHealth features for prediabetes self-management as illustrated in Figure 2.

Figure 2. Sample of user interfaces in the proposed prototype.

The prototype phase showed that all patients who participated in this study indicated a significant need for the proposed features of the mHealth app regardless of their gender, age, and educational levels. In our study, we reviewed several mHealth apps recognized by the US Centers for Disease Control and Prevention for the sake of realizing the current status of diabetes prevention-related mHealth apps. We found that these apps were designed to encompass most of the features found in the well-being and health apps used by patients who participated in this study such as Fitbit, Samsung Health, iHealth, Apple Health, and VitaDock. Features like food, weight, and BMI tracking and blood glucose monitoring were very common. For example, Noom and Omada are well-known apps whose users have shown significant improvements in terms of weight loss which can be an excellent proxy for the risk of developing type 2 diabetes in the future [59,60]. These apps provide self-monitoring tools such as smart scales to manage weight and step count systems to track physical activity. However, these apps provide what may be considered the most important components of prediabetes intervention, personalized health coaching and group support, which are usually provided through text messaging [9]. A systematic review of all currently available diabetes apps for the operating systems iOS and Android indicated that more than one-half of well-being and health apps for DM provide one function, the language of the dominant app was English, and most respondents go beyond the paid mobile

apps. Additionally, the number of functions in these apps was conversely correlated with usability [61]. Another study showed a significant improvement in monitoring glucose levels among adults with type 1 diabetes [62].

The prototype user interface proposed in this study showed that all 5 components of the lifestyle change program by Kirley and Sachdev, guided by Klansja and Pratt framework [9,22], are essential to make the mHealth app as usable as possible. Consequently, this study suggested that the constituent elements of a successful mHealth intervention for prediabetic patients should encompass a key features such as evidence-based contents of self-monitoring of diet, physical activity, and weight management features. Furthermore, the dietary options should consider alternatives in some cultural dishes with foods that are rich in carbohydrates that prediabetics should avoid. Additionally, a didactic curriculum of health education tailored to patient characteristics should be accompanied by physical activity and weight management features [63]. This can be delivered either by predefined notifications or text messaging as this was the most preferred means of coaching by both health care providers and prediabetic patients. To avoid patients opting out of the prediabetes management intervention and to ensure regular use of the proposed mHealth app, motivation elements should accompany the key features proposed. The motivation elements will help persuade patients to achieve recommended goals and constantly update their profile with achievements to allow more recommendations to be suggested. The proposed mHealth app should promote self-knowledge by facilitating access to important health information. This can be either in an interactive form such as quizzes that repeatedly pop up or static such as a list of frequently asked questions. Finally, the language of the contents must not be a barrier to the use of the mHealth intervention. Therefore, the proposed mHealth app should support the Arabic language in addition to English since the majority of Saudi Arabia's citizens are Arabic native speakers.

Limitations

Limitations of this study may include the cross-sectional design, sample size, time constraint, and confined group of patients. Furthermore, the study was done in a single round only for each phase. This study could be used as a baseline for future adoption of the app in the clinical practice context. Future work can then build on these findings and conduct as many iterative processes as needed to verify the findings. Future research also may consider qualitative methods such as interviews and focus groups approach to explore further insights about the current situation of the prediabetes management intervention. Another potential limitation is the low response rate of patients, which may not represent the whole population of prediabetic patients in KSUMC hospitals; this might be attributed to the short time of the study. Therefore, future work should overcome this issue in terms of encouraging prediabetic patients to participate in the study and allow for a sufficient period to conduct the study to ensure generalization.

Conclusion

This study provided real-world insights into the development of mHealth apps for diabetes prevention by involving both health care providers and prediabetic patients in KSUMC hospitals. The development of the proposed mHealth app for prediabetes using the CeHRes guidelines provided a careful understanding of its content and design. Prediabetic patients who participated in this study exhibited their willingness to use the proposed mHealth app for self-management. Therefore, the proposed app, which comprises all necessary features, could contribute to a significant improvement of their self-management and changes in their lifestyle. The results of this study could be used as a baseline to further improve the adoption of the mHealth app for self-management of prediabetic patients.

Acknowledgments

The authors would like to thank all participants who took part in this study. The authors also would like to express their special thanks to Mervat Alrasan, the head of the information technology department at the King Abdulaziz University Hospital, for her support and cooperation during the data collection stage of this study.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Healthcare provider questionnaire.
[PDF File (Adobe PDF File), 113 KB - formative_v5i7e22968_app1.pdf]

Multimedia Appendix 2
Patient questionnaire (Arabic version).
[PDF File (Adobe PDF File), 147 KB - formative_v5i7e22968_app2.pdf]

Multimedia Appendix 3
Evaluation form of the proposed mHealth features.
[PDF File (Adobe PDF File), 2379 KB - formative_v5i7e22968_app3.pdf]

Multimedia Appendix 4
Ethical approval letter.
[PDF File (Adobe PDF File), 1121 KB - formative_v5i7e22968_app4.pdf]

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Abbreviations

CeHRes: Centre for eHealth Research
DM: diabetes mellitus
KSUMC: King Saud University Medical City
KKUH: King Khalid University Hospital
KAUH: King Abdulaziz University Hospital
mHealth: mobile health

Edited by G Eysenbach; submitted 10.08.20; peer-reviewed by J Sieverdes, R Jayasuriya; comments to author 17.11.20; revised version received 29.05.21; accepted 31.05.21; published 20.07.21.

Please cite as:
Alshehri F, Alshaikh F
Exploring the Constituent Elements of a Successful Mobile Health Intervention for Prediabetic Patients in King Saud University Medical City Hospitals in Saudi Arabia: Cross-sectional Study
JMIR Form Res 2021;5(7):e22968
URL: https://formative.jmir.org/2021/7/e22968
doi:10.2196/22968
PMID:34061762

Original Paper

Associations Between Methods of Meeting Sexual Partners and Sexual Practices Among Heterosexuals: Cross-sectional Study in Melbourne, Australia

Heidi Constantinou[1,2], MD; Christopher K Fairley[1,2], MBBS; Jane S Hocking[3], PhD; Catriona S Bradshaw[1,2], MBBS; Edmond P H Choi[4], PhD; Kate Maddaford[2], MPH; Tiffany R Phillips[1,2*], PhD; Eric P F Chow[1,2,3*], PhD

[1]Central Clinical School, Monash University, Clayton, Australia

[2]Melbourne Sexual Health Centre, Alfred Health, Carlton, Australia

[3]Centre for Epidemiology and Biostatistics, Melbourne School of Population and Global Health, The University of Melbourne, Parkville, Australia

[4]School of Nursing, The University of Hong Kong, Hong Kong, Hong Kong

[*]these authors contributed equally

Corresponding Author:
Tiffany R Phillips, PhD
Central Clinical School
Monash University
Wellington Rd
Clayton, 3800
Australia
Phone: 61 03 9341 6200
Email: tiffany.phillips@monash.edu

Abstract

Background: The association between meeting partners on the web and sexual practices has been understudied in heterosexuals.

Objective: This study aims to examine the associations between the methods of meeting partners and sexual practices and HIV and sexually transmitted infections (STIs) in heterosexuals.

Methods: We conducted a survey among heterosexuals attending the Melbourne Sexual Health Centre in 2019. This survey asked about the methods through which the participants engaged in meeting their sexual partners, sexual practices, and intravenous drug use (IVDU) over the past 3 months. The participants' HIV and STI (chlamydia, gonorrhea, and syphilis) status was obtained from clinical testing. Multivariable logistic regression was used to examine the association between each method of meeting and the participants' sexual practices, IVDU, and STI status.

Results: A total of 698 participants (325 men and 373 women) were included in the study. Most of the participants reported using only one method to meet partners (222/325, 68.3% men; 245/373, 65.7% women; *P*=.05). The men met partners most commonly at social venues (eg, bar, pub, or party; 126/325, 38.8%), whereas the women met partners most commonly through friends or family (178/373, 47.7%). Paying for sex was associated with men meeting partners at sex venues (adjusted odds ratio [AOR] 145.34, 95% CI 26.13-808.51) and on the internet (AOR 10.00, 95% CI 3.61-27.55). There was no association between IVDU and methods of meeting. Social venues were associated with condomless vaginal sex among men (AOR 3.31, 95% CI 1.94-5.71) and women (AOR 2.58, 95% CI 1.61-4.13) and testing positive for STI among men (AOR 3.04, 95% CI 1.24-7.48) and women (AOR 3.75, 95% CI 1.58-8.89).

Conclusions: Heterosexuals who met partners at social venues had a more than threefold risk of testing positive for STIs, indicating that heterosexuals may benefit from health promotion campaigns that are delivered through a public setting.

(JMIR Form Res 2021;5(7):e26202) doi:10.2196/26202

KEYWORDS

internet; dating apps; mobile phone; sexually transmitted infections; health risk behaviors

Introduction

Background

There has been an increase in the number of web-based platforms available for individuals to meet sexual partners since the first internet dating site, *Match.com*, was introduced in 1995. The surge in the popularity of social networking sites such as *Instagram*, which was introduced in 2010, led to the launch of other web-based platforms through which individuals could meet partners. The advancing technology of smartphones saw a shift in the nature of web-based dating with the addition of smartphone dating apps, the most popular of which is *Tinder*, which was launched in 2012. As of 2020, *Tinder* had been downloaded 340 million times and claimed to have produced more than 43 billion matches [1].

A total of 2 population-based studies conducted in the United States [2] and Australia [3] have shown that the internet and apps have overtaken the more traditional offline face-to-face methods (eg, through friends or family) for individuals to meet their partners. However, there are limited studies globally that focus on the methods through which heterosexuals meet casual and regular sexual partners. In Australia, gonorrhea and syphilis among heterosexuals have been uncommon since the 1980s, but the incidence of both sexually transmitted infections (STIs) has increased among heterosexuals since the mid-2010s [4,5]. However, the reasons for this rise in the incidence of STIs remain unclear. Although some studies have suggested that meeting partners on the internet or apps are associated with condomless sex [6] and STI acquisition [7,8], other studies did not find this association [9-11]. Thus, the association between web-based meeting methods and sexual risk remains inconclusive. Most of these studies did not stratify by sexual orientation [7,8,10,11]. Very few studies have specifically analyzed heterosexuals exclusively and most were published before 2013 [9], when there were fewer web-based networking platforms (particularly apps). Given that the risk of STIs and sexual practices varies in different sexual orientations and that new web-based networking platforms have continued to surface throughout the mid-2010s to late 2010s [1], it is unclear from these studies whether the same associations of the internet and apps with condom use and STIs can be drawn for heterosexuals in the late 2010s.

Objective

This study aims to examine the associations between the methods of meeting partners and sexual practices, as well as HIV and STIs, in cisgender heterosexual men and women, which could assist in future HIV and STI prevention and safe sex campaigns.

Methods

Study Setting and Population

A cross-sectional study was conducted at the Melbourne Sexual Health Centre (MSHC) in Victoria, Australia, in March and April 2019. The MSHC is a large public sexual health clinic in metropolitan Melbourne. As part of the clinic's routine care, all new clients who attend the MSHC and clients who have not attended for more than 3 months are asked to complete a questionnaire using computer-assisted self-interview (CASI), which collects information on their sexual activities and demographic characteristics. Following the completion of the CASI, heterosexual clients aged 16 years or older were invited to participate in a voluntary survey on the CASI named *Australian Surveys of Sexual Activities and Practices* (ASAP), which collected additional questions on sexual practice that were not collected as part of the routine CASI questions. Consent was obtained from the participants who selected *yes* on the consent page through the CASI. We defined *heterosexuals* as cisgender male or cisgender female individuals who reported having sex with an opposite-gender partner over the past 12 months and did not report any sexual contact with someone of the same gender over the past 12 months.

The ASAP collected data on the methods through which the participants had met their sexual partners over the past 3 months. The predefined six methods of meeting partners were (1) the internet, (2) apps (eg, *Tinder*), (3) social venues (eg, bar, pub, nightclub, dance, party, disco, and gym), (4) sex venues (eg, sauna, beat, and other sex venues), (5) introduced by friends or family, and (6) other. The participants could choose more than one method. Participants selecting *other* were asked to specify the alternative methods through which they had met their sexual partners. Participants who wrote in *brothel* or *massage parlour* for *other* were recategorized into *sex venues* during analysis.

Data were collected on the participants' sexual practices and condom use for oral, vaginal, and anal sex; number of regular and casual partners; if they had paid for sex; and intravenous drug use (IVDU) over the past 3 months. All individuals were offered HIV and STI (chlamydia, gonorrhea, and syphilis) testing, and HIV and STI diagnoses were obtained from clinical data on the day the participants completed the survey. HIV and syphilis diagnoses were based on serology. Gonorrhea and chlamydia diagnoses were based on first void urine by nucleic acid amplification test using the Aptima Combo 2 assay (Hologic Panther system; Hologic). No participant tested positive for HIV; therefore, we only analyzed the STI diagnoses.

Statistical Analysis

Age was categorized into three groups: 16-24 years, 25-34 years, and ≥35 years, as per previous studies [12]. Descriptive statistics, including the frequency and proportion for each method of meeting stratified by age and gender, were calculated. A chi-square test was performed to compare the method of meeting partners between men and women. A chi-square trend test was performed to examine whether there was an increasing or decreasing trend in the method of meeting partners across the three age groups. The *other* category was deemed unreliable because a large proportion of the participants did not specify the alternative methods used to meet partners; hence, we removed *other* from the remaining analyses. Univariable logistic regressions were performed to examine the association between each method of meeting and a range of different variables to determine the sexual risk (eg, the number of sexual partners, condomless sex, having regular and casual partners, testing positive for STI, paying for sex, and IVDU) for men and women separately. Age and the methods of meeting partners were

considered potential confounders and adjusted in the multivariable logistic regression analyses. All analyses were performed using SPSS (version 26, IBM Corp). This study was approved by the Alfred Hospital Ethics Committee, Melbourne, Australia (number 571/17).

Results

Characteristics of the Study Population

In March and April 2019, there were 2961 heterosexual clients (1506 men and 1455 women) who attended the MSHC and completed the CASI and were invited to participate in the ASAP. Of the 2961 clients, 728 (24.59%) consented and completed the survey, and the proportion who participated did not differ between men (345/1506, 22.91%) and women (383/1455, 26.32%). There was no significant difference in the median ages of the clients who consented versus those who did not consent in both men (28 years vs 29 years; *P*=.16) and women (25 years vs 25 years; *P*=.50). There was also no significant difference in the proportion who consented to participate between Australian-born and overseas-born men (148/345, 25.6% vs 192/345, 21.8%; *P*=.10) and women (111/383, 27.9% vs 262/383, 25.9%; *P*=.50), or STI positivity among men (28/345, 8.1% vs 121/1161, 10.42%; *P*=.21) and women (28/383, 7.3% vs 100/1072, 9.32%); *P*=.41). We excluded 30 participants: 11 reported *other* method only and reported the status of their sexual partner (eg, wife) rather than specifying the *other* method through which they had met, and 19 reported no sexual partners in the past 3 months. Participants who reported the status of their partners under *other*, but had selected an additional method of meeting, were still included in the additional methods of meeting selected but were removed from the *other* category. The remaining 698 participants (325 men and 373 women) were included in the final analysis.

Of the 698 heterosexual participants who were included in the study, the median age was 28 (IQR 24-35) years for men and 25 (IQR 23-29) years for women. Most men and women were born overseas (184/325, 56.6% men and 256/373, 68.6% women). The median total number of partners (including those who only kissed) was 4 (IQR 2-8) for men and 4 (IQR 2-8) for women in the past 3 months. However, the median total number of sexual partners (excluding those who only kissed) was 3 (IQR 2-5) for men and 2 (IQR 2-4) for women.

Most of the participants reported using only one method to meet sexual partners (222/325, 68.3% among men; 245/373, 65.7% among women; *P*=.46). Overall, most of the men met their partners through social venues (eg, bar, pub, or party; 126/325, 38.8%), whereas most of the women met their partners through friends or family (178/373, 47.7%). Compared with men, fewer women met sexual partners through the internet (38/325, 11.7% vs 20/353, 5.4%; *P*=.003) and sex venues (21/325, 6.5% vs 3/373, 0.8%; *P*<.001), and more women met partners through friends or family (122/325, 37.5% vs 178/373, 47.7%; *P*=.007; Figure 1). There were no significant differences in the proportion of men and women who met partners through apps, social venues, or other methods (Figure 1). Of the 109 participants who reported *other* methods, 65 (59.6%) specified the method, with most meeting partners through work (n=26), travel and backpacking hostels (n=14), education facilities such as school and university (n=5), and public locations (n=5).

An age pattern was observed for some methods. Among men, the use of sex venues (P_{trend}=.005) was associated with increasing age, but the use of social venues (P_{trend}=.01) and friends or family (P_{trend}<.001) was associated with decreasing age. Among women, the use of the internet (P_{trend}=.01) was associated with increasing age but the use of social venues (P_{trend}=.004) was associated with decreasing age (Figure 2).

Figure 1. The proportion of heterosexual individuals who engaged in each method of meeting sexual partners over the previous 3 months, stratified by gender. *P* values were calculated from a chi-square test.

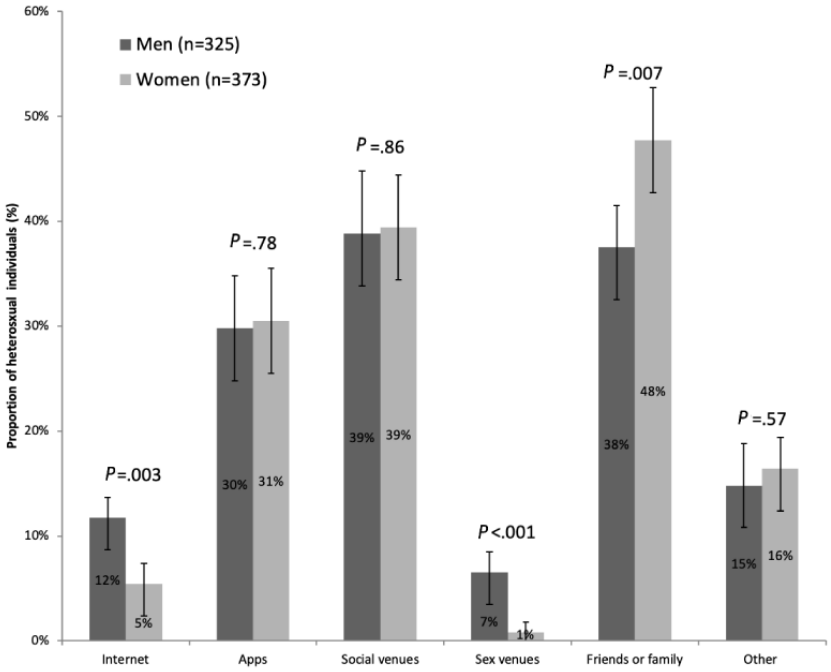
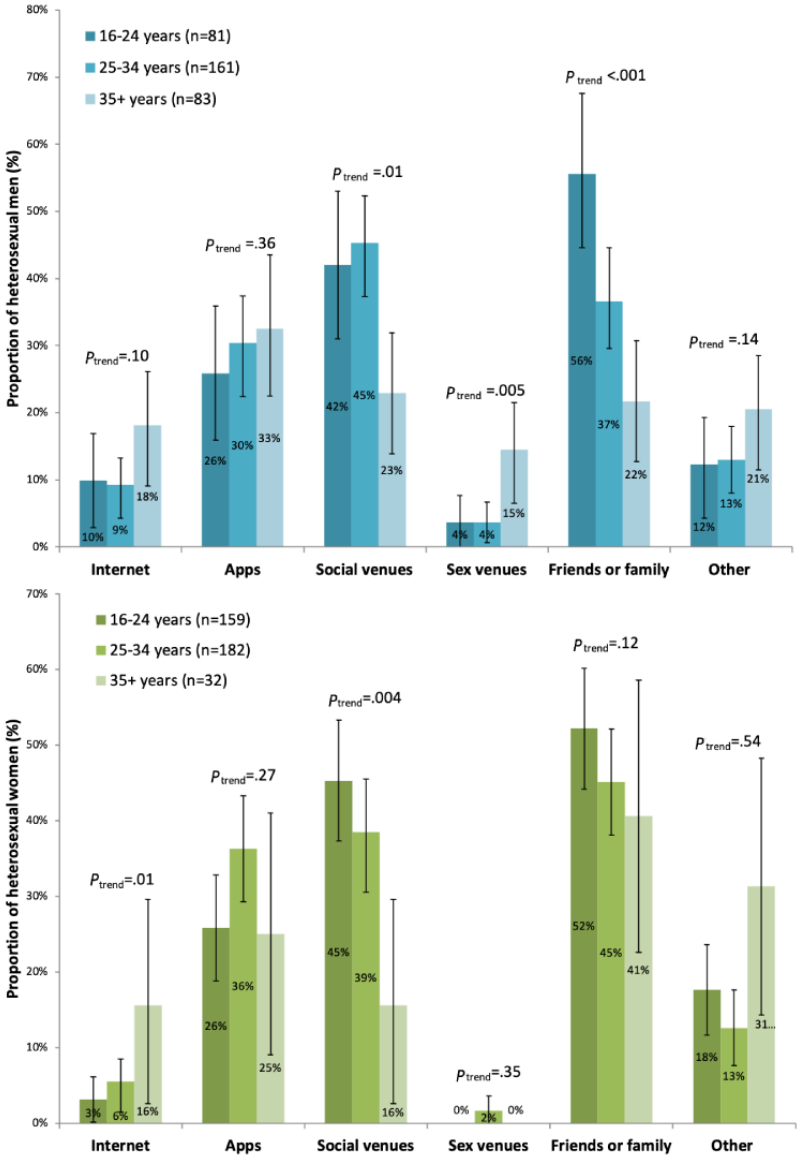


Figure 2. The proportion of heterosexual individuals who engaged in each method of meeting sexual partners over the previous 3 months, stratified by age. *P* values were calculated from a chi-square trend test.



Number and Type of Sexual Partners

Men were more likely to report ≥4 total partners, including *only kissing*, if they used social venues (adjusted odds ratio [AOR] 10.93, 95% CI 5.79-20.64) to meet sexual partners, followed by sex venues (AOR 4.16, 95% CI 1.47-11.77), apps (AOR 3.65, 95% CI 1.97-6.77), the internet (AOR 2.70, 95% CI 1.17-6.24), and friends or family (AOR 2.14, 95% CI 1.18-3.88), after adjusting for age and all methods of meeting partners (Table 1). Women were more likely to report ≥4 total partners, including *only kissing*, if they used the internet (AOR 4.97, 95% CI 1.62-15.22) to meet sexual partners, followed by social venues (AOR 4.38, 95% CI 2.64-7.28), apps (AOR 2.53, 95% CI 1.48-4.31), and friends or family (AOR 2.52, 95% CI 1.54-4.14). There was no statistically significant association between meeting at sex venues and the total number of partners among women. The results remained similar for all sexual partners when excluding those who kissed only.

The adjusted odds of having casual partners were highest among men meeting partners at sex venues (AOR 37.84, 95% CI 4.63-309.40), followed by social venues, the internet, apps, and friends or family (Table 1). Accordingly, men were less likely to have regular partners when meeting partners through apps (AOR 0.52, 95% CI 0.31-0.86) and social venues (AOR 0.53, 95% CI 0.33-0.87) but not when meeting them through the internet, friends or family, or at sex venues. The adjusted odds of having casual partners were highest among women meeting partners at social venues (AOR 12.47, 95% CI 5.15-30.20), followed by apps and friends or family but not the internet. All women who met partners at sex venues (N=3) had casual partners, preventing us from performing a logistic regression for sex venues among women. Accordingly, women were less likely to have regular partners when meeting partners through social venues (AOR 0.22, 95% CI 0.13-0.37), followed by apps and friends or family but not through the internet or sex venues.

Table 1. Association of method of meeting partners and number and type of sexual partners among heterosexual individuals in the past 3 months.

Sex and method of meeting	Number who had ≥4 partners, including only kissing, n (%)	Adjusted odds ratio (95% CI)[a]	Number who had ≥3 partners, excluding only kissing, n (%)	Adjusted odds ratio (95% CI)[a]	Number who had casual sex partners[b], n (%)	Adjusted odds ratio (95% CI)[a]	Number who had regular sex partners[c], n (%)	Adjusted odds ratio (95% CI)[a]
Men (n=325)								
Internet								
No (n=287)	164 (57.1)	1	148 (51.6)	1	201 (70)	1	134 (46.7)	1
Yes (n=38)	24 (63.2)	2.70 (1.17-6.24)[d]	23 (60.5)	3.27 (1.34-7.95)[d]	32 (84.2)	5.76 (1.98-16.71)[d]	21 (55.3)	1.25 (0.61-2.59)
Apps[e]								
No (n=228)	120 (52.6)	1	103 (45.2)	1	151 (66.2)	1	117 (51.3)	1
Yes (n=97)	68 (70.1)	3.65 (1.97-6.77)[d]	68 (70.1)	5.90 (3.09-11.24)[d]	82 (84.5)	5.56 (2.69-11.48)[d]	38 (39.2)	0.52 (0.31-0.86)[d]
Social venues								
No (n=199)	84 (42.2)	1	77 (38.7)	1	121 (60.8)	1	107 (53.8)	1
Yes (n=126)	104 (82.5)	10.93 (5.79-20.64)[d]	94 (74.6)	10.92 (5.74-20.78)[d]	112 (88.9)	11.78 (5.62-24.69)[d]	48 (38.1)	0.53 (0.33-0.87)[d]
Sex venues								
No (n=304)	176 (57.9)	1	157 (51.6)	1	213 (70.1)	1	146 (48)	1
Yes (n=21)	12 (57.1)	4.16 (1.47-11.77)[d]	14 (66.7)	10.41 (3.47-31.24)[d]	20 (95.2)	37.84 (4.63-309.40)[d]	9 (42.9)	0.42 (0.16-1.12)
Friends or family								
No (n=203)	112 (55.2)	1	99 (48.7)	1	143 (70.4)	1	96 (47.3)	1
Yes (n=122)	76 (62.3)	2.14 (1.18-3.88)[d]	72 (59)	3.19 (1.71-5.94)[d]	90 (73.8)	2.91 (1.49-5.71)[d]	59 (48.4)	1.08 (0.66-1.77)
Women (n=373)								
Internet								
No (n=353)	195 (55.2)	1	166 (47)	1	289 (81.9)	1	131 (37.1)	1
Yes (n=20)	14 (70)	4.97 (1.62-15.22)[d]	13 (65)	5.53 (1.83-16.71)[d]	15 (75)	2.05 (0.39-10.63)	7 (35)	0.44 (0.15-1.31)
Apps[e]								
No (n=258)	136 (52.7)	1	109 (42.2)	1	201 (77.9)	1	107 (41.5)	1
Yes (n=115)	73 (63.4)	2.53 (1.48-4.31)[d]	70 (60.9)	3.94 (2.27-6.81)[d]	103 (89.6)	3.51 (1.42-8.69)[d]	31 (27)	0.28 (0.16-0.50)[d]
Social venues								
No (n=226)	103 (45.6)	1	85 (37.6)	1	164 (72.6)	1	106 (46.9)	1
Yes (n=147)	106 (72.1)	4.38 (2.64-7.28)[d]	94 (63.9)	4.90 (2.93-8.18)[d]	140 (95.2)	10.38 (3.66-29.43)[d]	32 (21.8)	0.20 (0.12-0.35)[d]
Sex venues								
No (n=370)	207 (55.9)	1	177 (47.8)	1	301 (81.3)	—[f]	137 (37)	1
Yes (n=3)	2 (66.7)	2.95 (0.23-38.08)	2 (66.7)	5.54 (0.42-73.39)	3 (100)	—	1 (33.3)	0.32 (0.03-3.91)
Friends or family								

Sex and method of meeting	Number who had ≥4 partners, including only kissing, n (%)	Adjusted odds ratio (95% CI)[a]	Number who had ≥3 partners, excluding only kissing, n (%)	Adjusted odds ratio (95% CI)[a]	Number who had casual sex partners[b], n (%)	Adjusted odds ratio (95% CI)[a]	Number who had regular sex partners[c], n (%)	Adjusted odds ratio (95% CI)[a]
No (n=195)	100 (51.3)	1	84 (43.1)	1	154 (79)	1	80 (41)	1
Yes (n=178)	109 (61.2)	2.52 (1.54-4.14)[d]	95 (53.4)	2.90 (1.75-4.80)[d]	304 (82)[g]	3.08 (1.38-6.86)[d]	58 (33)	0.41 (0.24-0.68)[d]

[a]Odds ratio adjusted according to age and method of meeting.

[b]A total of 35 men declined to answer the question on casual partners in the last 3 months; these participants were added to the *no* group. A total of 29 women declined to answer the question on casual partners in the last 3 months; these participants were added to the *no* group.

[c]A total of 11 men declined to answer the question on regular partners in the last 3 months; these participants were added to the *no* group. A total of 11 women declined to answer the question on regular partners in the last 3 months; these participants were added to the *no* group.

[d]Statistically significant results with $P<.05$.

[e]Mobile dating apps.

[f]All women (N=3) who met partners at sex venues had casual partners, preventing a logistic regression from being performed.

[g]n=373.

Sexual Practices and Drug Use

Men were more likely to perform oral sex (cunnilingus) with partners they met through apps (AOR 2.62, 95% CI 1.20-5.74) and friends or family (AOR 3.08, 95% CI 1.44-6.58; Table 2). Similarly, men were more likely to receive oral sex (fellatio) from partners met through apps (AOR 7.78, 95% CI 1.75-34.62), social venues (AOR 4.22, 95% CI 1.44-12.34), and friends or family (AOR 3.19, 95% CI 1.13-9.01). Men were more likely to engage in vaginal sex with partners met through friends or family (AOR 6.46, 95% CI 2.11-19.73) and social venues (AOR 2.47, 95% CI 1.05-5.84). Among women, performing fellatio and vaginal sex was not associated with any method of meeting partners (Table 3). Women were more likely to receive cunnilingus from partners met through friends or family (AOR 2.17, 95% CI 1.05-4.46); however, there was no association with any other methods of meeting and receiving cunnilingus. Having anal sex was not associated with any method of meeting partners in either male or female participants.

Men were more likely to have condomless vaginal sex with partners met at social venues (AOR 3.31, 95% CI 1.94-5.71) and were less likely to receive condomless fellatio with partners met at sex venues (AOR 0.09, 95% CI 0.002-0.34; Table 4). Women were more likely to have condomless vaginal sex with partners met at social venues (AOR 2.58, 95% CI 1.61-4.13) and to perform condomless fellatio with partners met through apps (AOR 2.72, 95% CI 1.09-6.77). Neither the internet nor apps were associated with condomless sex among men or women.

The adjusted odds of having paid for sex were highest among men meeting partners at sex venues (AOR 145.34, 95% CI 26.13-808.51), followed by the internet (AOR 10.00, 95% CI 3.61-27.55; Multimedia Appendix 1). There was no association between paying for sex and meeting partners through apps, social venues, or friends or family among men. Only 1 woman paid for sex, and she met the partner through friends or family. There was no association between any methods of meeting partners and IVDU among men and women.

Table 2. Association of method of meeting partners and sexual practices among heterosexual men in the past 3 months (N=325).

Method of meeting	Men who performed oral sex (cunnilingus), n (%)	Adjusted odds ratio (95% CI)[a]	Men who received oral sex (fellatio), n (%)	Adjusted odds ratio (95% CI)[a]	Men who had vaginal sex, n (%)	Adjusted odds ratio (95% CI)[a]	Men who had anal sex, n (%)	Adjusted odds ratio (95% CI)[a]
Internet								
No (n=287)	238 (82.9)	1	262 (91.3)	1	257 (89.5)	1	57 (19.9)	1
Yes (n=38)	30 (78.9)	1.08 (0.43-2.68)	34 (89.5)	1.48 (0.44-4.93)	27 (71.1)	0.47 (0.20-1.13)	11 (28.9)	1.81 (0.81-4.02)
Apps[b]								
No (n=228)	180 (78.9)	1	201 (88.2)	1	195 (85.5)	1	43 (18.9)	1
Yes (n=97)	88 (90.7)	2.62 (1.20-5.74)[c]	95 (97.9)	7.78 (1.75-34.62)[c]	89 (91.8)	2.14 (0.90-5.09)	25 (25.8)	1.52 (0.85-2.73)
Social venues								
No (n=199)	161 (80.9)	1	175 (87.9)	1	167 (83.9)	1	38 (19.1)	1
Yes (n=126)	107 (84.9)	1.41 (0.71-2.77)	121 (96)	4.22 (1.44-12.34)[c]	117 (92.9)	2.47 (1.05-5.84)[c]	30 (23.8)	1.66 (0.93-2.99)
Sex venues								
No (n=304)	254 (83.6)	1	279 (91.8)	1	269 (88.5)	1	63 (20.7)	1
Yes (n=21)	14 (66.7)	0.77 (0.27-2.18)	17 (81)	1.21 (0.34-4.29)	15 (71.4)	0.83 (0.27-2.53)	5 (23.8)	1.55 (0.50-4.77)
Friends or family								
No (n=203)	158 (77.8)	1	180 (88.7)	1	116 (57.1)	1	41 (20.2)	1
Yes (n=122)	110 (90.2)	3.08 (1.44-6.58)[c]	116 (95.1)	3.19 (1.13-9.01)[c]	118 (96.7)	6.46 (2.11-19.73)[c]	27 (22.1)	1.51 (0.83-2.73)

[a]Odds ratio adjusted according to age and method of meeting.

[b]Mobile dating apps.

[c]Statistically significant results with $P<.05$.

Table 3. Association of method of meeting partners and sexual practices among heterosexual women in the past 3 months (N=373).

Method of meeting	Number of women who performed oral sex (fellatio), n (%)	Adjusted odds ratio (95% CI)[a]	Number of women who received oral sex (cunnilingus), n (%)	Adjusted odds ratio (95% CI)[a]	Number of women who had vaginal sex, n (%)	Adjusted odds ratio (95% CI)[a]	Number of women who had anal sex, n (%)	Adjusted odds ratio (95% CI)[a]
Internet								
No (n=353)	329 (93.2)	1	315 (89.2)	1	330 (93.5)	1	60 (17)	1
Yes (n=20)	19 (95)	1.60 (0.17-15.20)	16 (80)	0.69 (0.20-2.38)	18 (90)	0.82 (0.16-4.22)	7 (35)	2.51 (0.89-7.06)
Apps[b]								
No (n=258)	237 (91.9)	1	226 (87.6)	1	241 (93.4)	1	46 (17.8)	1
Yes (n=115)	111 (96.5)	2.62 (0.84-8.18)	105 (91.3)	1.90 (0.86-4.20)	107 (93)	1.01 (0.40-2.54)	21 (18.3)	1.12 (0.62-2.04)
Social venues								
No (n=226)	213 (94.2)	1	199 (88)	1	208 (92)	1	34 (19)	1
Yes (n=147)	135 (91.8)	0.78 (0.32-1.87)	132 (89.8)	1.32 (0.64-2.73)	140 (95.2)	1.61 (0.63-4.13)	24 (16.3)	1.03 (0.58-1.84)
Sex venues								
No (n=370)	346 (93.5)	1	328 (88.6)	—[c]	346 (93.5)	1	65 (17.6)	1
Yes (n=3)	2 (66.7)	0.19 (0.02-2.58)	3 (100)	—	2 (66.7)	0.21 (0.02-2.71)	2 (66.7)	8.16 (0.67-99.20)
Friends or family								
No (n=195)	181 (92.8)	1	167 (85.6)	1	182 (93.3)	1	32 (16.4)	1
Yes (n=178)	167 (93.8)	1.30 (0.54-3.12)	164 (92.1)	2.17 (1.05-4.46)[d]	166 (93.3)	0.98 (0.41-2.34)	35 (19.7)	1.45 (0.82-2.56)

[a]Odds ratio adjusted according to age and method of meeting.

[b]Mobile dating apps.

[c]All women (n=3) who met partners at sex venues received cunnilingus, preventing a logistic regression from being performed.

[d]Statistically significant results with $P<.05$.

Table 4. Association of method of meeting partners and condomless sex in the past 3 months and sexually transmitted infection status among heterosexual individuals.

Sex and method of meeting	Individuals who received condomless oral sex (fellatio)[a]		Adjusted odds ratio (95% CI)[b]	Individuals who had condomless vaginal sex[a]		Adjusted odds ratio (95% CI)[b]	Individuals who had condomless anal sex[a]		Adjusted odds ratio (95% CI)[b]	Individuals who tested positive for STI[c,d]		Adjusted odds ratio (95% CI)[b]
	Total, N	Participant, n (%)		Total, N	Participant, n (%)		Total, N	Participant, n (%)		Total, N	Participant, n (%)	
Men (N=325)												
Internet												
No	262	247 (94.3)	1	257	144 (56)	1	57	38 (66.7)	1	287	25 (8.7)	1
Yes	34	31 (91.2)	0.90 (0.20-4.04)	27	15 (55.6)	1.23 (0.52-2.86)	11	5 (45.5)	0.52 (0.11-2.40)	38	1 (2.6)	0.38 (0.05-3.08)
Apps[e]												
No	201	186 (92.5)	1	195	112 (57.4)	1	43	27 (62.8)	1	228	19 (8.3)	1
Yes	95	92 (96.8)	1.68 (0.44-6.41)	89	47 (52.8)	0.93 (0.54-1.59)	25	16 (64)	0.91 (0.29-2.86)	97	7 (7.2)	1.01 (0.39-2.63)
Social venues												
No	175	160 (91.4)	1	167	76 (45.5)	1	38	23 (60.5)	1	199	10 (5)	1
Yes	121	118 (97.5)	2.51 (0.63-10.00)	117	83 (70.9)	3.31 (1.94-5.71)[f]	30	20 (66.7)	0.88 (0.28-2.73)	126	16 (12.7)	3.04 (1.24-7.48)[f]
Sex venues												
No	279	268 (96.1)	1	269	151 (56.1)	1	63	42 (66.7)	1	304	24 (7.9)	1
Yes	17	10 (58.8)	0.09 (002-0.34)[f]	15	8 (53.3)	1.42 (0.47-4.31)	5	1 (20)	0.12 (0.01-1.55)	21	2 (9.5)	2.80 (0.50-15.80)
Friends or family												
No	180	167 (92.8)	1	166	90 (54.2)	1	41	27 (65.9)	1	203	13 (6.4)	1
Yes	116	111 (95.7)	1.25 (0.34-4.55)	118	69 (58.5)	1.50 (0.88-2.56)	27	16 (59.3)	0.62 (0.20-1.93)	122	13 (10.7)	1.53 (0.63-3.74)
Women (N=373)												
Internet												
No	329	304 (92.4)	1	330	179 (54.2)	1	60	45 (75)	__g	353	26 (7.4)	1
Yes	19	18 (94.7)	2.56 (0.30-21.71)	18	11 (61.1)	2.03 (0.69-5.92)	7	6 (85.7)	—	20	2 (10)	3.81 (0.71-20.49)
Apps[e]												
No	237	218 (92)	1	241	128 (53.1)	1	46	34 (73.9)	1	258	21 (8.1)	1
Yes	111	104 (93.7)	1.72 (0.66-4.51)	107	62 (57.9)	1.37 (0.84-2.25)	21	17 (81)	1.14 (0.30-4.37)	115	7 (6.1)	0.83 (0.33-2.10)
Social venues												
No	213	195 (91.5)	1	208	97 (46.6)	1	43	32 (74.4)	1	226	9 (4)	1

Sex and method of meeting	Individuals who received condomless oral sex (fellatio)[a]		Adjusted odds ratio (95% CI)[b]	Individuals who had condomless vaginal sex[a]		Adjusted odds ratio (95% CI)[b]	Individuals who had condomless anal sex[a]		Adjusted odds ratio (95% CI)[b]	Individuals who tested positive for STI[c,d]		Adjusted odds ratio (95% CI)[b]
	Total, N	Participant, n (%)		Total, N	Participant, n (%)		Total, N	Participant, n (%)		Total, N	Participant, n (%)	
Yes	135	127 (94.1)	1.80 (0.72-4.51)	140	93 (66.4)	2.58 (1.61-4.13)[f]	24	19 (79.2)	1.11 (0.29-4.29)	147	19 (12.9)	3.75 (1.58-8.89)[f]
Sex venues												
No	346	320 (92.5)	__[g]	346	190 (54.9)	__[h]	65	51 (78.5)	__[i]	370	28 (7.6)	__[j]
Yes	2	2 (100)	__[g]	2	0 (0)	__[h]	2	0 (0)	__[i]	3	0 (0)	__[j]
Friends or family												
No	181	163 (90.1)	1	182	100 (54.9)	1	32	26 (81.3)	1	195	12 (6.2)	1
Yes	167	159 (95.2)	2.72 (1.09-6.77)[e]	166	90 (54.2)	1.25 (0.79-1.99)	35	25 (71.4)	0.62 (0.16-2.42)	178	16 (9)	1.83 (0.81-4.13)

[a]Only participants who engaged in each sexual activity were included in the analyses of condomless sex.

[b]Odds ratio adjusted according to age and method of meeting.

[c]All women (n=3) who met partners at sex venues tested negative for sexually transmitted infection, preventing a logistic regression from being performed.

[d]STI: sexually transmitted infection (chlamydia, gonorrhea, and syphilis).

[e]Mobile dating apps.

[f]Statistically significant results with $P<.05$.

[g]The logistic regression for women who had condomless anal sex produced an adjusted odds ratio >300 million and did not produce a 95% CI upper limit, preventing reliable interpretation of these results.

[h]All women (n=2) who met partners at sex venues who performed fellatio used a condom, preventing a logistic regression from being performed.

[i]All women (n=2) who met partners at sex venues who had vaginal sex used a condom, preventing a logistic regression from being performed.

[j]All women (n=2) who met partners at sex venues who had anal sex used a condom, preventing a logistic regression from being performed.

STI Positivity

The STI positivity for men was 8.0% (26/325) and that for women was 7.5% (28/373). There was no association between STI positivity and methods, except for social venues. Both men (AOR 3.04, 95% CI 1.24-7.48) and women (AOR 3.75, 95% CI 1.58-8.89) who met partners at social venues were three times more likely to have an STI (Table 4).

Discussion

Principal Findings

Despite the increasing use of web-based networking platforms (eg, the internet or apps) [1], this study shows that face-to-face methods (eg, social venues and friends or family) continue to be the most common methods used among heterosexuals to meet sexual partners. After adjusting for the five different methods of meeting, those who met at sex venues were less likely to have condomless sex, whereas meeting at social venues (eg, bar, pub, or party) was strongly associated with having more sexual partners, condomless sex, and testing positive for an STI. To our knowledge, this is the first study to analyze a range of both long-established and contemporary methods of meeting sexual partners among heterosexuals and their associations with sexual practices and STI diagnoses, providing important insights for future health promotion campaigns. The inconsistencies in our findings compared with those in previous studies are likely due to several reasons. First, our study looked at how heterosexuals met their regular and/or casual partners; however, the American study [2] only examined how heterosexual *couples* met, and casual partners were not considered. Second, our study was conducted exclusively among heterosexuals, whereas the Australian Talks National Survey [3] was conducted among 54,000 Australians from all sexual orientations, which found that apps are the most popular method for Australians to meet partners. This is consistent with a previous Melbourne-based study published in 2016 showing that apps are the most popular method to meet partners among 1902 men who have sex with men (MSM) [13]. These are important distinctions to be aware of if we want to develop health promotion campaigns that target heterosexuals with casual partners, and an indication that current campaigns using web-based platforms may not be reaching most of the heterosexual population. To the best of our knowledge, there have been no studies investigating why heterosexuals are more likely to meet partners through friends or family and why friends or family is associated with performing condomless fellatio among women. Further qualitative research could explore

whether individuals feel more comfortable and safe engaging in sexual activities with those they have mutual contacts with.

Our results found that individuals meeting partners at social venues had higher odds of having ≥4 partners among both men and women. In addition, meeting partners at social venues was strongly associated with risks, including condomless vaginal sex and STI positivity in men and women. Social venues such as bars, pubs, nightclubs, and parties are common locations where binge drinking and recreational drug use occur. Individuals who binge drink at social venues are six times more likely to engage in sexual activities [14], providing a likely explanation for social venues, alongside friends or family, being the most common method through which heterosexuals meet sexual partners. Alcohol consumption and recreational drug use at social venues are also strongly associated with engaging in risky sexual behaviors—such as condomless sex—and STIs [14-17], providing a likely explanation for our results. Some studies found an association between STIs and meeting partners through the internet and apps [7,8]; however, these included participants of all sexual orientations and found that the internet and apps were more commonly used by participants identifying as homosexual or bisexual, making it unclear if the same conclusion can be drawn for heterosexuals. Furthermore, the fact that our study analyzed a population of participants attending a sexual health clinic, who are presumably more sexually active than the general population, and still did not find an association with STIs and meeting partners through methods other than social venues strongly supports the notion that meeting on the internet and apps does not increase the risk of heterosexuals testing positive for STIs in the wider community.

Certain types of sex venues such as brothels and massage parlors have been long-standing methods through which individuals meet sex workers whom they pay for sex. We found that men who met partners at sex venues were less likely to receive condomless fellatio. Similarly, condomless vaginal and anal sex were not associated with meeting partners at sex venues. A previous Melbourne study found that consistent condom use was high among 106 female sex workers operating in sex venues such as brothels—90% (95) for fellatio, 98% (104) for vaginal sex, and 100% (106) for anal sex among female sex workers with their male clients—[18] because condoms must be used during sex work in accordance with the law in Victoria [19]. As web-based technology has evolved, the internet has become an increasingly common platform in the sex work industry [20]. This may explain why heterosexual men who met partners on the internet were 10 times more likely to report paying for sex in our study. Almost 40% (15/38) of the men in our study who met partners on the internet had paid for sex, of which one-third reported that they used the internet as their sole method of meeting partners.

Our study includes some limitations. First, this study was conducted at a sexual health clinic, which may not be representative of all heterosexuals in Australia. This is because individuals attending a sexual health clinic may be more sexually active and more likely to have casual partners. Second, we predefined six methods of meeting partners from another survey [13], which was originally designed for MSM. Interpretation of these methods could have varied from participant to participant. The examples of sex venues supplied were more applicable to MSM, and additional methods that we did not list may have been underrepresented because the participants did not specify these alternative methods in the *other* category. Third, our response rate was low (728/2961, 24.58%) among both men and women. It is possible that there are some differences in sexual risk between those who participated and those who did not, although there was no difference in demographic characteristics. Fourth, we did not provide examples of who would classify as a *regular* versus *casual* partner. Previous studies have shown ambiguity around how to classify *fuckbuddies* among MSM [21], and although no such research has been conducted among heterosexuals, there may be a similar conundrum of how to classify certain partners (eg, *friends with benefits*). Further research is needed in this area. Finally, this cross-sectional study can only describe associations between the methods of meeting with sexual practices and outcomes, and we cannot rule out all confounders that may have influenced the results, such as marital status, ethnicity, alcohol use, or recreational drug use [14-17].

Conclusions

Heterosexuals who met partners at social venues such as bars and nightclubs were more likely to have condomless vaginal sex and had a more than three-fold risk of testing positive for STIs. Most sexual health promotion campaigns are directed toward MSM, who, in contrast, have been shown to meet more sexual partners through apps [13]. Our study indicates that heterosexuals may benefit from more targeted health promotion campaigns that are delivered through a more public setting (eg, advertisements at social venues or physical face-to-face interventions). More research is warranted that further examines the association of different methods of meeting partners with STIs and investigates other potential reasons for the rise in the incidence of STIs.

Acknowledgments

EPFC is supported by the Australian National Health and Medical Research Council (NHMRC) Emerging Leadership Investigator grant (GNT1172873). CKF and CSB are supported by Australian NHMRC Leadership Investigator grants (GNT1172900 and GNT1173361). JSH was supported by an NHMRC Senior Research Fellowship (GNT1136117). The authors would like to thank Afrizal Afrizal at the MSHC for his assistance with data extraction and Jun Kit Sze for his assistance in implementing the survey on the CASI system at the MSHC.

Authors' Contributions

EPFC and CKF designed the study and developed the survey. CSB and JSH assisted with the development of the survey. HC performed the data analysis and wrote the first draft of the manuscript. KM was involved in study management. EPFC and TRP oversaw the study and provided statistical advice. All authors were involved in data interpretation, revised the manuscript critically for important intellectual content, and approved the final version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Association of method of meeting partners and paying for sex and intravenous drug use status among heterosexual individuals.
[DOCX File , 17 KB - formative_v5i7e26202_app1.docx]

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Abbreviations

AOR: adjusted odds ratio
ASAP: Australian Surveys of Sexual Activities and Practices
CASI: computer-assisted self-interview
IVDU: intravenous drug use
MSHC: Melbourne Sexual Health Centre
MSM: men who have sex with men
NHMRC: Australian National Health and Medical Research Council
STI: sexually transmitted infection

Edited by R Kukafka, G Eysenbach; submitted 02.12.20; peer-reviewed by V Minichiello, D Pförringer; comments to author 04.02.21; revised version received 04.02.21; accepted 31.05.21; published 20.07.21.

Please cite as:
Constantinou H, Fairley CK, Hocking JS, Bradshaw CS, Choi EPH, Maddaford K, Phillips TR, Chow EPF
Associations Between Methods of Meeting Sexual Partners and Sexual Practices Among Heterosexuals: Cross-sectional Study in Melbourne, Australia
JMIR Form Res 2021;5(7):e26202
URL: https://formative.jmir.org/2021/7/e26202
doi:10.2196/26202
PMID:34283024

Original Paper

Pregnant Women's Attitudes Toward and Experiences With a Tablet Intervention to Promote Safety Behaviors in a Randomized Controlled Trial: Qualitative Study

Bente Walter[1], MSc; Hege Indreboe[1], MSc; Mirjam Lukasse[1,2], Prof Dr; Lena Henriksen[1], PhD; Lisa Garnweidner-Holme[1], PhD

[1]Department of Nursing and Health Promotion, Oslo Metropolitan University, Oslo, Norway

[2]Faculty of Health and Social Sciences, University of South-Eastern Norway, Vestfold, Norway

Corresponding Author:
Lisa Garnweidner-Holme, PhD
Department of Nursing and Health Promotion
Oslo Metropolitan University
St Olavs Plass, PO Box 4
Oslo, 0130
Norway
Phone: 47 +4748091956
Email: lgarnwei@oslomet.no

Abstract

Background: Intimate partner violence (IPV) is recognized as a global health problem. Women with low education and limited resources are more vulnerable, as are immigrant women. There is a lack of evidence on how health care professionals should communicate about and intervene against IPV during pregnancy. Earlier research has shown that when women manage digital questionnaires, they are more likely to disclose IPV. However, little is known about how women experience eHealth interventions with safety behaviors to prevent IPV.

Objective: The aim of this study was to explore pregnant women's attitudes toward and experiences with a tablet intervention to promote safety behaviors in a randomized controlled trial (RCT) in antenatal care.

Methods: Individual semistructured interviews were conducted with 10 women who participated in the Safe Pregnancy Study. The Safe Pregnancy Study was a randomized controlled trial (RCT) using a tablet intervention containing IPV questions and a film to promote safety behaviors. Six women from the intervention group and four women from the control group were recruited. The content was available in Norwegian, Somali, and Urdu. Five of the women participating in the interviews spoke Norwegian at home and five spoke another language. The majority of the women who did not speak Norwegian at home perceived themselves as relatively well integrated. The interviews were conducted at different maternal and child health centers (MCHCs) in Norway between March 2020 and June 2020. The analysis was guided by thematic analysis.

Results: Women who participated in the tablet intervention appreciated being asked questions about IPV on a tablet. However, it was important to supplement the tablet intervention with face-to-face communication with a midwife. The MCHC was regarded as a suitable place to answer questions and watch a film about safety behaviors. Women suggested making the tablet intervention available in other settings where women meet health care professionals. Some women expressed uncertainty about their anonymity regarding their answers in the questionnaire. We found no real differences between ethnic Norwegian and immigrant women's attitudes toward and experiences with the tablet intervention.

Conclusions: Questions about IPV and a film about safety behaviors on a tablet, as a supplement to face-to-face communication, might initiate and facilitate communication about IPV in antenatal care. Uncertainty regarding anonymity has to be addressed when questions about IPV are being asked on a tablet.

Trial Registration: ClinicalTrials.gov NCT03397277; https://clinicaltrials.gov/ct2/show/NCT03397277

(JMIR Form Res 2021;5(7):e28680) doi:10.2196/28680

KEYWORDS

intimate partner violence; eHealth; pregnancy; antenatal care, safety behaviors; tablet intervention

Introduction

Background

Intimate partner violence (IPV) is recognized as a global health problem [1]. According to the World Health Organization, IPV may include physical aggression, sexual coercion, psychological abuse, or controlling behaviors by current or former partners [1]. IPV can occur among people of any gender, identity, or sexual orientation and does not require sexual intimacy [2]. Almost one-third of women worldwide have been exposed to physical and/or sexual violence by an intimate partner throughout their life [2]. A meta-analysis of IPV during pregnancy, which included 92 studies from 23 countries, reported a prevalence of physical abuse of 13.8%, sexual abuse of 8.4%, and emotional abuse of 28.4% [3]. In Norway, the prevalence of IPV was reported to range from 1% to 5% in different studies [4,5]. IPV has been associated with multiple adverse physical and mental health conditions among women of all backgrounds [6]. Pregnancy does not protect against IPV [7,8]; it can be a motivator to stay in the relationship or a driving force to break out of a violent relationship [7]. IPV prior to pregnancy, during pregnancy, or in the neonatal period is associated with depression, unwanted pregnancy, miscarriage, stillbirth, premature birth, or intrauterine growth restriction [4,9-11]. IPV occurs in all social strata. Women with low education and limited resources are more vulnerable, as are immigrant women [12].

The Norwegian guidelines for antenatal care strongly recommend that all women should be asked about current and/or past experiences of IPV [13]. There is a lack of evidence on how health care professionals should communicate about and intervene against IPV during pregnancy [8,14]. Women exposed to IPV report weaknesses in conversations about violence with health care professionals, which could reduce the possibility to disclose their experiences [7,15,16]. Health care providers report challenges in conversations about IPV due to personal barriers and lack of knowledge about how to intervene [17-20]. Studies have examined eHealth interventions in IPV screening in different settings and patient populations. They show that women are more likely to disclose IPV when they use digital tools in violence screening [17,21].

Qualitative research alongside randomized controlled trials (RCTs) can improve the understanding and effects of complex health care interventions [22]. Other studies have conducted qualitative research as part of the process evaluation phase of RCTs concerning IPV [23-25]. This research provided insights into the complexity of women's help-seeking behaviors and the factors that influence the experience of different kinds of support [24,26]. The aim of this study was to explore pregnant women's attitudes and experiences with a tablet intervention to promote safety behaviors as part of an RCT in antenatal care.

The Safe Pregnancy Study

The Safe Pregnancy Study is an RCT to test the effectiveness of a tablet-based, culturally adapted intervention in antenatal care aiming to promote safety behaviors and prevent IPV among Norwegian, Pakistani, and Somali women [4]. The RCT was performed in a routine antenatal care setting at 19 maternal and child health centers (MCHCs) in Norway. The recruitment took place between January 2018 and June 2019 [4], and 317 women participated in the study.

Upon giving consent to participate in the study, all participants were asked to answer a baseline questionnaire on a tablet. A modified version of the Abused Assessment Screen (AAS) [27,28] was part of the baseline questionnaire. Exposure to violence was determined by a positive response to at least one of the five questions in the AAS. Women who screened positive in the AAS were included in the RCT and received detailed questions on IPV and their experiences with actions to make themselves safer. Subsequently, they were randomized to an intervention group or a control group. Women in the intervention group watched a film about the nature of IPV and behaviors that can increase safety [4]. Women in the control group watched a film with general information about health during pregnancy, including information about where to find help if experiencing violence. User involvement was highly prioritized, and women from Norway, Pakistan, and Somalia participated in the development process to culturally adapt the intervention film [4]. The intervention film and the control film lasted for approximately 7 minutes.

The questionnaire included items about pregnancy, health, quality of life, IPV, education, language, income, and personal perception of integration. Women who screened positive in the AAS were asked to complete the Composite Abuse Scale R-SF (CAS), an instrument containing 15 questions about physical, psychological, and sexual violence [29,30], and the Safety Behavior Questionnaire [31,32].

In this study, we defined tablet intervention as the use of an electronic device to pose detailed questions on IPV and safety behaviors and to show a film. However, the film in the RCT differed for the control and interventions groups, as described above. Thus, all participated in the tablet intervention, but only the intervention group, viewed the film on IPV and safety behaviors.

Methods

Interviews

Semistructured individual interviews with 10 women who participated in the Safe Pregnancy RCT were conducted by BW and HI (master's students in midwifery). LGH (qualitative researcher) participated in the pilot interview. Interviews were conducted in Norwegian between March 2020 and June 2020. Nine interviews were performed in an office or meeting room at a MCHC, and one interview took place in a private room in a library. The interviews lasted from 21 minutes 23 seconds to 53 minutes 43 seconds. The interviews followed a semistructured interview guide developed by the interdisciplinary research group in the Safe Pregnancy Study. The interview guide had the following three themes: (1) background for participation, (2) experience with the questionnaire, and (3) experience with the film about safety behaviors. A pilot interview was conducted to test the interview guide, and this interview was included in the analysis. Findings from the pilot interview were that the women had poor

recollection of the questionnaire and film. The interview guide was therefore modified before the next interview took place. The themes in the interview guide remained unchanged, but the questions were changed to a descriptive form with short and simple questions to obtain spontaneous descriptions. The interdisciplinary research group decided that the women should have the opportunity to see the questions and the film again during the interview (Multimedia Appendix 1).

Recruitment

Women were recruited through phone calls by BW and HI. Inclusion criteria for individual interviews were women who spoke adequate Norwegian and had participated in the Safe Pregnancy RCT Study in 2019. BW and HI received lists of participants with phone numbers from the Safe Pregnancy Study register. The first five women who agreed to participate were chosen from a list with participants from both the control and intervention groups. All received detailed questions about the experience of violence and use of safety behaviors, and only the intervention group viewed the film with information about the nature of violence and behaviors to increase safety. After conducting and transcribing the interviews from the control group, BW, HI, and LGH found that little new nuanced information was added to the data set. Hence, the last five women were chosen from a register with participants in the intervention group only. Recruitment was carried out until a rich set of data was obtained. The Regional Committee for Medical and Health Research Ethics approved the study (reference number 2017/358). The participants provided their written consent.

Analysis

The analysis was guided by thematic analysis, as described by Braun and Clarke [33], and included the following steps: (1) Familiarizing with the data by repeated reading of each informant's transcript; (2) Generating initial codes that were relevant to the research question across the entire data set; (3) Organizing the codes into subthemes; (4) Arranging the subthemes into overreaching themes; and (5) Defining and naming the themes.

Interviews were audiotaped and transcribed by BW and HI. BW and HI compared a random part (6 minutes) of each other's transcripts with the audiotapes to ensure accuracy of the transcription process. LGH, LH, and ML read all the transcripts during the interview process. BW and HI performed the analysis guided by LGH. BW and HI together coded each transcript. The process of generating initial codes and findings of potential themes and subthemes was discussed with LGH. ML and LH participated in the discussion of defining and naming the themes to strengthen the reliability of the findings. A qualitative software program (Nvivo 12 Pro) was used to identify codes and systematize subthemes.

Results

Characteristics of the Women

Six women from the intervention group and four women from the control group were recruited. Five of the women spoke Norwegian at home and five spoke another language. The majority of the women who did not speak Norwegian at home perceived themselves as relatively well integrated. Time from participation in the tablet intervention to the interview varied from 11 to 25 months (Multimedia Appendix 2).

The analysis resulted in the following themes representing the women's attitudes and experiences with a tablet intervention to promote safety behaviors: (1) Positive attitudes toward and experiences with questions asked about IPV via a tablet shown at the MCHC; (2) Negative attitudes toward and experiences with the film about IPV via a tablet shown at the MCHC; (3) Positive attitudes toward and experiences with the film about IPV on a tablet shown at the MCHC; (4) Motivation to participate in the Safe Pregnancy Study; and (5) Women's suggestions for improvements to the tablet intervention (Table 1).

Table 1. Themes and subthemes.

Theme and subtheme	Identified in the control (C) and/or intervention group (I)
Positive attitudes toward and experiences with questions about IPV[a] via a tablet shown at the MCHC[b]	
Remembered the questions related to IPV because they were unexpected	I
The MCHC was a safe place to be asked questions related to IPV on a tablet	C and I
Using a tablet enabled honest answers in a nonconfrontational setting without being disrupted	C and I
Provided an opportunity for a conversation with the midwife	C and I
Easy to answer when you can choose your own mother tongue	C and I
Reflected about their own life situation	C and I
Negative attitudes toward and experiences with questions about IPV via a tablet shown at the MCHC	
The questions gave the feeling of being interrogated	C
Have thought about the questions since	I
Positive attitudes toward and experiences with the film about IPV via a tablet shown at the MCHC	
The MCHC was a safe environment to watch a film about IPV	I
The film gave a feeling of not being alone in experiencing IPV	I
Information given in the film can be of importance for women with different cultural backgrounds	I
Made them aware of different types of IPV and the situation for victims of IPV	I
Motivation to participate in the Safe Pregnancy Study	
Wanted to contribute with experience and knowledge that could improve the service at the MCHC	C and I
Usually participated in research projects	C and I
IPV was a topic of importance	C and I
Wanted to be integrated	I
Women's suggestions to improve the tablet intervention	
Women who claim they are living with IPV should be invited to a second consultation with the midwife	I
Believed that women who are exposed to IPV should be given the chance to consent for receiving help	I
Lacked contact details for the support services when they answered questions about IPV	I
Of the opinion that the tablet intervention is appropriate in other settings	I
It should be clearer in the film that abused women are not alone in their experience and that they can feel safe contacting supportive services	I

[a]IPV: intimate partner violence.

[b]MCHC: maternal and child health center.

Attitudes Toward and Experiences With Questions Asked About IPV Via a Tablet Shown at the MCHC

Most of the women remembered the questions about IPV from the tablet intervention. A woman from the intervention group said that she remembered the questions because she was surprised being asked about IPV.

> *Obviously…I remember the questions I was shocked by.* [Informant 8]

Women who did not remember the questions said that time from participation in the tablet intervention could have contributed to the lack of memory. They said that they received a lot of information during pregnancy, and there was a possibility that they mixed it up.

The women considered the MCHC as a safe and suitable place to be asked about IPV on a tablet, whether or not they had been exposed to IPV. They appreciated the opportunity to answer the questions alone, without a partner, as described by a woman in the control group as follows:

> *I think it's a very smart place to get it. After all, this is a place where you can go and talk about your problems related to the pregnancy.* [Informant 1]

The women explained that questions about IPV on a tablet gave them the opportunity to first consider the questions undisrupted before answering. It felt safe, and it was positive that visitors and employees at the MCHC could not observe their body language while answering the questions. Most of the women believed it was easier to answer honestly on a tablet than face to face. One woman expressed how she found it as follows:

> *It is much easier when you're able to think…have that extra time to read for yourself…and consider yes because I sometimes wondered was it a common quarrel…it is a very good thing that you have time…[to] make some reflections and considerations.* [Informant 8]

Some women felt that questions about IPV on a tablet opened for a conversation with the midwife. Being asked on a tablet led to a feeling that the topic was not unknown for the midwife, and it felt safe to talk with her. A woman who had been exposed to IPV and was an immigrant felt relieved when she was asked about IPV and said that it felt good. She reflected upon this as follows:

> *It was an opportunity for me, if I wanted to tell something to the midwife afterwards or the next visit…I felt confident that I could talk to her because it was not unknown to her.* [Informant 6]

Most of the women, independent of which group they belonged to, did not have issues answering the questions about IPV because they experienced them as concrete and distinct. One bilingual Norwegian woman valued the opportunity to answer the questions in her mother tongue.

Many women believed that it was important to be asked about IPV because it was a common reality of everyday life. Most experienced the questions as being relevant, although one woman from the control group had a different opinion as follows:

> *To answer such questions about violence, you go through your own thoughts really thoroughly, you think what do you want to answer? What do you not want to answer? Will it be saved? Is it an interrogation? You become a little skeptical.* [Informant 5]

The questions about IPV made an impression on some of the women. One described that it was painful to be reminded about her own experiences with IPV. Another woman who had been exposed to IPV commented that she had thought about the questions after participating in the tablet intervention.

> *I actually have, it may sound very stupid, but I have thought about it a lot…I was a bit thoughtful, by the questions, absolutely. After the last child was born, I have thought a lot more about things, probably…because of this questionnaire and the video and that kind of thing.* [Informant 9]

Some of the women said that the questions made them reflect about their own life situation. Most women mentioned they were grateful of being in a good relationship with their current partner. A woman from the control group said the following:

> *It is something about the deeper questions that you may not usually think about, how satisfied you are with things. But, it felt a bit nice to reflect over it, and that, yes, I'm pretty good.* [Informant 4]

One woman expressed her gratitude to her husband as follows:

> *I realized that it is a reality in many families, but I was a little proud of my husband, who is very nice and loving to me.* [Informant 1]

Attitudes Toward and Experiences With the Film About IPV on a Tablet Shown at the MCHC

Most women did not remember anything from the film, and all of them chose to watch it during the interview. They perceived the MCHC as a safe place to watch a film about IPV, noting that not every woman was safe in her own home. A woman from the intervention group described the film as follows:

> *It can really give a feeling that there is someone who cares here, and maybe there are some ways out…the film gives concrete advice…I got the impression that it is perhaps easy to do the things like contacting the police or women's shelter or just talk to the midwife…immediately when you are at the MCHC.* [Informant 8]

A woman with an immigrant background expressed that the film could be of importance for women who lacked knowledge about their civil rights. She felt that immigrant women needed to know where they could receive help if they were a victim of IPV. After watching the film again during the interview, many participants understood that IPV was a reality for some women. They thought that the film could help women who had experienced IPV feel that they were not alone. Some women stated that the film made them aware of different types of IPV and that it was important to receive this information. One participant who had experienced IPV was of the opinion that physical violence was more obvious and therefore easier to detect than psychological violence.

> *When it is physical violence, it is quite clear to a woman it is violence…it is important that they mention there is also violence when they control you…I think it has a lot of information and describes very well if you have doubts about whether you are in a violent relationship or not, it is very well described.* [Informant 6]

Some women thought that the film was useful because they learned how victims of IPV could experience their lives, and it could contribute to care for these women.

> *It is also useful for me to be aware that someone can experience it, and maybe when I talk to other pregnant women…be concerned that someone may experience it…if I see it, respond to it.* [Informant 8]

Motivation to Participate in the Safe Pregnancy Study

The women had different reasons for participating. Some wished to participate because they wanted to influence and contribute to improvement of the service at the MCHC. Others were motivated to participate if it would help to improve the intervention. Informant 6 expressed her motivation as follows:

> *I decided it was very important for me to participate, but also give feedback to develop the program.* [Informant 6]

Like others, she also thought that the topic was important.

> *For me it was very important, it is a reason why I am here today, because I found it especially important.* [Informant 6]

Many stated that they participated because they usually participate in research projects. They believed that someone had to participate to make research possible, as described by a woman who was in the control group as follows:

> *I usually participate in most research projects I am asked to participate in…I don't mind…it is important to receive information.* [Informant 3]

Informant 10 thought that participating in the tablet intervention and the interview could help her to become integrated into Norwegian society.

> *Because I also need to talk…because I came here to learn something new…and at least integrate into society, which I have not before.* [Informant 10]

Women's Suggestions to Improve the Tablet Intervention

Women with an immigrant background thought that it was important to make the film available elsewhere, not only at the MCHC. They suggested that general practitioners' offices or Norwegian language courses could be good locations. They thought that by doing this, women could receive the information at an earlier stage.

Informant 6 suggested that there should be an opportunity for women to consent in the questionnaire if they wanted help with IPV. She reported that women who stated they were exposed to IPV may want help and therefore should be invited to a new consultation with a midwife.

Informant 9 had the opinion that the tablet intervention was not good enough alone and should be supplemented with support from health care professionals.

> *It is a bit incomplete, in a way…if you are going to start with it, then you have to get a little closer to the person in an individual way.* [Informant 9]

It was suggested that there should be contact information for support services when women answered the questionnaire. Informant 6 felt it was important that information in the film about support services was given in a way that assures women are safe if they wish to contact them. She also thought that the film should contain more information on IPV being a common problem and women being not alone in experiencing IPV.

> *Many families experience problems with violence, you are not alone and maybe something that makes the woman trust a crisis center or makes it feel close, because it isn't easy to just call a number, I need help. That is a very, very, very difficult thing to do.* [Informant 6]

Discussion

Principal Findings

This study showed that women who participated in the tablet intervention had positive attitudes and experiences to answer questions and see a film about IPV on a tablet. The MCHC was regarded as a suitable place for questions and a film on IPV, particularly when staff followed up on it. The majority of the women in this study found the questions on the tablet intervention easy to answer. However, it was important to supplement the questions and film with face-to-face communication with the midwife. Furthermore, they suggested making the tablet intervention available in other settings, such as Norwegian language courses and general practitioners' offices. Women's negative attitudes were mainly related to uncertainty about their anonymity regarding the answers they gave in the questionnaire.

Comparison With Previous Work

Other studies have identified women's positive attitudes toward and experiences with eHealth tools to communicate about IPV [23-25]. Women in our study said that questions and a film about IPV on a tablet provided an opportunity for a conversation with the midwife because they felt that the topic was known to them. Bacchus et al [25] conducted semistructured interviews with participants in an RCT with a computer tablet intervention for IPV. They found that women regarded a computer tablet intervention for IPV screening during perinatal home visits as an opportunity to talk to health professionals, and it gave women a feeling of being cared for. This is supported by Chang et al [23], who performed a qualitative study to compare in-person and computerized screening for IPV. They found that electronic questions about IPV prepared women to talk about their experiences with their health care provider.

Women in our study acknowledged the opportunity to answer the questions about IPV on a tablet undisturbed. Other studies have found that questions about IPV on a tablet are regarded as a safe and confidential way for abused women to disclose their experiences of IPV [18,19,23,25]. Women in this study expressed that they were able to reflect on the questions while answering alone, which in turn probably enhanced their level of honesty. Tarzia et al [24] did a qualitative study as part of an evaluation process of two Australian RCTs about safety for women experiencing IPV. They found that women exposed to IPV appreciated answering questions about violence in private and reflected about their life situation via an interactive online intervention. Previous studies have found that women who are exposed to IPV express challenges in disclosing this in face-to-face situations because they are worried about confidentiality and judgmental responses [7,16,19,23,34]. Interventions delivered via the internet have been rated as a preferred alternative method to face-to-face support for women experiencing IPV [24]. This might have the potential to overcome some barriers associated with accessing face-to-face screening [24]. Self-administrated questionnaires for IPV, including computer-based assessment tools, may thus be more effective than face-to-face questioning [17].

However, women who had positive attitudes toward and experiences with the tablet intervention in our study expressed that the tablet intervention should be supplemented with face-to-face support from health care professionals. A trusting relationship in a face-to-face intervention can create a safe place to talk, facilitate disclosure, and meet individual needs [24].

Bacchus et al [25] also found that a trusting relationship with a provider as a supplement to eHealth intervention was important to achieve disclosure of IPV. Chang et al [23] found that in-person screening provided for tailored questioning and more emotional connection with the provider and suggested that both in-person intervention and computerized screening were good methods for women to disclose IPV.

In line with this study, an earlier Norwegian study showed that women regarded the MCHC as an appropriate place to receive information about IPV [16]. Antenatal care was regarded as a suitable place to talk about IPV because pregnant women make repeated visits during their pregnancy [35,36]. The visits at an antenatal clinic can help create a trusting relationship between the pregnant woman and the health care provider [35]. Women in this study suggested that places other than MCHCs, such as general practitioners' offices and Norwegian language centers, could also be appropriate places to introduce the tablet intervention. Other settings for IPV interventions have been examined. Bacchus et al [25] found that an eHealth tool for IPV could successfully be used in perinatal home visits. Bacchus et al [25] asserted that the context in which IPV technology was being introduced had to be considered. There should be a possibility for a patient-provider relationship in addition to IPV technology.

We also identified negative attitudes and experiences to answer questions about IPV on a tablet. For some women, participation in the tablet intervention led to further reflection on the topic. Some expressed that it was painful to be reminded about their experiences with IPV. A qualitative user-involvement study with the purpose of developing the film, which was a part of the Safe Pregnancy Study, found that women acknowledged that the film potentially could trigger painful memories [18]. This emphasizes the importance of face-to-face support from a provider as a supplement to questions about IPV on a tablet. In order not to influence the RCT outcome, health professionals in the Safe Pregnancy Study were blinded to the responses of the women, which is why all women were offered to watch a film. Thus, only women who took initiative themselves or screened positive on the routine questions on violence asked by the midwife received more follow-up if desired.

Interestingly, our study showed no real differences between ethnic Norwegian and immigrant women's attitudes toward and experiences with the tablet intervention. This is in line with another Norwegian study that found independent of ethnicity, women said that they want to be asked and talk about IPV [16]. In line with other qualitative studies, both ethnic Norwegians and immigrant women in this study said that the questions were easy to answer, and that the topic was important [18,23]. However, some women expressed a feeling of being interrogated when answering the questions about IPV. Despite reassurance of confidentiality, there was uncertainty about their anonymity regarding the answers they gave in the questionnaire. Chang et al [23] also found that women answering questions about IPV on a tablet were uncertain who would get the information from their IPV disclosure. Previous studies indicate that anonymity is crucial for disclosing IPV [18,25]. eHealth tools aim to provide easy access to tailored health care information. However, eHealth tools might involve a risk within information security and privacy [37]. This might affect users' willingness to share information because they reveal sensitive information [37]. This emphasizes the importance of health care professionals giving out information about the trustworthiness of eHealth technology [25].

Limitations and Strengths

Time from participation in the tablet intervention to the interview might have caused recall bias, as several women had poor or no recollection of the film. They chose to see the questions and film again during the interview. Ideally, the interview should have been conducted shortly after the tablet intervention. The sample in this study was limited to the population in the Safe Pregnancy Study and was too small to draw conclusions about a broader population of women. It is a limitation that few immigrant women were recruited in this study. Inclusion criteria included that they had to speak Norwegian because the interviews were conducted in Norwegian. This may be the reason why this study did not find a clearer distinction between ethnic Norwegian and immigrant women. The findings in this study can be compared to other RCT studies where women's responses to IPV technology have been examined [23-25]. It can contribute to further development of eHealth interventions for IPV screening and information about safety behaviors. The researchers who conducted the interviews were not involved in the design of the Safe Pregnancy Study. This is a strength because it might have contributed to facilitating data collection where the women could share nuanced views. The data set was read by all the authors. The interpretation and potential themes were discussed among the authors to improve the credibility of the findings.

Few studies have examined women's attitudes and experiences with eHealth interventions to promote safety behaviors in order to reduce IPV. This study provides insights into the evaluation of complex interventions about IPV to promote safety behaviors.

Conclusions

Women who participated in the tablet intervention had positive attitudes and experiences to answer questions about IPV and watch a film about safety behaviors on a tablet. The majority of the women in this study thought that a questionnaire on a tablet was easy to answer and they acknowledged that the MCHC was an appropriate place. They considered that the intervention might initiate and facilitate communication about IPV in antenatal care. Thus, IPV technology should be supplemented with the possibility of face-to-face communication. Women's negative attitudes and experiences to answer questions about IPV on a tablet were mainly related to uncertainty regarding anonymity. Hence, tablet interventions to promote safety behaviors in pregnant women should be accompanied by information about women's privacy.

Acknowledgments

We thank the women who participated in the interviews.

Authors' Contributions

LGH, LH, and ML conceived the idea and design of the study. BW, HI, and LGH formulated the interview guide, which was approved by ML and LH. BW and HI collected the data. BW and HI performed the analyses, guided by LGH. All authors contributed to the interpretation of the findings. HI and BW wrote the manuscript, supervised by LGH. All authors approved the final draft.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Interview guide.
[DOCX File , 25 KB - formative_v5i7e28680_app1.docx]

Multimedia Appendix 2
Characteristics of the study participants.
[DOCX File , 25 KB - formative_v5i7e28680_app2.docx]

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Abbreviations

AAS: Abused Assessment Screen
IPV: intimate partner violence
MCHC: Mother and Child Health Center
RCT: randomized controlled trial

Edited by G Eysenbach; submitted 11.03.21; peer-reviewed by LJ Li, AM Almeida; comments to author 11.05.21; revised version received 13.05.21; accepted 29.05.21; published 20.07.21.

Please cite as:
Walter B, Indreboe H, Lukasse M, Henriksen L, Garnweidner-Holme L
Pregnant Women's Attitudes Toward and Experiences With a Tablet Intervention to Promote Safety Behaviors in a Randomized Controlled Trial: Qualitative Study
JMIR Form Res 2021;5(7):e28680
URL: https://formative.jmir.org/2021/7/e28680
doi:10.2196/28680
PMID:34283023

Original Paper

Studying How Individuals Who Express the Feeling of Loneliness in an Online Loneliness Forum Communicate in a Nonloneliness Forum: Observational Study

Anietie Andy[1], PhD

Penn Medicine, Philadelphia, PA, United States

Corresponding Author:
Anietie Andy, PhD
Penn Medicine
3400 Civic Blvd
Philadelphia, PA,
United States
Phone: 1 202 486 4095
Email: andyanietie@gmail.com

Abstract

Background: Loneliness is a public health concern, and increasingly, individuals experiencing loneliness are seeking support on online forums, some of which focus on discussions around loneliness (loneliness forums). Some of these individuals may also seek support around loneliness on online forums not related to loneliness or well-being (nonloneliness forums). Hence, to design and implement appropriate and efficient online loneliness interventions, it is important to understand how individuals who express and seek support around loneliness on online loneliness forums communicate in nonloneliness forums; this could provide further insights into the support needs and concerns of these users.

Objective: This study aims to explore how users who express the feeling of loneliness and seek support around loneliness on an online loneliness forum communicate in an online nonloneliness forum.

Methods: A total of 2401 users who expressed loneliness in posts published on a loneliness forum on Reddit and had published posts in a nonloneliness forum were identified. Using latent Dirichlet allocation (a natural language processing algorithm); Linguistic Inquiry and Word Count (a psycholinguistic dictionary); and the word score–based language features *valence*, *arousal*, and *dominance*, the language use differences in posts published in the nonloneliness forum by these users compared to a control group of users who did not belong to any loneliness forum on Reddit were determined.

Results: It was found that in posts published in the nonloneliness forum, users who expressed loneliness tend to use more words associated with the Linguistic Inquiry and Word Count categories on sadness (Cohen *d*=0.10) and seeking to socialize (Cohen *d*=0.114), and use words associated with *valence* (Cohen *d*=0.364) and *dominance* (Cohen *d*=0.117). In addition, they tend to publish posts related to latent Dirichlet allocation topics such as relationships (Cohen *d*=0.105) and family and friends and mental health (Cohen *d*=0.10).

Conclusions: There are clear distinctions in language use in nonloneliness forum posts by users who express loneliness compared to a control group of users. These findings can help with the design and implementation of online interventions around loneliness.

(JMIR Form Res 2021;5(7):e28738) doi:10.2196/28738

KEYWORDS

loneliness; Reddit; nonloneliness; mental health; eHealth; forum; online forum; communication; natural language processing; language; linguistics

Introduction

Loneliness is a public health challenge [1]; it affects the well-being of individuals of all age groups [2,3] and has been linked to early death [4,5], depression [6,7], and heart disease [8].

Several prior works [1,9,10] have analyzed data from social media platforms and online forums, some of which focus on discussions around loneliness (loneliness forums) to understand the support needs of individuals who express loneliness on these platforms. These individuals may also seek support and express concerns as it relates to loneliness, such as how to develop or

maintain relationships, on online forums not focused on discussions around loneliness or well-being (nonloneliness forums). To better understand the support needs of users who express loneliness on online loneliness forums and to design and implement appropriate and efficient online interventions, it is important to study how these individuals communicate in nonloneliness forums.

Using natural language processing methods, prior works determined that the language used in posts published on social media platforms and online forums can be used to gain insights into how users communicate on these forums and the types of support they seek and express, as it relates to their health and well-being. For example, language used in posts published on Facebook was used to train a machine learning model to predict patients risk for cardiovascular disease [11]. In addition, language used on online forum posts were used to determine the support needs of users in substance use recovery forums [12], a COVID-19 online forum [13,14], and an online cancer forum [15-17]. Regarding loneliness, prior works analyzed social media data belonging to individuals who expressed loneliness; for example, Guntuku et al [1] analyzed Twitter posts from users who self-declared feeling lonely, and it was determined that the language used by these users in their Twitter posts was more associated with mental health concerns. Kivran-Swaine et al [18] determined that posts in which users expressed loneliness tended to receive more responses compared to other posts by the same users. Ruiz et al [9] showed that the more loneliness users express on social media, the less online relationships they had. Hunt et al [10] showed that there is an association between less social media use and a decrease in the feeling of loneliness and depression.

Similar to prior works, in this study, using natural language processing methods, language used on posts published on a nonloneliness online forum are analyzed to gain insights into the support needs and concerns of individuals who express loneliness in a loneliness online forum. Potentially, information gleaned from the analyses in this study will provide further insights into the support needs and concerns of individuals expressing loneliness on online loneliness forums, thereby informing loneliness interventions.

Methods

Data and Design

For the analysis in this study, data from Reddit was used. Reddit is made up of more than 1 million subforums (called subreddits) [19] focused on discussions around specific topics such as depression, loneliness, and open-ended questions spanning various topics. In addition, Reddit allows members to join several of these forums; hence, it is possible to get posts published in a nonloneliness forum by users who are members of a loneliness forum. Using Google's BigQuery [20], which is a data warehouse with publicly accessible Reddit data sets published between December 2015 and August 2019, posts from Reddit forums focused on discussions around loneliness were identified by selecting the forums that contained the word "Lonely" in its name (eg, "/r/lonelyheartbeats," "/r/iAMlonely," and "/r/Lonely"). It was observed that the forum */r/Lonely* had more posts and members compared to the other forums, which each had less than 200 published posts during the time period in which the data was collected. Hence, for the analysis in this study, usernames of members of */r/Lonely* were used; specifically, the usernames of 9956 users who had published a total of 15,012 posts on the */r/Lonely* forum were selected.

To identify the other Reddit forums in which these users belong to and tend to publish posts, using the usernames from */r/Lonely*, all the forums on Reddit were searched to determine the forums in which these */r/Lonely* users tend to publish posts. It was observed that the forums with the most number of these users as members are */r/AskReddit* (a forum in which users seek advice and ask open-ended questions on various topics) and */r/depression* (a forum focused on discussions around depression) with posts by 24% (n=2401) and 20% (n=2031), respectively, of the */r/Lonely* users (N=9956) in the data set. Since the focus of this study is to determine how individuals who express loneliness on an online loneliness forum communicate in nonloneliness forums (ie, forums not focused on loneliness or well-being), for all the analysis in this study, data from */r/AskReddit* by 2401 users who expressed loneliness in */r/Lonely* were used. The author reviewed the posts (N=4001) published on */r/Lonely* by these users and observed that these users expressed feeling lonely in their */r/Lonely* posts by stating that they were feeling lonely (eg, rephrased "I am a 25 years old female and I am always lonely"), implied that they were feeling lonely (eg, rephrased "I moved to a new city and I don't know anyone"), or sought support as it relates to loneliness (eg, rephrased "Where can I find tools online to help with loneliness?").

Each of the 2401 users who posted on */r/Lonely* and had published posts on */r/AskReddit* were matched with a control group user who had no published posts on any loneliness forum on Reddit and had published posts on */r/AskReddit* between December 2015 and August 2019.

Table 1 shows information about the data set.

Table 1. Summary of /r/AskReddit posts published between December 2015 and August 2019 by /r/Lonely users and a control group.

Variables	/r/Lonely users	Control group
Users, n	2401	2401
Posts, n	25,834	34,718

In this study, the following methods were used to determine language use differences in */r/AskReddit* posts by users who express loneliness compared to the control group: a topic modeling approach, a dictionary-based approach, and a word score–based approach. Cohen *d*, which indicates the standardized difference between means, was used to report the effect sizes. In this study, only results with Cohen *d* greater than

or equal to a threshold (ie, 0.10) and that are significant at Bonferroni-corrected *P* values <.001 are reported.

The topic modeling approach and the dictionary-based approaches were used because prior works used these approaches to gain insights from social media data about the language use differences between individuals in different genders [21] and age groups [22], and to determine the language use differences between users who express loneliness compared to a control group of users who did not express loneliness [1]. The word score–based approach was used because prior work [23] used these methods to better understand language features associated with persuasion in online forum posts and comments.

Topic Modeling Approach

In this section, the natural language processing topic modeling method latent Dirichlet allocation (LDA) [24] was used. LDA works by, first, splitting words in Reddit posts into single words or tokens (tokenization). Second, words that co-occur together are clustered together; the cluster of words are referred to as topics, and based on the content words associated with each topic, a label can be assigned to the topics. For example, LDA could group the words "family," "mom," "dad," "daughter," and "son" as a reference to family. LDA assumes that the topics consist of a combination of words, and each Reddit post is made up of a combination of topics. Using the Dlatk package [25], 20 LDA topics were generated from the */r/AskReddit* posts associated with */r/Lonely* users and the control group users; to determine the number of LDA topics, the number of topics varied between 5 and 50 topics by starting with 5 topics and incrementing by 2 topics up to 50 topics. A total of 20 topics had the most coherent topic themes when reviewed by the author. With the generated topics, using the Dlatk package [25], the topic themes that frequently occurred in the */r/AskReddit* posts by */r/Lonely* users when compared with the control group users were identified.

Dictionary-Based Approach

In this approach, language from */r/AskReddit* posts associated with the */r/Lonely* users and the control group users were used to determine the prevalence of Linguistic Inquiry and Word Count (LIWC) [26] dictionary word categories in posts associated with these groups of users. LIWC is a psycholinguistic dictionary made up of 73 predefined categories such as positive and negative emotions; each of these categories has a curated list of words associated with it. LIWC has been used in several prior works [1,22,27]. Using the Dlatk package [25], for each group of */r/AskReddit* posts (ie, posts belonging to */r/Lonely* users and the control group users), the proportion of token words associated with LIWC categories were determined.

Word Score–Based Approach

The word score–based features v*alence*, *arousal*, and *dominance* have been used by prior works to study communication strategies in an online forum [23,28]. *Valence* indicates the measure of the positive or negative denotation of a word; for example, "enjoyable" is a high *valence* word and "nightmare" is a low valence word. *Arousal* measures the emotional intensity expressed in a word; an example of a high *arousal* word is "exhilarated," and an example of a low *arousal* word is "siesta." Dominance indicates the measure of the locus of control expressed in a word; for example "powerful" is a high dominance word, and "weak" is a low dominance word. Mohammad [28] provided a lexicon of human ratings for *valence*, *arousal*, and *dominance* for 20,000 words in English; using this lexicon, for each post in the data set, the average ratings of all content words in each of these word categories (ie, *valence*, *arousal*, and *dominance*) was computed.

Results

Topic Modeling Approach

Table 2 shows the most significant LDA topics in */r/Askreddit* posts by */r/Lonely* users compared to the control group.

Table 2. Results from latent Dirichlet allocation analysis on /r/AskReddit posts by /r/Lonely users compared to the control group users.

Label	Highly correlated words	Cohen *d*	Mean (SD)
Relationships	people, love, hate, relationship, find, can't, lose, meet, stop, married	0.105	0.038 (0.048)
Family and friends/mental health	family, friends, deal, talk, experience, depression, mental, care, service, dear	0.10	0.038 (0.053)

Dictionary-Based Approach

Table 3 shows the different LIWC categories in */r/AskReddit* posts most associated with */r/Lonely* users compared to the control group users.

Table 3. Results from LIWC analysis on /r/AskReddit posts by /r/Lonely users compared to the control group users.

LIWC[a] category	Cohen *d*	Mean (SD)
Social processes	0.114	0.157 (0.08)
Sadness	0.10	0.083 (0.042)

[a]LIWC: Linguistic Inquiry and Word Count.

Word Score–Based Approach

Using Cohen *d*, the effect size between the features that represent the average *valence*, *arousal*, and *dominance* scores for posts in the data set and a feature that represents if a */r/AskReddit* post was by a */r/Lonely* user or a control group user was determined, as shown in Table 4.

Table 4. Results from word score–based language feature analysis on /r/AskReddit posts by /r/Lonely users compared to the control group users.

Attribute	Cohen *d*
Valence	0.364
Arousal	–0.004
Dominance	0.117

Discussion

Findings

Using natural language processing methods, this study shows the distinction in language use in posts published on a nonloneliness forum by users who express and seek support around loneliness in an online loneliness forum compared to a control group of users. These language use differences reflect the support needs and concerns of these users. The findings from this study are summarized in this section.

This study determined that users who express the feeling of loneliness in */r/Lonely* tend to seek advice and ask questions about relationships on */r/AskReddit* (Table 2) compared to the control group users. This finding is in line with prior work [1] that determined that individuals who expressed loneliness on Twitter tend to publish Twitter messages related to themes about difficult interpersonal relationships.

In addition, this study has findings that were not in prior work; specifically, it was observed that individuals who express loneliness in a loneliness forum tend to seek advice and ask questions about mental health concerns as it relates to their family members and friends; for example, the following are examples of */r/AskReddit* posts (rephrased) by */r/Lonely* users seeking advice as it relates to their relationships with family members and friends:

> *I need advice on how to deal with a family member / friend who keeps criticizing me.*
>
> *I need help, if one is struggling with mental health, what is the best way to explain it to family members and friends?*

Using LIWC, it was observed that users who expressed loneliness in the loneliness forum tended to use more words associated with sadness and wanting to socialize in the nonloneliness forum.

Using the word score–based language features v*alence*, *arousal*, and *dominance*, it was determined that the average v*alence* and *dominance* scores in */r/AskReddit* posts are more associated with posts by users who express loneliness on */r/Lonely*. A potential explanation for *dominance* being more associated with */r/AskReddit* posts by */r/Lonely* users is that some of these users seek support and express vulnerability in these posts; low dominance words suggest vulnerability, hence the association. Additionally, a potential explanation for v*alence* being more associated with */r/AskReddit* posts by */r/Lonely* users is that these users tend to use low *valence* words in these posts, hence the association.

This study shows that users who express loneliness in a loneliness forum seek support and communicate differently from a control group of users in a nonloneliness forum. The findings from this study can aid in the design and implementation of online loneliness interventions; for example, given that users who express loneliness in the loneliness forum ask questions and seek advice as it relates to their relationships (with family and friends) and use more words associated with seeking to socialize and sadness (Table 3), online loneliness interventions can provide services in which advice and tips are given to users on how to develop, maintain, and navigate relationships.

From this study's findings, when designing and implementing online loneliness interventions, it is important to not only focus on user communication in loneliness forums but also look into how these users communicate in nonloneliness forums.

Limitations

In this study, data from Reddit users was used and may not be representative of all individuals (some of whom may not publish posts on online forums expressing their feeling of loneliness) who feel lonely.

Ethics and Privacy

The data set used for this study is publicly available. For all the analyses in this study, no user or moderator of any loneliness forum on Reddit (including */r/Lonely*) was contacted. In addition, besides the usernames of */r/Lonely* users, no other information from user profiles was used or accessed.

Conclusion

In this study, using natural language processing methods, it was determined that users who express loneliness in an online loneliness forum communicated differently in a nonloneliness forum when compared to a control group of users. The findings from this study can aid with the design and implementation of online loneliness interventions.

Conflicts of Interest

None declared.

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Abbreviations

LDA: latent Dirichlet allocation
LIWC: Linguistic Inquiry and Word Count

Edited by G Eysenbach; submitted 12.03.21; peer-reviewed by C Entwistle, M Fiordelli; comments to author 10.05.21; revised version received 04.06.21; accepted 17.06.21; published 20.07.21.

Please cite as:
Andy A
Studying How Individuals Who Express the Feeling of Loneliness in an Online Loneliness Forum Communicate in a Nonloneliness Forum: Observational Study
JMIR Form Res 2021;5(7):e28738
URL: https://formative.jmir.org/2021/7/e28738
doi:10.2196/28738
PMID:34283026

Original Paper

Associations Between Physiological Signals Captured Using Wearable Sensors and Self-reported Outcomes Among Adults in Alcohol Use Disorder Recovery: Development and Usability Study

Parastoo Alinia[1], PhD; Ramesh Kumar Sah[1], MS; Michael McDonell[2], PhD; Patricia Pendry[3], PhD; Sara Parent[2], PhD; Hassan Ghasemzadeh[1], PhD; Michael John Cleveland[3], BPharm, MS, PhD

[1]School of Electrical Engineering and Computer Science, Washington State University, Pullman, WA, United States

[2]Elson S. Floyd College of Medicine, Washington State University, Pullman, WA, United States

[3]Department of Human Development, Washington State University, Pullman, WA, United States

Corresponding Author:
Michael John Cleveland, BPharm, MS, PhD
Department of Human Development
Washington State University
501 Johnson Tower
Pullman, WA, 99164
United States
Phone: 1 509 335 2870
Email: michael.cleveland@wsu.edu

Abstract

Background: Previous research has highlighted the role of stress in substance misuse and addiction, particularly for relapse risk. Mobile health interventions that incorporate real-time monitoring of physiological markers of stress offer promise for delivering tailored interventions to individuals during high-risk states of heightened stress to prevent alcohol relapse. Before such interventions can be developed, measurements of these processes in ambulatory, real-world settings are needed.

Objective: This research is a proof-of-concept study to establish the feasibility of using a wearable sensor device to continuously monitor stress in an ambulatory setting. Toward that end, we first aimed to examine the quality of 2 continuously monitored physiological signals—electrodermal activity (EDA) and heart rate variability (HRV)—and show that the data follow standard quality measures according to the literature. Next, we examined the associations between the statistical features extracted from the EDA and HRV signals and self-reported outcomes.

Methods: Participants (N=11; female: n=10) were asked to wear an Empatica E4 wearable sensor for continuous unobtrusive physiological signal collection for up to 14 days. During the same time frame, participants responded to a daily diary study using ecological momentary assessment of self-reported stress, emotions, alcohol-related cravings, pain, and discomfort via a web-based survey, which was conducted 4 times daily. Participants also participated in structured interviews throughout the study to assess daily alcohol use and to validate self-reported and physiological stress markers. In the analysis, we first used existing artifact detection methods and physiological signal processing approaches to assess the quality of the physiological data. Next, we examined the descriptive statistics for self-reported outcomes. Finally, we investigated the associations between the features of physiological signals and self-reported outcomes.

Results: We determined that 87.86% (1,032,265/1,174,898) of the EDA signals were clean. A comparison of the frequency of skin conductance responses per minute with previous research confirmed that the physiological signals collected in the ambulatory setting were successful. The results also indicated that the statistical features of the EDA and HRV measures were significantly correlated with the self-reported outcomes, including the number of stressful events marked on the sensor device, positive and negative emotions, and experienced pain and discomfort.

Conclusions: The results demonstrated that the physiological data collected via an Empatica E4 wearable sensor device were consistent with previous literature in terms of the quality of the data and that features of these physiological signals were significantly associated with several self-reported outcomes among a sample of adults diagnosed with alcohol use disorder. These results suggest that ambulatory assessment of stress is feasible and can be used to develop tailored mobile health interventions to enhance sustained recovery from alcohol use disorder.

(JMIR Form Res 2021;5(7):e27891) doi:10.2196/27891

KEYWORDS

alcohol relapse prevention; stress markers; alcohol consumption; electrodermal activity; heart rate variability; emotion; mobile phone

Introduction

Background

A well-established literature describes the important role of stress in addiction and the risk of relapse. For example, laboratory studies have shown that acute stressors increase drug-seeking behaviors in animals [1] and that physiological stress responses in laboratory situations predict relapse among humans [2]. There is also considerable overlap in the neural circuitry affected by stress and substance use [1]. Thus, the associations among cravings, negative emotions, and substance use have been described by a negative reinforcement model whereby the combination of craving, withdrawal-induced negative effect, and a dysregulated reward system during abstinence leads to increased vulnerability to relapse [1]. This model suggests that the ability to automatically detect moments of stress in real-world settings and deliver just-in-time tailored interventions can provide a powerful tool to prevent relapse, especially during the early stages of recovery when relapse risk is highest [3].

A common approach to monitoring stress is to analyze physiological signals, such as electroencephalography, blood volume pulse (BVP), heart rate variability (HRV), galvanic skin response, electrodermal activity (EDA), and electromyography [4-6]. In this study, we focus on assessing the quality of the measured EDA and HRV values as biomarkers of stress in human participants. These 2 signals have been identified as the most useful physiological signals for detecting stress in real-life, ambulatory settings [7]. EDA is one of the most direct methods for measuring the activation of the sympathetic nervous system induced by physical demands and mental stress. EDA measures the variation in the electrical conductance of the skin in response to sweat gland activity. The sympathetic nervous system controls sweat gland activity. If the sympathetic branch of the autonomic nervous system (ANS) is activated by physical demands or mental stress, the number of active sweat gland activity increases, which, in turn, increases skin conductance. Thus, higher levels of EDA are associated with increased levels of stress [8].

HRV refers to the variability of the time interval between consecutive heartbeats in individuals and can be computed from BVP signal readings. Previous research has established HRV as an objective measure of individual differences in emotional responses. In particular, HRV provides information about the flexibility of the ANS, the ease with which an individual can transition between high and low arousal states [9]. In general, higher HRV (or greater variability between the heartbeats) can mean that either the body has a strong ability to tolerate a current state of heightened stress or the body is recovering from previous accumulated stress. At rest, a higher HRV generally indicates a healthier state that shows greater resilience and flexibility in the ANS. In active states, relatively lower HRV might demonstrate better health conditions in individuals, as the heart adjusts to the increased demand [10].

To date, most research studies that have used physiological signals to detect stress have been conducted in controlled laboratory settings [7,11]. This research has demonstrated that multiple physiological signals and derived features can accurately detect induced stress using a variety of stimuli, such as Stroop color tests, mental arithmetic, or public speaking challenges [4]. One advantage of stress detection in these controlled environments is that most often, the *ground truth* of the condition is known (ie, stressed vs not stressed). However, induced stress in artificial laboratory settings may lack external assessment and thus may not represent the stress experienced by individuals in their daily lives [12]. As a result, recent efforts have used wearable sensors to provide continuous, ambulatory monitoring of stress in uncontrolled, real-world settings [7,11]. However, the potential of this nascent research is characterized by a number of challenges that limit its application. Among these gaps, most research has focused on the ambulatory assessment of stress among healthy adults; very little research has been conducted among clinical populations, such as adults diagnosed with alcohol use disorder (AUD). Furthermore, although previous research suggests that including additional information about the context of a stressful event can improve stress detection in ambulatory settings, this is not commonly achieved.

Objectives

To address these gaps, this study used a multimodal approach to investigate the associations between 2 physiological signals (EDA and HRV) and self-reported outcomes, including alcohol use, heightened stress, positive and negative emotions, alcohol-related cravings, pain, and discomfort, among adults seeking treatment for AUD during a 2-week uncontrolled data collection. Specifically, the aims of this study are 3-fold: (1) to assess the quality of the physiological signals collected from an unobtrusive wearable sensor device, (2) to examine the associations between EDA and self-reported outcomes, and (3) to examine the associations between HRV and self-reported outcomes.

Methods

Participants and Procedures

A convenience sample of 11 participants (10 females) was recruited from adults seeking care at a mental health facility in a Western state in the United States. Potential participants were identified from 2 points in the consort flow of a larger study examining the effectiveness of contingency management treatment among adults with co-occurring serious mental illness and moderate to severe AUD. First, we recruited participants among those who did not meet the primary inclusion criteria of the larger study: Diagnostic and Statistical Manual of Mental

Disorders, fifth edition (DSM-5) diagnosis of a serious mental illness or DSM-5 diagnosis of moderate to severe AUD. Participants were also identified from among those who did not meet the secondary eligibility criteria, after an induction phase and before randomization to the contingency management conditions. These individuals either failed to achieve an average urine ethyl glucuronide level that indicated recent heavy drinking (>349 ng/mL) or failed to attend at least one study visit during the last week of the 4-week induction phase.

Participants in this study met the following inclusion criteria: (1) aged 18-65 years and (2) self-reported consumption of 4 or more standard drinks on 5 or more occasions in the past 60 days. Participants were also required to own a smartphone with a data plan that allowed them to respond to the ecological momentary assessment (EMA) survey (described in the following section). Exclusion criteria included (1) current DSM-5 diagnosis of a severe drug use disorder, (2) inability to demonstrate competency to provide consent on the MacArthur Competence Assessment Tool for Clinical Research, (3) risk of medically dangerous alcohol withdrawal (ie, seizure within the last 12 months and concern by participant or clinician regarding a potentially dangerous withdrawal), (4) previous diagnosis of dementia, and (5) determination (by the principal investigator of the larger study) that participation would be medically or psychiatrically unsafe.

Data Collection

This study included 3 components: (1) a daily diary study using EMAs of self-reported emotions, cravings, and stress via a web-based survey, prompted 4 times daily; (2) a wearable sensor device (Empatica E4 wristband) that captured continuous physiological markers of stress, including heart rate (HR), skin temperature, bodily movement, HRV, and skin conductance; and (3) structured qualitative interviews to assess daily alcohol use, using a timeline follow-back calendar, and to validate self-reported and physiological markers of stress.

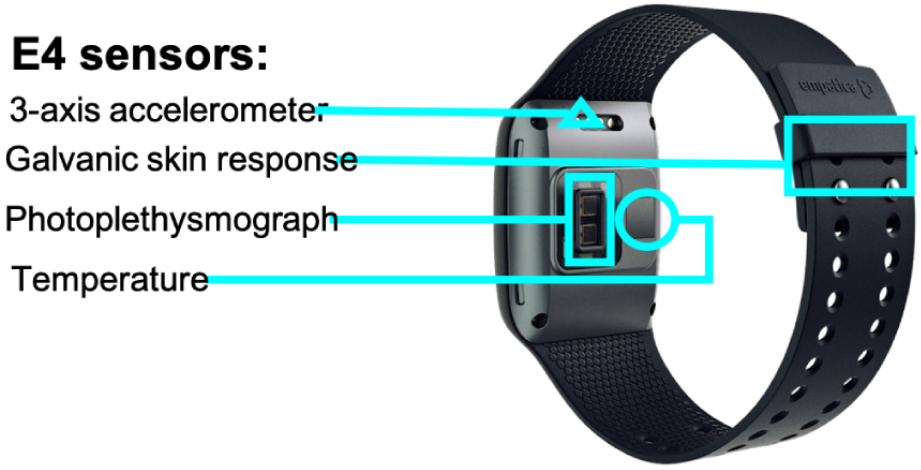
Measures

Continuous Monitoring of Physiological Stress

Each participant was asked to wear an Empatica E4 wristband to record continuous, real-time physiological measures of stress in their daily lives (Figure 1). The noninvasive E4 wristband is a wearable physiological sensor device that provides high-quality data that indicate arousal of the ANS (ie, stress). The E4 contains 4 sensors: (1) photoplethysmography to provide BVP, from which HR, HRV, interbeat interval (IBI), and other cardiovascular features may be derived; (2) EDA, used to measure sympathetic nervous system arousal and to derive features related to stress, engagement, and excitement; (3) a 3-axis accelerometer to capture motion-based activity; and (4) an infrared thermopile, used to measure skin temperature. Physiological data from these sensors were stored in the onboard memory of the E4 and downloaded by the research staff at each follow-up visit. The E4 weighs 40 g (1.41 oz) and is worn like a wristwatch, and all the sensors are embedded in the device. The E4 also includes a push-button interface that allows for data annotation. Previous research has assessed the validity of physiological signals recorded by an Empatica E4 device, such as EDA, HRV, and IBI, against the standard clinical ground truth [13,14]. Moreover, previous studies indicate that E4 is among the most commonly used physiological sensor devices in scientific research and validate its usefulness in detecting atrial fibrillation [15] and emotional arousal and stress [16,17].

The study staff provided instructions about proper handling and wear of the E4 wristband during a scheduled meeting after the individuals agreed to participate in the study. For example, participants were instructed to remove the wristband each night while sleeping and at other times during which the device may be damaged (eg, in the shower or bath) and to wear the device on the same wrist throughout the study. The training session also included instructions on how to use the *stress event marker button* on the E4 wristband. Participants were asked to press this button any time they felt *more stressed, overwhelmed, or anxious than usual*. These tag markers were summed for each participant to provide a daily tally of the number of perceived stress events.

Figure 1. Empatica E4 sensor.



EMA-Based Survey

Data collection for the EMA component was performed using a mobile phone–based survey. The survey assessed the perceptions of positive and negative emotions, alcohol-related cravings, and experiences of pain and discomfort. Participants responded to 4 timed signals throughout the day that corresponded to early morning (waking), noon, late afternoon, and bedtime for up to 14 consecutive days.

The measurement of *alcohol-related cravings* was derived from previous research [18,19] and included 3 items: (1) "[since last assessment], the idea of using alcohol has intruded upon my thoughts;" (2) "[since last assessment], I have missed the feeling alcohol can give me;" and (3) "[since last assessment], I have thought about how satisfying alcohol can be." Response options included a 5-point scale, ranging from 1 (strongly disagree) to 5 (strongly agree). An aggregate measure of alcohol-related cravings was created by averaging the 3 items in each of the 4 assessments. An average daily alcohol-related craving score was then created for each participant for each day of the study.

Positive and negative emotions were assessed using items drawn from the extended version of the Positive and Negative Affect Scale (PANAS) [20]. Negative affect was assessed by asking, "[Since last assessment], have you felt [irritable/lonely/sad/guilty/ashamed/anxious/stressed]?" Similarly, participants reported their positive affect using the following terms: warmhearted, enthusiastic, affectionate, relaxed, calm, happy, joyful, and loving. Responses for each item were assessed on a 5-point scale, ranging from 1 (not at all) to 5 (extremely). Aggregate measures of daily negative and positive affect were created by first averaging across the respective items in each of the 4 assessments. Next, average positive and negative emotion scores were created for each participant on each day of the study.

Measurement of *pain and discomfort* was assessed with 2 items: (1) "[since last assessment], have you felt any physical discomfort?" and (2) "[since last assessment], have you felt any physical pain?" Five response options included 1=nonexistent, 2=slight, 3=moderate, 4=intense, and 5=unbearable. Average pain and discomfort scores were created for each participant on each day of the study.

Qualitative Debriefing Interview

Throughout the study, participants attended up to 6 short follow-up sessions to meet with study staff on an every-other-day basis (eg, Monday, Wednesday, and Friday). During the follow-up sessions, the study staff ascertained whether the participants were experiencing any problems or difficulties with either the wearable wristband device or completing the EMA surveys on their cell phones. The follow-up sessions also included administration of a timeline follow-back measure of recent alcohol use [21]. In this procedure, participants were first presented with a chart of the US Standard Drink definition and then asked to indicate the number of drinks consumed on each calendar day since the previous assessment. At each follow-up visit, participants exchanged their current E4 wristband device for a fully charged device with available onboard memory for new data collection.

Statistical Analysis

Overview

We conducted a series of statistical analyses in 4 steps. First, we assessed the quality of the physiological signals, EDA and BVP. As described in the following sections, we used the recommended tools and procedures of the Empatica 4 guidelines to remove artifacts and extract features of the EDA and BVP signals for use in further analyses. Empatica E4 assesses the HR and IBI from the BVP signal using a proprietary algorithm [22]. Second, we examined descriptive statistics, including interitem correlations among patient-reported outcomes, aggregated at the day level. In the final 2 steps, we investigated the associations of the EDA signal (step 3) and the HRV signal (step 4) with the day-level self-reported outcomes.

EDA Quality Assessment

Physiological signals such as EDA are prone to noise and artifacts, especially when acquired in uncontrolled real-life scenarios. Therefore, we preprocessed the EDA signal to remove the most common artifacts, including environmental, sensor motion, and muscle movement artifacts. We used EDA Explorer public scripts to perform automatic artifact and noise detection [23]. During the process, a high-pass filter was first applied to smooth the raw EDA signals and remove low-frequency noise. Then, a multiclass classifier labeled the signal as clean, noisy, or questionable. The accelerometer and temperature data as well as the EDA were used in this process. Further analyses were performed using only the clean parts of the signal.

Trough-to-peak (TTP) and continuous decomposition analysis (CDA) are 2 commonly used analyses to assess the quality of EDA signals. We performed these analyses using the LedaLab toolbox (MATLAB program [MathWorks] suggested by the Empatica Manual for signal processing). In the TTP analysis, we set the sample rate to 1 Hz and the minimum amplitude threshold to 0.01 μS. In the CDA analysis, the EDA signal was decomposed into phasic and tonic components to increase the temporal precision. LedaLab provides information on the number of skin conductance responses (SCRs) and the SCR onset for each TTP and CDA analysis of the EDA signal. We downsampled the data from 4 Hz to 1 Hz and then computed the average SCRs per minute for all 11 participants to compare the results of the CDA and TTP analysis with previous research by plotting the frequency of the SCRs per minute [24].

The next step was to extract the features that captured the patterns in the EDA signal. The EDA peak detection analysis provides a set of features corresponding to each EDA peak. We used EDA Explorer public scripts to detect the EDA peaks [23]. Previous studies have shown that peaks from EDA signals correlate with emotional arousal in humans. As shown in Figure 2, the values at apex, rise time, decay time, amplitude, and SCR width are standard features that can be extracted from the peaks of the EDA signal. Table 1 lists the features extracted from the EDA peaks.

Figure 2. An example of an electrodermal activity peak. EDA: electrodermal activity; SCR: skin conductance response.

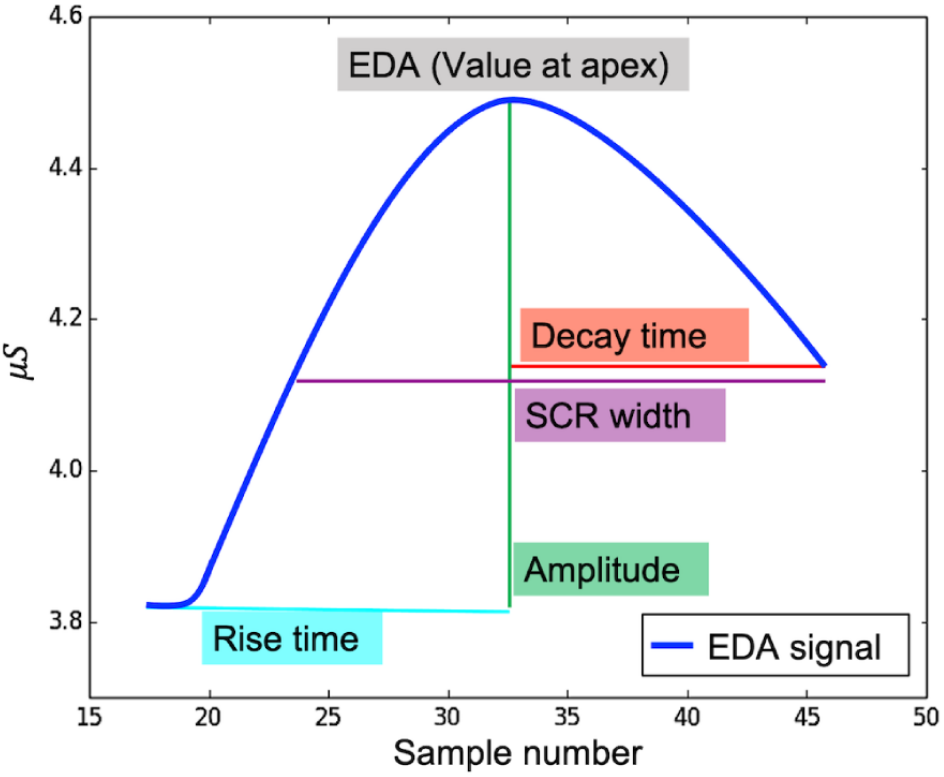


Table 1. Description of the features that are extracted from the electrodermal activity peaks.

Feature	Description
EDA[a]	The EDA value at apex of the peak
Rise time	Time (microseconds) taken by the EDA peak to reach its maximum value
Maximum derivative	The maximum
Amplitude	The amplitude
Decay time	Time (microseconds) taken by the signal to drop from the apex to the minimum of the peak
Skin conductance response width	The width of the peak (number of the samples)
AUC[b]	2D area under the EDA peak curve

[a]EDA: electrodermal activity.

[b]AUC: area under the curve.

HR Quality Assessment

Measuring HR is a routine part of a clinical examination. The resting HR (RHR) of individuals reflects their overall health. We measured the RHR of the participant using IBI derived from the photoplethysmography sensor to identify any irregularities in the HR data. We note that the IBI data for this study were provided by Empatica and represent the time in milliseconds between two successive heartbeats (the R-R interval). This proprietary algorithm [22] removed incorrect peaks because of noise and artifacts in the BVP signal. Using the IBI sequence provided by Empatica, we extracted statistical features from the HR, including the mean value of the HR (MHR), minimum value of the HR (MNHR), maximum value of the HR (MXHR), and SD of the HR signal during the study.

Time domain analysis and frequency domain analysis are 2 standard methods for investigating HRV. In the time domain analysis, HRV measures were directly extracted from the IBI or RR interval signals. Frequency domain analysis extracts HRV measures from the power spectrum of the Fourier transform of the RR interval signals. In this study, we focus on the time domain HRV measures, including the mean of the RR interval (MRR), the SD of the RR interval (STDRR), the root mean square successive differences of the RR intervals (RMSSDs), and the coefficient of variance of the RR intervals (CVRR) [25,26].

Results

Demographics

The mean age of the participants was 40.27 years (SD 3.66; range 27-60 years). The majority of the sample was White, non-Hispanic (n=9). One participant identified as White, Hispanic, and one participant identified as American Indian or Alaskan Native. Of the 11 participants, 10 (91%) identified as female, and 1 (9%) participant identified as male.

Data Set Quality Assessment

Previous research suggests that the collected physiological signals must maintain a number of quality measures to be considered valid for data analysis. For this research, we examined the quality of the collected data across several dimensions, including (1) the number of clean signals after artifact removal, (2) the distribution of the SCR values, using TTP and CDA analyses, and (3) the distribution of the HRV values. On the basis of the results of artifact detection, out of 1,174,898 EDA signal measurements, 1,032,265 (87.86%), 108,208 (9.21%), and 34,424 (2.93%) collected in total from all the participants were clean, noisy, and questionable, respectively. In both the TTP and CDA analyses, the EDA data were downsampled to a sampling rate of 1 Hz, and a minimum amplitude threshold of 0.01 μS was considered.

As expected, in both analyses, the SCRs per minute were positively skewed with most SCR values near or at 0.0 per minute. The results from the TTP analysis show a peak at 0 SCRs per minute, with a continuous decrease of up to 17.5 SCRs per minute. The results from the CDA analysis show a peak at 0 SCRs per minute, followed by a sharp decline at 1 SCRs per minute and later by a small increase from 15.0 to 17.5 SCRs. Thus, our data demonstrated results similar to those of a previous study that used the same analyses on 8 participants to assess the quality of EDA and HRV data collected with the E4 [24].

Table 2 reports the distribution of the HR averaged across low, normal, and high ranges separately for each participant. All the participants except participant 11 experienced similar distribution of HR during the data collection period. Among these 10 participants, 1.11% (59,982/5,399,250) of the study data were in the low range of 40-59 beats per minute (bpm), 82.76% (4,468,337/5,399,250) were in the normal range of 60-100 bpm, and 16.01% (4,468,337/5,399,250) were in the high range, above 100 bpm. However, for participant 11, only 44.87% (310,876/692,901) of the experienced HRs were in the normal range of 60-100 bpm, whereas more than half (379,119/692,901, 54.71%) of the HRs were in the high range of 101-200 bpm. On the basis of these results, we conclude that all the participants except participant 11 demonstrated normal HR distribution.

Table 3 reports the means and SDs for the HR features, including mean value the heart rate (MHR), MXHR, MNHR, and SD of the heart rate (STDHR) signal of the participants during the data collection. Likewise, Table 4 shows means and SDs for the heart variability measures for each participant during the entire data collection period.

Table 2. Total numbers and percentages of participants' heart rate (bpm) across low, normal, and high ranges during the study period.

Subject	Total, N	Low (40–59 bpm[a]), n (%)	Normal (60-100 bpm), n (%)	High (101-200 bpm), n (%)
Participant 1	402,257	3626 (0.91)	290,316 (72.17)	108,267 (26.91)
Participant 2	715,794	9599 (1.34)	605,916 (84.65)	100,146 (13.99)
Participant 3	473,283	2601 (0.55)	386,090 (81.58)	84,554 (17.87)
Participant 4	606,614	15,592 (2.57)	533,903 (88.01)	50,999 (8.41)
Participant 5	738,475	953 (0.13)	555,673 (75.25)	181,685 (24.6)
Participant 6	650,860	14,739 (2.26)	551,797 (84.78)	84,276 (12.95)
Participant 7	340,036	399 (0.12)	263,814 (77.58)	75,801 (22.29)
Participant 8	388,833	6394 (1.64)	340,905 (87.67)	41,496 (10.67)
Participant 9	535,352	3592 (0.67)	467,507 (87.33)	64,213 (11.99)
Participant 10	547,746	2487 (0.45)	472,416 (86.25)	72,789 (13.29)
Participant 11	692,901	2164 (0.31)	310,876 (44.87)	379,119 (54.71)

[a]bpm: beats per minute.

Table 3. Means and SDs for the statistical features extracted from the heart rate signal.

Subject	Mean value of the heart rate, mean (SD)	Minimum value of the heart rate, mean (SD)	Maximum value of the heart rate, mean (SD)	SD of the heart rate, mean (SD)
Participant 1	104.72 (9.81)	51.17 (19.27)	167.32 (17.9)	10.21 (1.74)
Participant 2	87.05 (6.15)	45.08 (5.01)	186.11 (14.61)	12.1 (2.86)
Participant 3	88.83 (5.29)	51.26 (6.18)	182.97 (14.71)	11.28 (3.15)
Participant 4	71.27 (6.15)	35.64 (6.15)	159.71 (27.55)	9.21 (2.90)
Participant 5	86.3 (8.03)	45.92 (11.18)	171.66 (21.96)	9.85 (2.27)
Participant 6	74.11 (7.88)	37.40 (4.73)	185.45 (12.29)	14.97 (3.94)
Participant 7	91.07 (7.84)	45.48 (5.06)	168.99 (19.72)	11.72 (2.91)
Participant 8	78.54 (9.48)	38.53 (4.52)	180.56 (12.34)	10.37 (2.23)
Participant 9	79.04 (6.88)	48.22 (4.28)	169.47 (30.22)	9.87 (1.54)
Participant 10	84.79 (3.38)	42.88 (5.47)	166.88 (13.08)	12.54 (0.98)
Participant 11	95.19 (8.14)	44.29 (9.58)	180.7 (29.88)	22.53 (8.45)

Table 4. Means and SDs for the statistical features extracted from the heart rate variability measures.

Subject	Mean value of all of the RR intervals, mean (SD)	SD of the RR interval, mean (SD)	Root mean square, mean (SD)	Covariance of SD, mean (SD)	Covariance of all the RR intervals, mean (SD)
Participant 1	0.58 (0.05)	0.06 (0.01)	0.06 (0.01)	0.11 (0.02)	0.10 (0.02)
Participant 2	0.70 (0.05)	0.00 (0.02)	0.07 (0.02)	0.10 (0.02)	0.13 (0.02)
Participant 3	0.69 (0.04)	0.08 (0.02)	0.07 (0.02)	0.11 (0.03)	0.12 (0.02)
Participant 4	0.86 (0.07)	0.10 (0.01)	0.07 (0.01)	0.08 (0.02)	0.12 (0.03)
Participant 5	0.71 (0.06)	0.08 (0.01)	0.07 (0.01)	0.10 (0.03)	0.11 (0.02)
Participant 6	0.84 (0.08)	0.13 (0.03)	0.11 (0.02)	0.13 (0.03)	0.15 (0.05)
Participant 7	0.68 (0.06)	0.09 (0.02)	0.07 (0.02)	0.10 (0.03)	0.13 (0.03)
Participant 8	0.78 (0.10)	0.10 (0.02)	0.09 (0.02)	0.11 (0.01)	0.12 (0.03)
Participant 9	0.78 (0.08)	0.09 (0.01)	0.07 (0.01)	0.09 (0.02)	0.12 (0.01)
Participant 10	0.72 (0.03)	0.10 (0.01)	0.09 (0.01)	0.13 (0.02)	0.14 (0.01)
Participant 11	0.68 (0.05)	0.13 (0.01)	0.09 (0.01)	0.13 (0.02)	0.19 (0.06)

Self-reported Outcomes: Descriptive Statistics and Bivariate Correlations

Table 5 reports the descriptive statistics for the self-reported outcomes, computed at the daily level, including mean, SD, median, minimum and maximum, and 1st and 3rd quartiles. Overall, the participants reported a mean of 3 stressful events each day (SD 2.9), with a range of 0-17 stressful moments per day. Participants reported consuming between 0 and 18 servings of alcohol daily, with a mean of 2.8 servings per day (SD 5.2). Mean values for self-reported alcohol cravings, positive and negative emotions, and pain and discomfort ranged from 2.2-2.9, with values ranging between 1 and 5.

Table 5. Descriptive statistics of the self-reported outcomes.

Self-reported outcomes	Mean (SD)	Median	Minimum	Maximum	1st quartile	3rd quartile
Stress events	3 (2.9)	2	0	17	1	3.5
Alcohol use	2.8 (5.2)	0.0	0.0	18.0	0.0	3.0
Alcohol cravings	2.9 (0.9)	3.0	1.0	4.8	2.3	3.5
Positive emotion	2.5 (0.6)	2.5	1.3	3.9	2.1	2.9
Negative emotion	2.3 (0.8)	2.5	1.0	2.9	1.5	2.9
Discomfort	2.3 (1.0)	2.3	1.0	5.0	1.0	3.0
Pain	2.2 (1.1)	2.5	1.0	5.0	1.0	3.0

Table 6 shows the results of the correlation analysis of the self-reported outcome variables. The intersection of a pair of outcomes on the left side of the diagonal displays the correlation coefficient, indicating the strength of the relationship between them. As seen in Table 6, the number of stress events was significantly and positively associated with self-reported negative mood (r=0.21; P=.002) and pain (r=0.18; P=.006). Self-reported alcohol use was significantly and positively correlated with self-reported cravings (r=0.46; P<.001) and negatively correlated with self-reported negative mood, discomfort, and pain, with coefficient correlation values of −0.38, −0.44, and −0.45, respectively (all P values <.001). Self-reported alcohol-related cravings were also negatively correlated with days characterized by pain (r=−0.20; P=.005) and discomfort (r=−0.25; P=.007). Participant self-reports of discomfort and pain were significantly and positively correlated (r=0.93; P<.001). Each of these 2 measures was also significantly and positively correlated with participant self-reports of negative mood, with coefficient correlation values of 0.49 and 0.48 (both P values <.001)

Table 6. Bivariate correlation coefficient values of the self-reported outcomes.

Self-reported outcomes.	Stress events	Alcohol use	Alcohol cravings	Positive emotion	Negative emotion	Discomfort	Pain
Stress events	__[a]	—	—	—	—	—	—
Alcohol use	−0.11	—	—	—	—	—	—
Alcohol cravings	−0.001	0.46	—	—	—	—	—
Positive emotion	0.07	0.001	−0.16	—	—	—	—
Negative emotion	0.21	−0.38	0.02	−0.15	—	—	—
Discomfort	0.04	−0.44	−0.20	−0.02	0.49	—	—
Pain	0.18	−0.45	−0.25	−0.05	0.48	0.93	—

[a]Not applicable.

Correlations Among EDA and Patient-Reported Outcomes

Table 7 shows the Spearman correlation coefficients between the EDA features and the daily aggregated self-reported outcomes. As seen in the table, the number of stress events was positively associated with the amplitude (r=0.26; P=.005) and counts (r=0.27; P=.003) of the EDA peaks. In contrast, the number of stress events was negatively correlated with the decay time (r=−0.20; P=.03), SCR width (r=−0.34; P<.001), and area under the curve (r=−0.32; P<.001) of the EDA peaks. These results suggest that participants experienced more and higher peaks in the EDA signal on days characterized by more stress and that the peaks in the EDA signal tended to drop more rapidly—and were narrower—during more stressful days. Among the other self-reported outcomes, the number of alcohol drinks was positively associated with the decay time of the EDA peaks (r=0.18; P=.08). Daily averages of positive mood were positively associated with EDA rise time (r=0.23; P=.02), amplitude (r=0.20; P=.06), and decay time (r=0.17; P=.09). Rise time (r=0.28; P=.005) and amplitude (r=0.41; P<.001) were also positively associated with aggregate levels of self-reported negative mood. In contrast, the decay time of the EDA signal was negatively correlated with the daily levels of discomfort (r=−0.18; P=.08) and pain (r=−0.22; P=.03).

Table 7. Spearman correlation coefficients between the daily electrodermal activity features and the daily self-reported outcomes.

Feature	Self-reported outcome						
	Stress	Alcohol	Cravings	Positive emotion	Negative emotion	Discomfort	Pain
Electrodermal activity	−0.09	−0.03	0.01	−0.14	0.17	−0.06	−0.07
Rise time	0.11	−0.06	0.10	0.23[a]	0.28[b]	−0.12	−0.12
Maximum derivative	0.04	0.01	0.16	0.09	0.11	−0.07	−0.07
Amplitude	0.26[b]	−0.02	0.16	0.20[c]	0.41[d]	0.01	0.01
Decay time	−0.20[a]	0.18[c]	0.12	0.17[c]	−0.10	−0.18[c]	−0.22[a]
Skin conductance response width	−0.34[d]	0.06	0.15	−0.01	0.02	−0.12	−0.14
Area under the curve	−0.32[d]	0.04	0.17	0.01	0.05	−0.07	−0.08
Counts	0.27[b]	0.05	0.09	0.09	0.09	0.10	0.10

[a]Significance code .05.

[b]Significance code .01.

[c]Significance code .10.

[d]Significance code .001.

Correlations Among HRV and Self-reported Outcomes

Table 8 displays the Spearman correlation coefficients for the associations between HRV measures and self-reported outcomes. With the exception of the RMSSD and covariance of SD (CVSD), all the HRV features were positively associated with the number of stress reported at the daily level: MRR (r=0.22; P=.02), STDRR (r=0.22; P=.02), CVRR (r=0.27; P=.004), MHR (r=0.28; P=.002), and STDHR (r=0.21; P=.02). Similarly, almost all the HRV features were positively correlated with aggregate levels of self-reported positive mood: MRR (r=0.26, P=.01), STDRR (r=0.21; P=.04), RMSSD (r=0.26; P=.01), CVSD (r=0.24; P=.02), CVRR (r=0.20, P=.049), and MHR (r=0.26; P=.009). All but one of the HRV features was positively correlated with aggregate levels of self-reported negative mood: MRR (r=0.18; P=.08), STDRR (r=0.22; P=.03), CVSD (r=0.22; P=.03), CVRR (r=0.29; P=.005), MHR (r=0.33; P=.001), and STDHR (r=0.32; P=.002). The MRR was negatively associated with aggregated levels of self-reported discomfort (r=−0.21; P=.04) and pain (r=−0.18; P=.08). The MHR was also negatively associated with aggregated levels of self-reported discomfort (r=−0.22; P=.003) and pain (r=−0.20; P=.05). No significant associations were found between HRV features and self-reported alcohol use or alcohol-related cravings.

Table 8. Spearman correlation coefficients between the daily heart rate variability measures and the daily self-reported outcomes.

Feature	Self-reported outcome						
	Stress	Alcohol	Cravings	Positive	Negative	Discomfort	Pain
Mean value of all the RR intervals	0.22[a]	−0.07	0.00	0.26[a]	0.18[b]	−0.21[a]	−0.18[b]
SD of the RR interval	0.22[a]	−0.07	0.04	0.21[a]	0.22[a]	−0.06	−0.06
Root mean squared SD	0.08	−0.04	0.02	0.26[a]	0.15	−0.10	−0.12
Covariance of SD	0.12	0.00	0.05	0.24[a]	0.22[a]	−0.10	−0.13
Covariance of all the RR intervals	0.27[c]	−0.05	0.04	0.20[a]	0.29[c]	−0.08	−0.08
Mean value of heart rate	0.28[c]	0.01	0.03	0.26[c]	0.33[d]	−0.22[a]	−0.20[b]
SD of the heart rate	0.21[a]	−0.02	0.04	0.14	0.32[c]	−0.07	−0.07

[a]Significance code .05.

[b]Significance code .10.

[c]Significance code .01.

[d]Significance code .001.

Discussion

Principal Findings

The overall goal of this study is to examine the feasibility of using 2 physiological markers of stress, EDA and HRV, obtained from an unobtrusive wristband device in an ambulatory setting, as a first step toward developing mobile health (mHealth) interventions to help prevent alcohol relapse. To achieve this goal, we first assessed the quality of the continuous monitoring of physiological signals using an Empatica E4 wearable sensor device. We determined that 87.88% (1,032,265/1,174,898) of the EDA signals were clean, whereas only 9.21% (108,208/1,174,898) of the EDA signals could be considered noise. A comparison of the distribution of the EDA SCRs also demonstrated high correspondence between our study and previous studies that used similar techniques [24]. We also noted that the distribution of HR signals for 10 of the 11 participants was within a typical distribution. On the basis of these results, we can conclude that physiological data met the established quality criteria.

In the next steps, we examined associations between features of the EDA and HRV signals with a number of self-reported outcomes, including daily tallies of stress events and alcoholic drinks as well as aggregated levels of alcohol-related cravings, positive and negative moods, and experiences of pain and discomfort. In total, 2 features of the EDA signal (amplitude and peak counts) were positively associated with the number of stress events reported each day, whereas 3 features (decay time, SCR width, and area under the curve) were negatively associated with daily tallies of stress events. These results were as expected and suggest that participants experienced more and higher EDA peaks on days of heightened stress and that the EDA signal varied more rapidly during more stressful intervals. The results also showed that some (but not all) EDA features were positively associated with self-reported positive and negative emotions. In general, EDA features were not significantly correlated with the daily use of alcohol or alcohol-related cravings or with experiences of pain or discomfort.

However, almost all HRV features were significantly and positively associated with daily tallies of stress events. These results were as expected and indicated that participants experienced greater HRV on days characterized by higher levels of stress. Nearly all HRV features were also significantly and positively associated with the aggregate levels of positive and negative emotions. Thus, the results suggest an increased recovery ability of the participants in stressful situations or when feeling excessive positive or negative moods. Similar to the findings for the EDA features, HRV features were generally not significantly associated with daily use of alcohol or alcohol-related cravings or experiences of pain or discomfort.

Limitations

This study was designed to establish the feasibility of assessing physiological data in an ambulatory setting to inform the development of a future mHealth intervention. Thus, the major limitation of this pilot study is the small sample size, which limited our ability to test hypotheses regarding associations between physiological signals and self-reported outcomes with full statistical power. Future studies that include larger and more representative samples are needed to replicate our findings. We also note that our analyses did not account for demographic characteristics of the participants, such as age, personality characteristics, race, or gender. Future work that examines how these and other demographic characteristics might play a role in these processes is needed.

We further acknowledge that although the uncontrolled nature of the data collection in ambulatory settings was a strength of this study, this may have introduced some subjective bias into the assessment of stress events. Future research in ambulatory settings should also consider how HRV is affected by sleep and circadian processes [27] as well as by exercise or simple ambulatory activities [28] such as walking, which our analyses did not take into account. Finally, one reason for the lack of strong associations among the physiological signals and some of the self-reported outcomes may be attributed to the single-level correlation analyses used in this study. This approach did not take into account the nested nature of the data: 4 prompts each day, nested within multiple days, and nested within 11 participants. More sophisticated multilevel modeling of these associations that takes such clustering into account might provide additional insights about within-person associations as well as between-person differences in these effects.

Conclusions

We investigated the associations of physiological signals, EDA and HRV, with self-reported outcomes among adults diagnosed with AUD in a 14-day uncontrolled data collection. The results demonstrated that the physiological data collected via an Empatica E4 wearable sensor device were useful and that features of these physiological signals were significantly associated with several self-reported outcomes, including identification of stress events, daily use of alcohol, negative and positive emotions, and pain and discomfort. Future research is needed to further validate these findings to develop tailored mHealth interventions to enhance sustained recovery from AUD.

Acknowledgments

This project was funded by the Alcohol and Drug Research Program of Washington State University through grant funding to MJC. This investigation was supported in part by funds provided for medical and biological research by the State of Washington Initiative Measure (number 171).

Authors' Contributions

MJC and HG conceived and designed the study. MJC and SP acquired the data. PA and RKS analyzed and interpreted the data. PA and MJC prepared the manuscript. MM, SP, and PP contributed to project administration and reviewing and editing the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

ANS: autonomic nervous system
AUD: alcohol use disorder
BPM: beats per minute
BVP: blood volume pulse
CDA: continuous decomposition analysis
CVRR: coefficient of variance of the RR intervals

CVSD: covariance of SD
EDA: electrodermal activity
EMA: ecological momentary assessment
HR: heart rate
HRV: heart rate variability
IBI: interbeat interval
mHealth: mobile health
MHR: mean value of the heart rate
MNHR: minimum value of the heart rate
MRR: mean of the RR interval
MXHR: maximum value of the heart rate
PANAS: Positive and Negative Affect Scale
RMSSD: root mean square successive differences of the RR interval
SCR: skin conductance response
STDRR: SD of the RR interval
TTP: trough-to-peak

Edited by G Eysenbach; submitted 11.02.21; peer-reviewed by E Vanegas, M Altini; comments to author 09.03.21; revised version received 06.05.21; accepted 31.05.21; published 21.07.21.

Please cite as:
Alinia P, Sah RK, McDonell M, Pendry P, Parent S, Ghasemzadeh H, Cleveland MJ
Associations Between Physiological Signals Captured Using Wearable Sensors and Self-reported Outcomes Among Adults in Alcohol Use Disorder Recovery: Development and Usability Study
JMIR Form Res 2021;5(7):e27891
URL: https://formative.jmir.org/2021/7/e27891
doi:10.2196/27891
PMID:34287205

Original Paper

Health Care Professionals' Experiences With the Use of Video Consultation: Qualitative Study

Nina Primholdt Christensen[1], RN, MSc; Karen Emilie Skou[2], MSc; Dorthe Boe Danbjørg[3], RN, PhD

[1]Hematological Research Unit, Odense University Hospital, Odense C, Denmark

[2]Department of Hematology, Aarhus University, Aarhus N, Denmark

[3]Centre for Innovative Medical Technology, Department of Hematology, Odense University Hospital, University of Southern Denmark, Odense C, Denmark

Corresponding Author:
Nina Primholdt Christensen, RN, MSc
Hematological Research Unit
Odense University Hospital
Kløvervænget 10, 12 Floor
Odense C, 5000
Denmark
Phone: 45 24643617
Email: nins49@hotmail.com

Abstract

Background: The number of remote video consultations between doctors and patients has increased during the last few years and especially during the COVID-19 pandemic. The health care service is faced with rising rates of chronic illness and many patients who are more confident in self-management of their illnesses. In addition, there is an improved long-term outlook for serious conditions, such as cancer, that might require flexibility in everyday life.

Objective: This study aimed to investigate how medical doctors in the outpatient clinic use and experience the use of video consultations with hematological patients, with a focus on relational and organizational aspects.

Methods: The study was designed as an explorative and qualitative study. Data were collected via participant observations and focus group interviews with medical doctors.

Results: The study identified possibilities and barriers in relation to adapting to the alternative way of meeting patients in the clinical setting. One of the main findings in this study is that the medical doctors were afraid that they missed important observations, as they were not able to perform a physical examination, if needed. They also emphasized that handshake and eye contact were important in order to get an overall impression of the patient's situation. It also became clear that the medical doctors used body language a lot more during video consultation compared with consultation in a physical setting. The medical doctors found the contact with the patients via the screen to be good, and the fact that the technology was working well made them feel comfortable with the video consultation.

Conclusions: In this study, we found that the medical doctors were able to maintain good contact with the patients despite the screen and were able to assess the patients in a satisfying manner. However, there were still uncertainties among some doctors about the fact that they could not examine the patients physically. New knowledge about how to use gestures and body language during video consultation was obtained.

(JMIR Form Res 2021;5(7):e27094) doi:10.2196/27094

KEYWORDS

video consultation; hematology; outpatient clinic; telehealth; doctor's perspective

Introduction

Background

The number of remote video consultations between doctors and patients has increased during the last couple of years and especially during the COVID-19 pandemic [1,2]. Telemedicine is an important tool in health care when physical contact needs to be avoided. Politicians see technology-supported health care, such as the use of apps and video consultations, as a solution to the complex problems of demographic development. Delivering health care to an aging and diverse population is a

challenge due to the increase of the aging population and the diminishing number of health care professionals [3].

The health care service is faced by not only rising rates of chronic illness, but also many patients who are more confident in self-management of their illness. In addition, there is an improved long-term outlook for serious conditions, such as cancer, that might require flexibility in everyday life [4]. At the same time, there has been focus on centralizing the health care system, in order to attain the most efficient and specialized hospitals in Denmark [5]. This development means, among other things, that patients often must travel further to get to the hospital. Hematological patients in Denmark may spend several hours traveling to the hospital for a consultation [6]. It is therefore relevant to implement telemedicine solutions for patients to spend less time travelling back and forth to visit the hospital. Patients welcome telemedicine initiatives, and a Danish study identified that patients valued the freedom they got when being able to keep up a normal everyday life, take responsibility for their own course of treatment, and feel active, despite their illness [7]. These findings reflect the overall research within telemedicine, where the use of telemedicine has shown positive aspects [4,7-10].

The pandemic has resulted in the natural use of telemedicine [11]. Telemedicine has the potential to deliver health care at a distance, with the potential to improve access to health care and change the way health care is organized. However, the implementation and use of telemedicine can often lead to resistance among health care professionals, as they see it as a threat to their clinical work and professionalism. Many health care professionals still prefer face-to-face communication when interacting with patients and their relatives. A systematic review showed that the difficulties in implementation are linked to the culture among health care professionals. Resistance to change in working procedures and unwillingness to invest time in training for new workflows were significant barriers [12,13]. According to Ross et al, possible difficulties should be identified early in the process when planning implementation of new routines. This will allow preparation of initiatives to prevent resistance to change [14]. Another systematic literature review also identified barriers to the use of telemedicine. The study showed that technology-challenged staff and resistance to change were the most frequent barriers [12].

In the future, the intention of hospitals will be to have fewer admitted patients and instead treat patients in their own homes [15]. In the Region of Southern Denmark, the goal is to convert 30% of outpatient consultations to digital consultations [16]. As described in the above articles, the need for the use of telemedicine is expected to increase in the coming years. It is important to gain knowledge of the use of video consultation from not only the patient's perspective, but also the medical doctor's perspective, and in particular, how the use of video consultation can benefit patients.

Aim

The overall aim was to explore how medical doctors use and experience the use of video consultations. This was done using the following research questions: (1) How do medical doctors use video consultation? (2) How do medical doctors experience the use of video consultation instead of face-to-face consultation? (3) How do medical doctors experience the technical aspects of video consultation? (4) How do medical doctors experience the roles and relation to patients during video consultation?

Methods

Design

The study was designed as a qualitative and explorative intervention study. Data were collected using participant observations and focus group interviews.

Setting

This project was part of a larger pilot study, where patients with hematological diseases from a small island to the south of Funen were given the opportunity for video consultation. The patients could choose to have their consultation with a hematologist from the outpatient clinic in Odense through a video screen, instead of a face-to-face consultation. The patients would be seated in front of a video screen placed at the local hospital on the island, where site staff could help them connect with the doctor via the screen. The pilot study was introduced in April 2017 and continued until the end of December 2017. A total of 17 patients with different hematological diagnoses were included in the pilot project, which made the sample of informants very varied.

The intervention was initiated as a collaboration between the municipality on the island, the Innovation Department at Odense University Hospital, and the Hematological Research Unit at Odense University Hospital. Two identical video screens were purchased for use at the hospital on the island, and one screen was placed in the outpatient clinic in Odense.

The video consultations had two purposes, namely, monitoring and treating the patients. The medical doctor would use the video consultation in combination with blood results to determine whether the patients were eligible for the next treatment or needed to receive a different treatment for the diagnosis.

The patients were informed by a research nurse from the Hematological Research Unit about participation in video consultation. The research nurse would assist when the video consultation was initiated with the hematology specialist. At the local hospital on the island, the patients could choose to have a nurse participate during the consultation, if they articulated a need for this.

Sample

The study population consisted of medical doctors who participated in video consultations with patients with hematological diseases, living on a small island south of Funen. The medical doctors who participated in the focus group interview all worked at the Hematological Department at Odense University Hospital and had between one and five video consultations with the hematological patients. The medical doctors did not receive any introduction or guidelines regarding how to behave in front of the patients before, during, and after

the video consultations. The medical doctors' experiences are grounded in their own first-hand experiences.

Inclusion Criterion

The inclusion criterion for participating in the focus group interview was participation in at least one video consultation with hematological patients form the island to the south of Funen.

Data Collection

Participant Observations

Participant observations of the medical doctors during video consultations were conducted from November 2017 to December 2017. We conducted 5 hours of participant observation.

The last author observed the medical doctors. Green and Thorogood described how observational studies allow us to obtain knowledge about what the observed participants say and what they do in relation to the specific situation [17]. Here, the participant observations allowed us to obtain knowledge about what the medical doctors said and did during the video consultations with the patients [17].

The observations were inspired by James Spradley's description of passive participation and moderate participation [18]. The observations followed an observation guide that was designed using Spradley theory for observations (Textbox 1).

Passive participation was used in relation to the observations made during the pilot study period, when the video consultations were tested and implemented. The last author listened to and observed the medical doctors' work with the video consultation and the settings around the video consultation. The observations provided an opportunity for informal interviews with the medical doctors, immediately after the video consultation. Here, it was possible to talk to the medical doctors about their overall impression of the consultation, which provided us with their first-hand impressions [19].

Textbox 1. Participant observation and video consultation from the physician's end.

The physician and the encounter with the technology
How does the physician handle the technical side of things with the video screen?
Does it seem easy or cumbersome for the physician?
What does the physician comment on/say about the screen/technology?
Does the physician prepare beforehand (fixes hair or clothes, checks phone, etc)?
Are there any technical problems?
How is the sound? How is the image quality?
Physical setting
How is the physician placed in relation to the screen?
What does the room look like?
What does the physical setting look like? Is the room hot/cold?
What is the light like?
Conduct before, during, and after the video consultation
How does the physician act, verbally and nonverbally?
Does the physician act naturally during the video consultation?
Is there eye contact during the entire consultation?

Focus Group Interview and Interview Guides

In January 2018, the first and last authors conducted a focus group interview with seven doctors (two male and five female doctors) with different experiential backgrounds. The focus group interview lasted approximately 90 minutes and took place in a conference room at Odense University Hospital. The last author facilitated the focus group session. The first author was present as an observer, wrote down field notes from the session, and validated the content of the session.

The focus group interview was chosen, as focus group discussions can mobilize associations, where the group dynamic contributes to the creation of narratives [20]. It allowed the researchers to get knowledge from the interactions between the medical doctors with different academic experiences. The authors found it relevant to create a focus group of medical doctors that was not too homogeneous and to facilitate discussions between the medical doctors [18].

Before the focus group interview, an interview guide was created [19,21], based on themes from the participant observations and the semistructured interviews with the patients from an earlier Danish study (Multimedia Appendix 1) [7]. The authors also used photo elicitation as a data collection technique. Photos were taken during the participant observations, capturing the video consultations with the patients. They were used as an activity to make the medical doctors reflect on their experiences with the video consultations during the focus group interview [22].

The medical doctors were, at the beginning of the session, asked to write down three positive and three negative thoughts about their experiences with the use of video consultation. Afterwards,

they were asked to discuss their experiences with each other. Furthermore, quotes from the semistructured interviews were read aloud to make the medical doctors reflect on and discuss the patient statements.

Analysis

This study draws on a qualitative research tradition, which is adequate when seeking knowledge about subjective practice experiences, individual patient and professional perspectives, and interactional processes and dynamics involving technology as an actor [23]. The study draws on Don Ihde's hermeneutic-postphenomenological framework, making it possible to gain an understanding of the interaction between technology, humans, and their lifeworld. Ihde's methodology will be used to explore how the technological mediation of human practice shapes user experiences and how users attach meaning to certain experiences [24,25]. The analysis process was organized by following the steps from "systematic text condensation" [26-29]. The analysis was organized according to the steps in the systematic text condensation, as shown in Multimedia Appendix 2.

First, we gained an overall impression of the data. This gave us a preliminary set of main themes. Second, the data were broken into meaningful topics, relevant for the research question. Next, the meaningful topics were coded. The first and second authors coded individually, and then, they discussed each topic and the coding, and reached an agreement. Thereafter, the topics were condensed.

As the last step of the analysis, we synthesized the data by applying a shift from condensation to categories. We developed the codes based on the initial themes that were identified in the first step and the theories we applied.

To increase the validation, the analysis was prepared as a cooperation between the first and second authors. Their overall impressions of the data were discussed thoroughly, meaningful topics were highlighted, and codes were applied. The analysis was written by the first author. Then, all three authors met and discussed the findings in relation to relevant literature and the postphenomenological framework, while focusing on technology-mediated transformation, constitution, and perception.

Ethics

During data collection, the researchers were continuously reflective about the aim of the study and the methods applied. Furthermore, the participants were informed thoroughly about the project, allowing them to make an informed choice as to whether to participate in the study. The participants were informed both orally and in writing about the study and were included after providing their informed consent in compliance with the Helsinki Declaration [30,31]. The participants were guaranteed anonymity throughout the process. The study was registered with the Danish Data Protection Agency (2012-58-0018), and the data were stored at a secure SharePoint site.

Results

Overview

During the pilot study, 41 video consultations were performed with patients aged 55 to 85 years with different hematological diagnoses. All patients were in a stable period of their disease during the time when the video consultations took place.

In total, 12 doctors participated in this study. Seven medical doctors, who all had completed between one and five video consultations with different patients having different diagnoses, attended the focus group interview. Five medical doctors were observed during video consultations at Odense University Hospital and participated in informal interviews (Table 1).

Table 1. Baseline characteristics of the doctors who participated in the focus group interview.

Doctor ID	Age (years)	Sex	Seniority
Doc 1	43	Female	Doctor in a main education position
Doc 2	41	Female	Doctor in a main education position
Doc 3	31	Male	Doctor in a main education position
Doc 4	52	Female	Chief physician
Doc 5	38	Female	Doctor in a main education position
Doc 6	60	Female	Managing chief physician
Doc 7	45	Male	Chief physician

Results from the focus group interview and the participant observations revealed themes reflecting the medical doctors' use of and experiences with video consultations.

The themes were "Connecting at a distance – words, body language, laughter, and eye contact," "Can't touch this," "A handshake is not just a handshake," and "Adjusting to the transformation."

The themes have been presented and described in more detail below.

Connecting at a Distance – Words, Body Language, Laughter, and Eye Contact

The analysis of the focus group interview and the participant observations revealed that the medical doctors found it easy to assess and sense the patient's current condition, despite the consultation being digital. Most of them agreed that verbal connection with the patients was important when seeing the patients.

Comparison of the field notes revealed that both the medical doctors and patients appeared relaxed. The analysis of the field notes showed that the medical doctors were acting confidently and were comfortable with sitting in front of the video screen, as they had good and relaxed interaction with the patients through the screen, characterized by laughter and small talk with the patients. One field note was as follows:

> *Laughter. Chatting about the weather. Medical doctor sits in front of the screen, relaxed body language. Looking at the screen, smiling.*

The statements of the medical doctors who identified that they got a good sense of the patients supported the observations.

> *So, I almost think that the technology is so good that you actually sense them quite well. [Female doctor, 43 years old]*

We also found in the data material that a few of the medical doctors mentioned that they found it difficult to maintain eye contact with the patients through the screen. The analysis showed that the medical doctors experienced that they could not achieve the same eye contact as when they were sitting next to the patients in the consultation room.

> *No, because it is not there. You can never make eye contact with someone inside a screen. [Female doctor, 52 years old]*

Yet, the analysis also indicated that some doctors experienced that they had eye contact with the patients, and some questioned the need for "physical" eye contact.

> *I think that sounds right enough, but I do not think it's such a big problem.* [Male doctor, 38 years old]

Overall, we can derive that the medical doctors experienced the contact with the patients during the video consultation as more relaxed, because the patients were not stressed, as they remained on the island close to home and did not have to worry about time and transportation.

> *I also sometimes think that you can actually have better contact via the screen, because I think if you are a little behind and the patients are pressured, because they have to catch the car and the ferry and all that. Then you sometimes have extremely bad contact, because we have only 7.5 minutes left, and sometimes it might be a quarter of an hour that was necessary. Yes, dialogue and contact via the screen is good, because then there are not all these stressful moments.* [Female doctor, 41 years old]

The analysis of the observations revealed that the medical doctors were using their body language a lot. They waved to say hello and goodbye to the patients, and the patients did the same. They also used their arms and fingers to illustrate what they said, looked straight into the screen while talking, and were laughing with the patients. One field note was as follows:

> *When the patient talks, the doctor leans towards the screen, focusing on the screen. Looking directly at the screen, slightly furrowed eyebrows. The patient also leans all the way to the screen, looking at the doctor.* [November 16, 2018; 11 am]

The data from the focus group interview also supported these observations.

> *I have not met my patient in real life. I have only met her on the screen, and we have done so 3 times. … So, we're starting to know each other and waving goodbye and stuff like that… yes.* [Female doctor, 43 years old]

Yet, the analysis also indicated that for some of the medical doctors, it was important to know and see the patients before the first video consultation. Therefore, it seems to be a subjective perception and not related to the technology.

> *Yes, it requires that it is the same doctor who has met them physically before, I would say, so you kind of know who it is.* [Female doctor, 38 years old]

Can't Touch This

For medical doctors who are used to using their hands when examining patients, it is a big change not to be able to use the sense of touch. It transforms the consultation because they cannot use "a tool" that they normally use when seeing patients.

In general, throughout the analysis, it became clear that it was challenging for the medical doctors to get used to the new practice with video consultation instead of physical consultation, where the doctors would normally be able to examine the patient physically, if required. The doctors felt that they missed some important information when they were unable to observe and examine the patients in the usual way. Some of the medical doctors were also afraid that they might miss how the patients' general condition develops.

> *We risk exactly those 80-year-old patients with myeloma in the stable phase. We will end up following them for 10 years, and they are in a nursing home and they put a screen in front of them, and it makes no sense if we are phoned and say, no the patient cannot do this trip to the hospital. And if we get that phone call, then we can say well, then we do not have to take blood samples, and if the patient doesn´t manage the trip, then you never get in chemo, but she manages well to get a screen in front of the her. The monitoring will be dragged out for too long.* [Male doctor, 42 years old]

The analysis identified that the medical doctors observed and examined the patients in many different ways and that the medical doctors are not always aware of what tools they use to diagnose and evaluate the patients. They do several things instinctively.

> *Yes, here you become aware that there are some things we do subconsciously.* [Female doctor, 52 years old]

The medical doctors found the possibility of performing a physical examination important in the consultation with the patients. The medical doctors were therefore concerned by the fact that they were unable to perform an examination during the video consultation. However, during the project period, only a few doctors needed to see the patients physically following the video consultation. It became evident that it was a problem

if the patients had a new medical condition that they wanted the medical doctors to investigate. One fieldnote was as follows:

> *The patient tells of itchy rash. The doctor points to her forearm and says that the patient should show her forearm. The doctor leans all the way to the screen. She says, yes it´s hard to see on the screen, and I can´t touch it.* [November 16, 2018; 11 am]

Some of the medical doctors also expressed that during the video consultation they were able to retrieve important information through the screen, which is opposite to telephone contact with no visual contact. Via the video consultation, the doctors got indirect information, for example, facts about how the patient and the surroundings appear.

> *I just think the video provides something else than just a voice, that is. Of course, you do not see the patient sitting in the waiting room, but you still get an impression of whether it is someone who is sitting with their hair hanging in a mess, someone who is still sitting in a dressing gown - you get a picture of that via the video.* [Female doctor, 56 years old]

The analysis indicated that the medical doctors were afraid of missing important details about the patients when they could not be hands on with them, as they could during a physical consultation. However, at the same time, the medical doctors also expressed that they experienced that the patients were very satisfied with the video consultation.

> *And the patients are satisfied. They really are. And as you also say, there is a good quality of sound and picture. And it goes both ways. The patient is also very focused when we talk.* [Female doctor, 52 years old]

The quality of the sound and picture during the video consultations was satisfying and contributed to an overall secure feeling for the doctors, because they could see the patients as clearly as if it was a face-to-face consultation.

> *I think there is a good sound and picture quality. So that way it seems very real.* [Female doctor, 43 years old]

A Handshake is Not Just a Handshake

The analysis revealed that a handshake gives the doctors a lot of information about the patients. Many of the medical doctors also expressed that they missed the physical handshake and being able to take in the general appearance of the patients, though the connection with the patients was sufficient.

> *Then I might also miss a bit… that handshake you have at the consultation, where you get a feeling of what kind of patient who comes in. Is it someone who is nervous or is it someone who is strong? [Female doctor, 43 years old]*

Some of the objective parameters that the doctors used in their overall assessment of the patients were found to be difficult to recreate during the video consultations. It is clear that the way a doctor senses a patient is from the "whole experience."

> *But I am also thinking about what you said. You don´t get the handshake and you can't follow them walking to the waiting room. Those 8 steps to see if they jump out of the chair or… They are sitting in that chair – and there you can look reasonably fresh and cheat. Or not cheat. You will get a more positive view than you would, if you saw them in real life, when they walk to the consultation room? You lose some objective information about the patient when you only see them via the screen. We see so many different patients, there is no continuity, so I would miss seeing them physically.* [Female doctor, 38 years old]

The analysis points to important aspects. The handshake and the way patients walk into the room are important observations for doctors. Even though the consultation is mostly "talk," the movements and handshake reveal important information, which is necessary to address when discussing telemedicine. The fact that video consultation is not a 3D experience is a big change, and therefore, doctors need to redefine and reinvent the way they see patients.

> *But it's probably also something to do with the fact that we have been used to the consultation starting when you meet the patient out there, and you observe how the handshake is, how they get up from a chair, how fast their disease develops. So, it feels completely wrong that this part is missing.* [Female doctor, 43 years old]

Adjusting to the Transformation

Seeing patients through a screen changed something for the doctors. They all experienced it as a challenge, and they emphasized that they need help with adapting to the new types of consultations. The medical doctors experienced that they somehow were making their own guidelines for video consultation, as they needed guidance and they had not been introduced to guidelines on how to conduct a video consultation.

The medical doctors considered it relevant to receive instructions on how to navigate in front of the screen before the initiation of video consultations in the outpatient clinic.

> *I´ll be surprised if someone hasn´t found tips and tricks to say "hello" and "goodbye" in a decent way. You throw yourself into it, like everything else. But for sure, some might say that there might be some standard practices or something.* [Female doctor, 41 years old]

The medical doctors experienced situations where they acted differently in the video consultation when compared with a traditional face-to-face consultation. One example was when another person, besides the patient, was visible during the video consultation.

> *It was not expected that someone would sit next to the patient during the consultation. It was exactly the point, that there shouldn´t?* [Female doctor, 52 years old]
>
> *Sometimes there is a person sitting who has not participated as such in the conversation, but where*

> *I have just thought; who are you?* [Female doctor, 41 years old]

The physical framework was important in how the doctors experienced the consultation and how they placed themselves in front of the screen.

> *There is also something about how you place yourself in the room. Maybe we could try that some more.* [Female doctor, 43 years old]

> *The doctor is adjusting the camera. The doctor sits straight in front of the screen. Obviously aware to sit in an angle, so the patient can see her. The doctor smiles and uses facial expressions. Emphasizes the words, talks a bit slowly, hesitant with a nod, sees if the patient wants to say something before, she continues talking.* [Field note; November 24, 2018; 12:45 pm]

In continuation of the physical framework, the video consultations also involved some technical aspects regarding how to show the patient the laboratory results and how the doctor should be placed in the room, so the patient can see the doctor and the surroundings.

> *And sometimes I like the fact when I have the patient in front of me, to turn the screen and show the blood results. And you don´t do that the same way via the video consultation. But it is probably also something that can be solved technically.* [Female doctor, 43 years old]

Discussion

Principal Findings

This study explored how medical doctors used and experienced the use of video consultation in the outpatient clinic instead of or as a supplement to face-to-face consultation. The study identified possibilities and barriers in relation to adapting to the alternative way of meeting patients in the clinical setting. One of the main findings in this study is that the medical doctors were afraid that they missed important observations, as they were not able to perform a physical examination, if needed. They also emphasized that a handshake and eye contact were important to get an overall impression of the patient's situation. It also became clear that the medical doctors were using body language a lot more during video consultation compared with physical consultation. The medical doctors found the contact with the patients via the screen to be good, and the fact that the technology was working well made them feel secure with the video consultation.

Video-Mediated Contact

In many Western cultures, the most common way to initialize a social interaction is a handshake between people [32]. In Denmark, the handshake has several meanings and holds a long tradition. The handshake is often debated, as in some other cultures, it is not socially acceptable for a man and a woman to shake hands. Yet, the handshake is essential in the Danish culture and is also a subject of political debate. Shaking hands with the patients was not possible during the video consultations. The question about the handshake has a new perspective owing to the current COVID-19 pandemic. It is no longer possible to shake hands with your doctor, and it will be interesting to observe how this will affect the doctor-patient relationship in the long run [2].

We also found that the medical doctors were using body language a lot during the video consultations. They waved to the patients to compensate for the missing handshake. We know from another study of video consultations that patients also wave or use facial expressions when talking to their doctors [7]. The study revealed that it was not an issue for the patients as they would compensate the missing handshake with a wave or with enhanced facial expressions. The study showed that having the contact mediated through a screen invited the participants to use other gestures. Ihde explained that technology is shaping our experiences of a situation and invites humans to act in certain ways [24]. In the specific situations with video consultations, the technology invited the participants to greet each other in a different way than when meeting face to face. This compensated for the lack of physical contact.

A well-known fear of technology is that machines will replace human contact, making care "cold" by reducing it to mechanical interactions with machines [31]. Yet, the results of a previous study showed that the patients experienced intimacy at a distance, even though they could not touch the doctor with a physical handshake [7].

In the actual study, the technology invited the medical doctors to greet the patients in a different way than that when meeting the patients face to face, to compensate for the missing physical presence, and the medical doctors adapted to the new technology. Yet, we found that it was a concern that the medical doctors could not shake hands with the patients, as they, as professionals, used the handshake for medical observations in the form of observations of how the patients walk, smell, and interact. Therefore, it was not only the social interaction that was at stake, but also the medical observation that they would miss when not greeting the patients physically.

Other findings revealed that the medical doctors found video consultation less stressful than traditional consultation at the outpatient clinic, because the patient was not in a hurry to catch public transport, and the overall experience of the meeting with the patient was more relaxed. This finding is supported by other Danish studies, where patients expressed how important it was to not spend time on travelling to the hospital and to have the ability to keep up a normal everyday life [7,13,33,34]. It is very important for patients to keep up a normal everyday life when sick [7].

Present Without Being Present

In this study, we found that the medical doctors had a professional relation with the patients even though the consultation was through a screen. The medical doctors also experienced better contact with the patients even though the patients were not in the room. In another study by Van Gurp et al, it was noted how teleconsultants managed an empathic patient-professional relation with outpatients receiving palliative care [35].

Van Gurp et al found that the team members chose not to discuss sensitive and emotional topics with vulnerable patients [35]. This choice was made because of the inability to physically comfort the patients, because of the physical distance. However, the same patients reported that a nonphysical professional listener provided the exact freedom they needed to define their own role and co‐design their own care in equal patient-professional relationships [35]. The same feeling of freedom without being physically present was found in a Danish study [7], where the patients felt the same level of intimacy with the medical doctors, even though the contact between them was mediated through a screen. In a Danish study on palliative care, it was found that both patients and relatives were more actively involved in treatment and care when consultations with nurses and medical doctors took place via a screen [33]. In a Swedish study from 2020, it was found that most doctors had a positive attitude toward the use of video consultations and that the reliability of the technical platform was very important for doctors to feel comfortable during the consultation [36].

The Transition

This study discovered that the technology was easy to use, and the quality of the sound and picture was impressive. However, the fact that a screen was present between the medical doctors and patients posed some challenges as to how the medical doctors would assess the patients. The change from the possibility of examining the patients when required to the fact that it was not an option was challenging for some of the medical doctors. Ihde stated that handling new technology is a learning process and that it is experienced as stressful until the user has learned how to use it for specific practices [26]. Ihde used the term “embodiment” to describe the process that takes place when a certain technology becomes integrated as a useful tool for the ones using it. In another study, where patient rounds with video-consulted relatives was examined, it was found that health care professionals experienced changes regarding workload, culture, and organization when the new way of doing the rounds with the relatives was introduced [13].

The medical doctors missed seeing the patients walk from the waiting room and being able to evaluate their general status. The medical doctors in this study did not receive any instruction as to how to act in front of the video screen or how to use the technology to get the desired and necessary information from the patients. According to Kotter, it is important to give a sense of meaning to the individual when facing changes in an organization. Moreover, that the change is experienced as being urgent is important as to how successful the change or implementation will be [37]. In this study, the test of the video consultations was not urgent, and the observations of the medical doctors showed that they tried to navigate in this new setting, but without any guidance. The medical doctors’ motivation for working with the change involving replacing face-to-face consultation with video consultation was the patients’ statements about their satisfaction with the flexibility and the good contact they had with the doctors through the screen [7].

Strengths and Limitations

Our study was limited by the reduced number of medical doctors participating in the focus group interview, making this a small-scale study. In qualitative research, most studies are typically small scale [17].

The aim of this study was to perform an in-depth exploration of the phenomenon under investigation. Therefore, the intention of this study was to understand and explain medical doctors’ experiences of video consultations with hematological patients located in front of a screen at a small island.

We have provided detailed descriptions of the context of the study, as well as the observations and the doctors’ experiences with video consultations. The results do not show statistical generalizability, but analytical generalization, which emerges by means of the dialectic between theory and practice.

The first two authors conducted the analysis jointly to increase reliability. We presented the analysis process in a table to ensure transparency. Quotations from the data were used to link to the participants’ original statements to ensure validity.

Conclusions and Implications for Practice

When data for this study were collected, there was a lack of evidence on how medical doctors experience video consultations. At present, after the start of the COVID-19 pandemic, more scientific literature about doctors’ experiences is available. In this study, we found that doctors were able to maintain good contact with their patients despite the screen and were able to assess the patients in a satisfying manner. However, there were still insecurities among some doctors about the fact that they could not examine the patients physically. New knowledge about how to use gestures and nonverbal body language during a video consultation was also discovered.

The new knowledge about how medical doctors can use video consultations will benefit both patients and health care professionals in allowing the health care system to provide more tailored treatment, which will mean improved flexibility for the patients. Understanding how medical doctors experienced the use of the new consultation form can inspire other medical doctors to implement and use video consultations in outpatient clinics or other clinical settings. Especially during the COVID-19 pandemic, it has become imperative to implement video consultations quickly at hospitals, and scientific knowledge sharing has become more relevant than ever. It will also be possible to create guidelines for medical doctors using video consultation as a supplement to normal consultation in the outpatient clinic, with the results of this study as a starting point. Even though the data of this study were obtained before the COVID-19 pandemic, the results can be used as an important supplement for the history of novel experiences with video consultations before the pandemic and can be used for the development of video consultations in the perspective of today’s situation.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Focus group interview guide.
[PDF File (Adobe PDF File), 302 KB - formative_v5i7e27094_app1.pdf]

Multimedia Appendix 2
The analysis process, with examples from the analysis.
[PDF File (Adobe PDF File), 358 KB - formative_v5i7e27094_app2.pdf]

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Edited by G Eysenbach; submitted 15.01.21; peer-reviewed by B Dinesen, C Kruse, L Seuren; comments to author 12.02.21; revised version received 08.04.21; accepted 31.05.21; published 21.07.21.

Please cite as:
Primholdt Christensen N, Skou KE, Boe Danbjørg D
Health Care Professionals' Experiences With the Use of Video Consultation: Qualitative Study
JMIR Form Res 2021;5(7):e27094
URL: https://formative.jmir.org/2021/7/e27094
doi:10.2196/27094
PMID:34287207

Original Paper

Internet-Administered Cognitive Behavioral Therapy for Common Mental Health Difficulties in Parents of Children Treated for Cancer: Intervention Development and Description Study

Joanne Woodford[1], PhD; Paul Farrand[2], PhD; Josefin Hagström[1], MSc; Li Hedenmalm[1], MSc; Louise von Essen[1], PhD

[1]Uppsala University, Healthcare Sciences and e-Health, Department of Women's and Children's Health, Uppsala, Sweden

[2]Clinical Education, Development, and Research (CEDAR), Psychology, College of Life and Environmental Sciences, University of Exeter, Exeter, United Kingdom

Corresponding Author:
Louise von Essen, PhD
Uppsala University
Healthcare Sciences and e-Health
Department of Women's and Children's Health
MTC-huset: Dag Hammarskjölds väg 14B, 1 tr
Uppsala, 751 85
Sweden
Phone: 46 070 4250714
Email: louise-von.essen@kbh.uu.se

Abstract

Background: Following the end of a child's treatment for cancer, parents may report psychological distress. However, there is a lack of evidence-based interventions that are tailored to the population, and psychological support needs are commonly unmet. An internet-administered low-intensity cognitive behavioral therapy (LICBT)–based intervention (EJDeR [internetbaserad självhjälp för föräldrar till barn som avslutat en behandling mot cancer]) may provide a solution.

Objective: The first objective is to provide an overview of a multimethod approach that was used to inform the development of the EJDeR intervention. The second objective is to provide a detailed description of the EJDeR intervention in accordance with the Template for Intervention Description and Replication (TIDieR) checklist.

Methods: EJDeR was developed through a multimethod approach, which included the use of existing evidence, the conceptualization of distress, participatory action research, a cross-sectional survey, and professional and public involvement. Depending on the main presenting difficulty identified during assessment, LICBT behavioral activation or worry management treatment protocols are adopted for the treatment of depression or generalized anxiety disorder when experienced individually or when comorbid. EJDeR is delivered via the Uppsala University Psychosocial Care Programme (U-CARE) portal, a web-based platform that is designed to deliver internet-administered LICBT interventions and includes secure videoconferencing. To guide parents in the use of EJDeR, weekly written messages via the portal are provided by e-therapists comprising final year psychology program students with training in cognitive behavioral therapy.

Results: An overview of the development process and a description of EJDeR, which was informed by the TIDieR checklist, are presented. Adaptations that were made in response to public involvement are highlighted.

Conclusions: EJDeR represents a novel, guided, internet-administered LICBT intervention for supporting parents of children treated for cancer. Adopting the TIDieR checklist offers the potential to enhance fidelity to the intervention protocol and facilitate later implementation. The intervention is currently being tested in a feasibility study (the ENGAGE study).

International Registered Report Identifier (IRRID): RR2-10.1136/bmjopen-2018-023708

(JMIR Form Res 2021;5(7):e22709) doi:10.2196/22709

KEYWORDS

parents; eMental health; internet-administered cognitive behavioral therapy; ICBT; TIDieR; CBT self-help; low-intensity CBT; mobile phone

Introduction

Background

Each year, approximately 300,000 children and young people (aged 0-19 years) are diagnosed with cancer worldwide [1]. Despite significant treatment advances resulting in a 5-year survival rate of 81.2% across Northern Europe [2], childhood cancer remains a leading cause of death [3] and disease burden [4] among children worldwide. As parents are the primary source of support for children with cancer, they are faced with significant negative psychological [5-10] and socioeconomic [11-15] impacts, along with increased caregiving burden [16] and poor health-related quality of life [17].

Compared with population controls, parents of children treated for cancer report a higher prevalence of mental health difficulties, including depression, anxiety, and posttraumatic stress symptoms [6-10]. Despite the prevalence of mental health difficulties, parents report a number of significant barriers to accessing psychological treatment to meet their needs [18-20]. These barriers occur at the individual level: lack of time, putting the needs of their child first, and guilt [21,22]; provider level: lack of knowledge of mental health difficulties and willingness to diagnose and treat mental health problems; and systemic level: limited availability of trained and qualified health care providers [23-25].

Innovative strategies to address barriers and improve access to evidence-based psychological interventions are being implemented worldwide [26]. One such innovation is the Improving Access to Psychological Therapies (IAPT) program in England [27,28], which is now also being piloted in countries including Australia [29] and Norway [30]. The IAPT program was established in recognition that improving access to evidence-based psychological therapies required a fundamental transformation of mental health service delivery. This transformation was achieved through the delivery of psychological treatments within a stepped care service delivery model [31]. One important feature of the stepped care model is that the least restrictive evidence-based treatment available that is likely to result in a significant health gain is provided initially [32,33]. For example, lower demands placed on patients in terms of cost and personal inconvenience [32,33]. At step 2, low-intensity cognitive behavioral therapy (LICBT) is provided by a psychological practitioner workforce trained in competencies to support patients to engage in LICBT interventions [34]. At step 3, high-intensity cognitive behavioral therapy (HICBT) is delivered to patients, primarily face-to-face, by traditional psychological therapists.

LICBT interventions are delivered through a range of cognitive behavioral therapy (CBT) self-help interventions, including print-based formats or e-mental health (eg, internet administered and smartphone apps) formats [35]. Using LICBT interventions to deliver specific CBT techniques enables treatment to be provided with shorter session times while ensuring that patients receive a similar dose of therapy to that delivered by HICBT therapists [34]. With HICBT, evidence-based treatment protocols specify the delivery of several CBT techniques as part of a multistrand approach, such as cognitive therapy for depression [36]. With LICBT, a single-strand approach is adopted, in which a clinical decision is made to adopt a single evidence-based CBT technique for the treatment of a specific, common mental health difficulty [34]. Given the evidence base highlighting larger effect sizes associated with guided LICBT versus those associated with self-administered LICBT [37,38], interventions are supported by a psychological practitioner workforce [34].

The evidence base for LICBT has been demonstrated in over 30 systematic reviews and 50 controlled trials [39]. Controlled trials of guided internet-administered LICBT interventions versus face-to-face psychological therapies have been demonstrated to produce equivalent overall effects [40], and acceptability has been demonstrated in usual care settings [41]. In addition to placing fewer demands on parents of children treated for cancer, guided internet-administered LICBT may represent a solution to address individual-and provider-level barriers to access [42-44]. An existing internet-administered CBT intervention for parents of children treated for cancer has been found to be acceptable and feasible [45]. However, this was an HICBT intervention, delivered in real time by a qualified psychologist using a group treatment format. To the best of our knowledge, there is no guided internet-administered LICBT intervention for parents of children treated for cancer.

Objectives

The objectives are twofold. The first objective is to provide an overview of the multimethod approach informing the development of a guided internet-administered LICBT intervention for parents of children treated for cancer (EJDeR [internetbaserad självhjälp för föräldrar till barn som avslutat en behandling mot cancer]), following phase I (development) of the Medical Research Council complex interventions framework [46]. The second objective is to provide a detailed description of the EJDeR intervention in accordance with the Template for Intervention Description and Replication (TIDieR) checklist [47] to overcome criticisms concerning poor and incomplete reporting of complex nonpharmacological interventions [48].

Methods

Overview

Mixed methods, including a systematic review [6], interview studies [5,49], a single-arm trial [50], participatory action research [51], and a cross-sectional web-based survey [52] informed the initial development of EJDeR (Figure 1). Subsequently, public [53] and professional involvement was adopted to improve the quality, relevance, and acceptability of the intervention. The parent research partner (PRP) group consisted of 2 mothers and 2 fathers of a child treated for cancer who were aged between 45 and 54 years and recruited via word of mouth. Professional involvement included collaboration with a multidisciplinary team of licensed clinical psychologists, e-therapists, pediatric oncologists, and web developers (Figure 2). We included 10 publications [54-63] in Figure 2.

Figure 1. Previous research informing the development of EJDeR. CBT: cognitive behavioral therapy; EJDeR: internetbaserad självhjälp för föräldrar till barn som avslutat en behandling mot cancer; ICBT: internet-administered cognitive behavioral therapy; PTSS: posttraumatic stress symptoms.

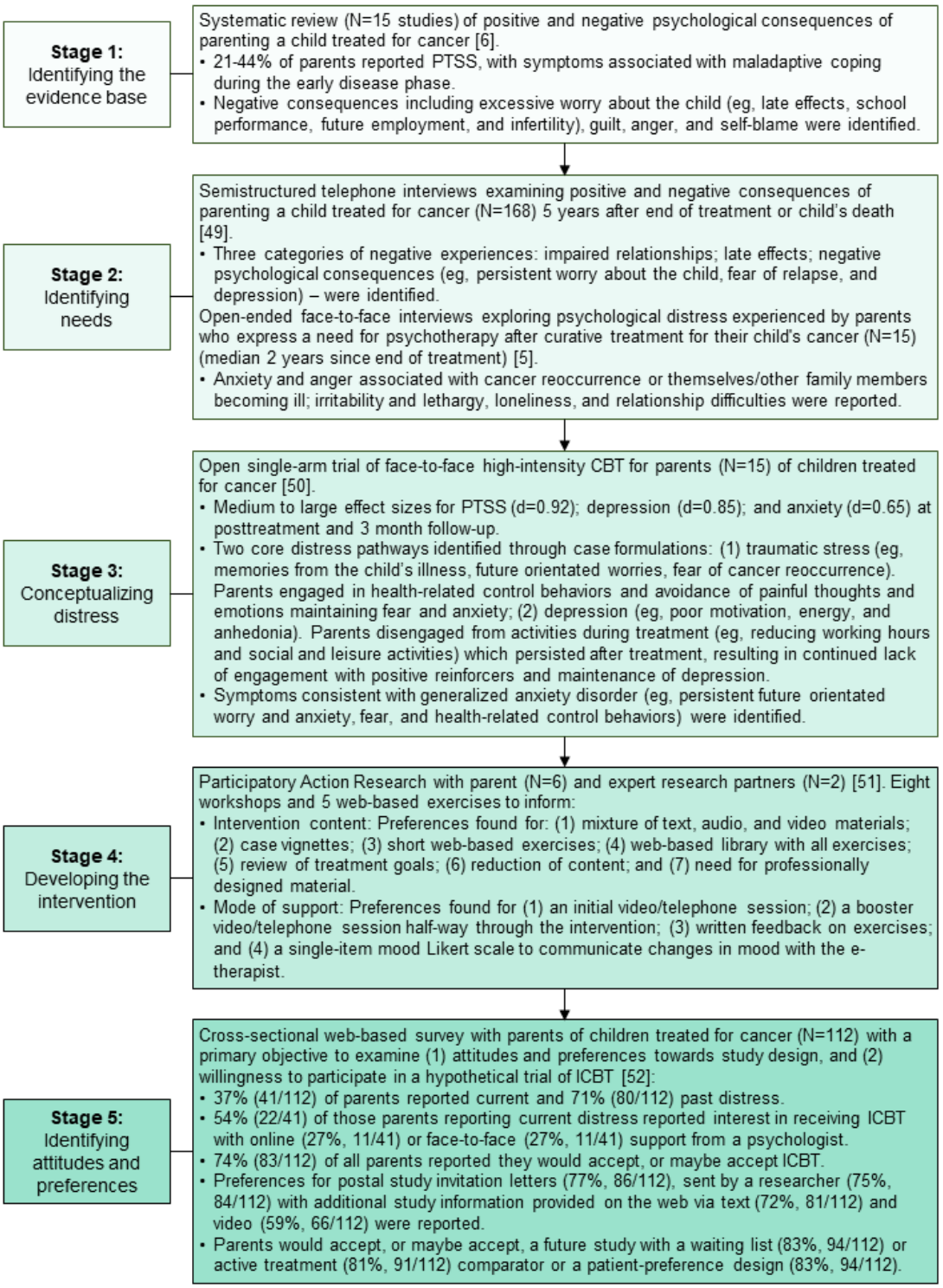
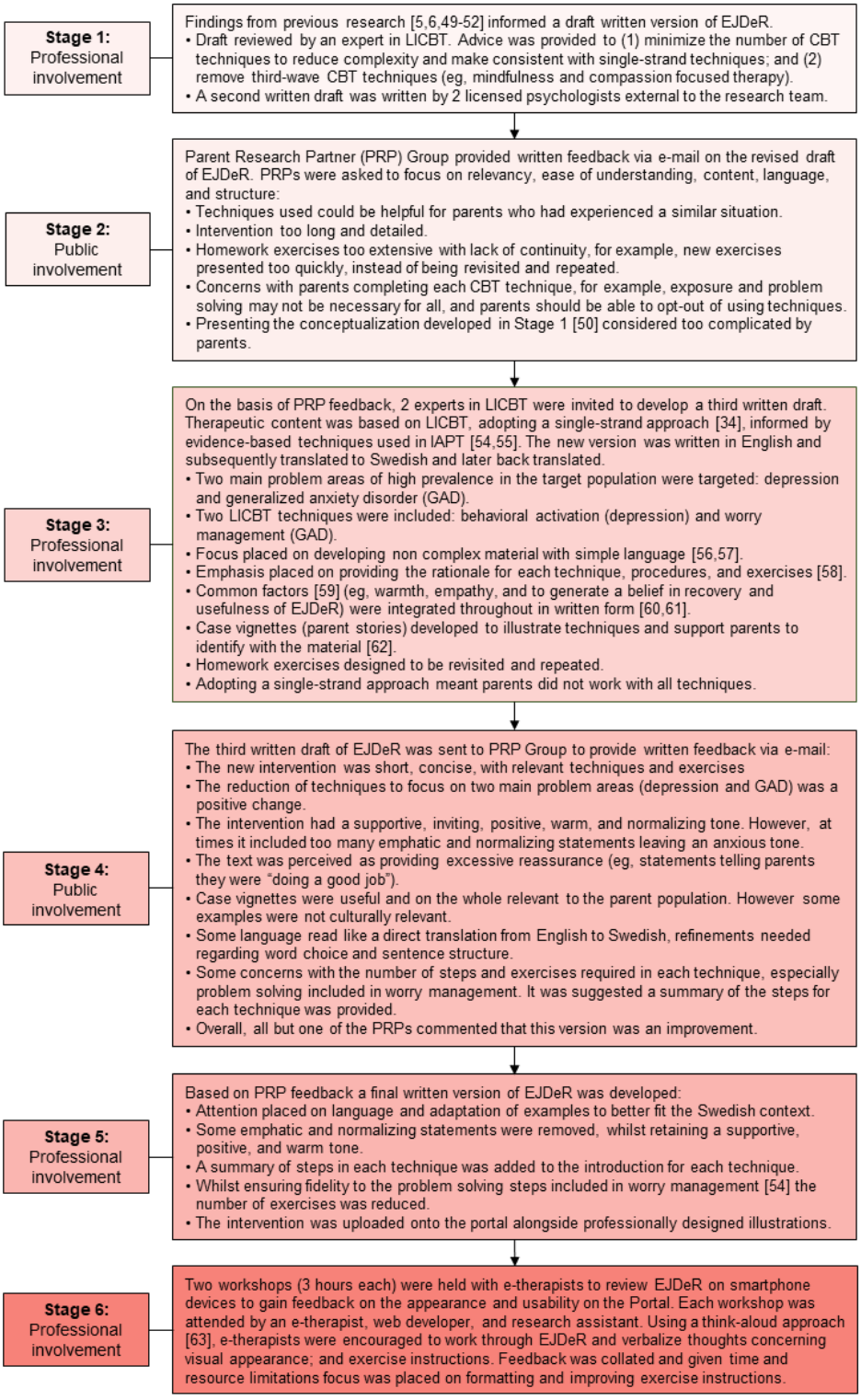


Figure 2. Public and professional involvement. CBT: cognitive behavioral therapy; EJDeR: internetbaserad självhjälp för föräldrar till barn som avslutat en behandling mot cancer; GAD: generalized anxiety disorder; IAPT: Improving Access to Psychological Therapies; LICBT: low-intensity cognitive behavioral therapy; PRP: parent research partner.



Ethics

Ethical approval for studies informing the EJDeR intervention development process was granted by the regional ethical review board in Uppsala (DNR: 2012/440; DNR: 2015/426; DNR: 2017/527) and the Swedish Ethical Review Authority (DNR: 2019-03083).

Results

Overview of the EJDeR Intervention

EJDeR is a guided internet-administered LICBT intervention for parents 3 months to 5 years following their child ending treatment for cancer. For parents, the end of treatment is a period of psychological vulnerability [6], and a subgroup reports

long-term psychological distress after the end of treatment [10]. EJDeR is delivered on the Uppsala University Psychosocial Care Programme (U-CARE) portal (hereafter referred to as the portal), an in-house platform designed to deliver CBT interventions and support data collection [64,65]. EJDeR is intended to be delivered over 12 weeks and consists of 4 modules: (1) introduction and psychoeducation, (2) behavioral activation (BA), (3) worry management, and (4) relapse prevention. First, parents attend an initial assessment via videoconferencing or telephone interviews with an e-therapist. Consistent with an LICBT single-strand approach, a decision is made during the initial assessment to adopt BA to target depression or worry management for generalized anxiety disorder (GAD). Thereafter, e-therapists provide weekly written messages via the portal to guide parents to use the relevant module. Parents also receive a midintervention booster session with their e-therapist via videoconferencing or telephone. On occasions where difficulties remain after completion of BA or worry management, a collaborative decision may be reached to progress to the other LICBT technique. A detailed description of EJDeR is provided below in accordance with the items included in the TIDieR checklist [47].

TIDieR Checklist Item 1: Brief Name of the Intervention

The intervention was named EJDeR, which is a Swedish acronym for internetbaserat självhjälpsprogram för föräldrar till barn som avslutat en behandling mot cancer.

TIDieR Checklist Item 2: Rationale, Theory, or Goal of the Intervention

Overview

Theory related to the CBT model informing the development and maintenance of psychological distress was applied to understand the etiology and maintenance of distress in parents of children treated for cancer [50]. On the basis of the resulting conceptualization of distress in the population [50], depression and traumatic stress were proposed as the main psychological difficulties likely to arise in the population. Symptoms consistent with GAD (eg, persistent future-orientated worry and anxiety, fear, and health-related control behaviors) were also identified [50]. Given that depression and GAD are recommended for treatment with LICBT, EJDeR was developed to target depression and GAD, rather than posttraumatic stress disorder (PTSD) given the lack of evidence base for LICBT for PTSD [66]. Consistent with LICBT, EJDeR comprises two separate single-strand LICBT techniques: BA [67-69] and worry management [54,70,71] to target depression and GAD, respectively. EJDeR is not designed to support parents with a diagnosis of severe or enduring mental health difficulties or parents who are suicidal or have a history of persistent self-harm.

BA for Depression

To prioritize their child's cancer treatment, parents of children receiving cancer treatment commonly disengage from activities that make up a normal life routine, such as decreased engagement in work, social activities, and everyday household tasks [5,49,50]. At the time of the child's illness, prioritizing their child's cancer treatment can be helpful for parents in the short term to manage the difficult situation of being a parent to a child with cancer. However, even after treatment has ended, some parents continue to disengage from these activities. This can arise as a consequence of negative reinforcement, whereby continuing to focus on their child's needs at the expense of their own and not re-engaging with previously undertaken activities can provide relief. However, failing to re-engage with previous activities, in particular those found pleasant, reduces opportunities for positive reinforcement, whereas engagement in unnecessary activities associated with their child's treatment is maintained through negative reinforcement [67,69,72,73]. To break this maintenance cycle, EJDeR adopts an LICBT BA technique [69] theoretically informed by Hopko et al [74] to overcome sources of negative reinforcement and increase engagement with pleasurable activities in a structured and graded way [67-69].

Worry Management for GAD

Worry in parents of children treated for cancer is commonly related to the child's disease. To help avoid potential problems during cancer treatment, or to avoid thinking about the outcome of future threats, parents may engage in worry behavior in an attempt to problem solve current difficulties and avoid future threats [75,76]. When worry is related to a practical problem and results in successful problem solving, it can be highly productive; for example, ensuring the child avoids situations that increase the risk of exposure to infectious diseases [50]. However, worry can be unhelpful when hypothetical; therefore, solutions cannot be generated. For example, concerns related to future cancer reoccurrence in their child or sickness in themselves or family members without any reason [5]. On such occasions, worry may be used as a form of cognitive avoidance to reduce distress and discomfort associated with uncertainty [77,78]. When successful in reducing distress and discomfort, the use of worry behaviors becomes negatively reinforced, helping to manage an intolerance of uncertainty in the long term [77,78]. This intolerance of uncertainty is a core feature of GAD and is common among parents of children treated for cancer [79].

Behavior Change Models

To influence the degree to which patients are able to engage with the EJDeR intervention, behavior change theory [80] is integrated to supplement specific factors associated with single-strand LICBT techniques. For example, Self-Determination Theory [81] has been adopted to enhance autonomy, competence, and relatedness. A sense of autonomy is enhanced by providing a clear rationale for each LICBT technique. Clear instructions and guidance on how to complete exercises and guidance and feedback provided by an e-therapist foster competence. A sense of relatedness is established by directing significant attention to the language adopted throughout the intervention, such as the provision of empathy, normalization of common difficulties, and encouraging active engagement.

To complement Self-Determination Theory, the selection, optimization, and compensation (SOC) model [82-84] is embedded to support parents in re-engaging with activities that were given up while supporting their child through cancer

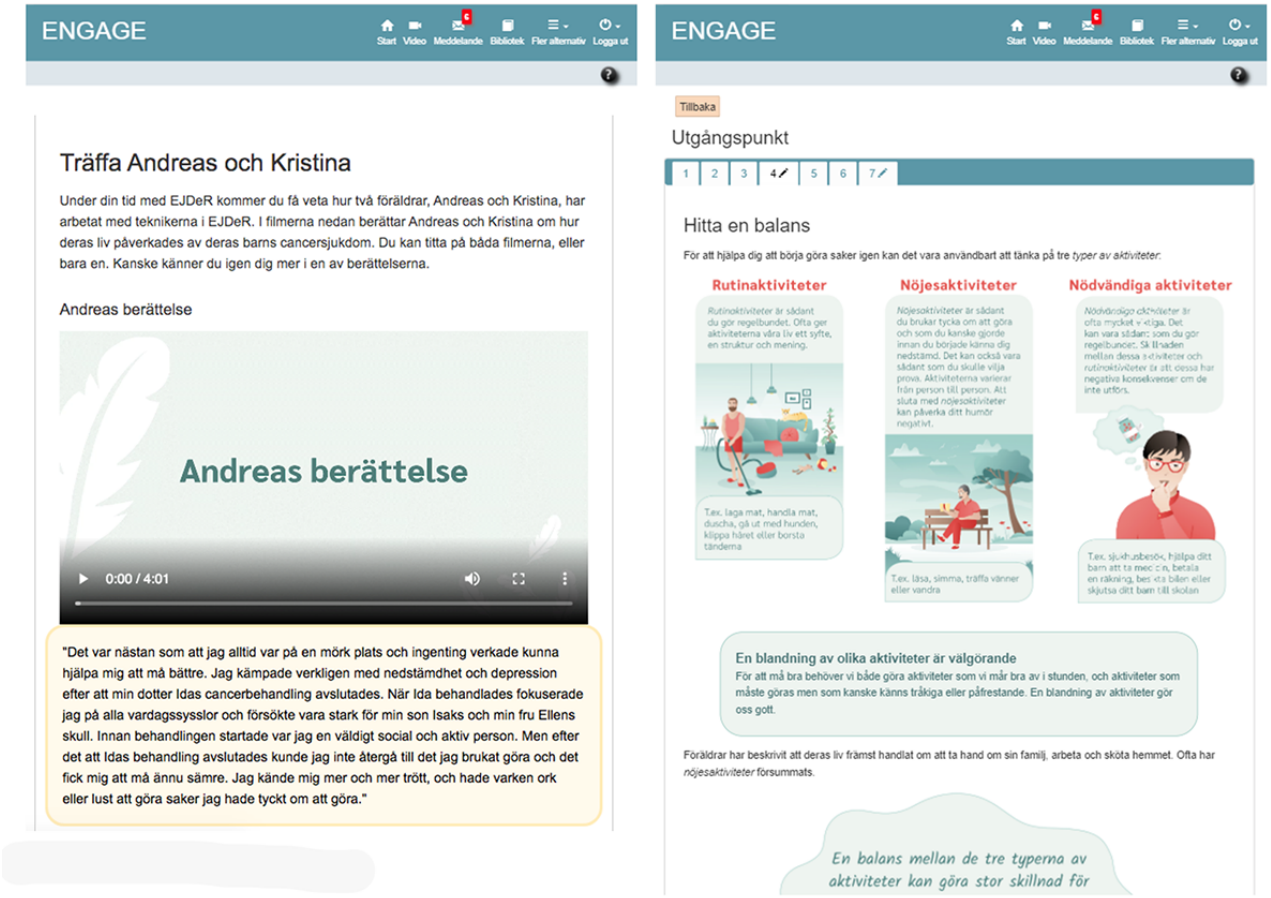
treatment or address worry by problem solving practical difficulties faced during treatment. The SOC model has been demonstrated to be a successful strategy for managing the multiple goals associated with different life domains (eg, work, family, and leisure) in middle adulthood [85,86] that may be experienced by parents of children treated for cancer. Within BA, the SOC model is used to support parents in replacing activities that were necessary to stop by selecting other activities that are more achievable and remain of importance and value. The SOC model can help support problem solving by adapting activities in the event of experiencing changes in resources (optimization; eg, lack of time and finance) and identifying ways of achieving the activity in light of changes (compensation; eg, finding time and asking for support). Applying the SOC model enables parents to maximize desirable gains, goals, and outcomes while minimizing undesirable losses, goals, and outcomes [82-84].

TIDieR Checklist Item 3: Physical or Informational Materials Used in the Intervention Delivery or Training

Intervention Delivery

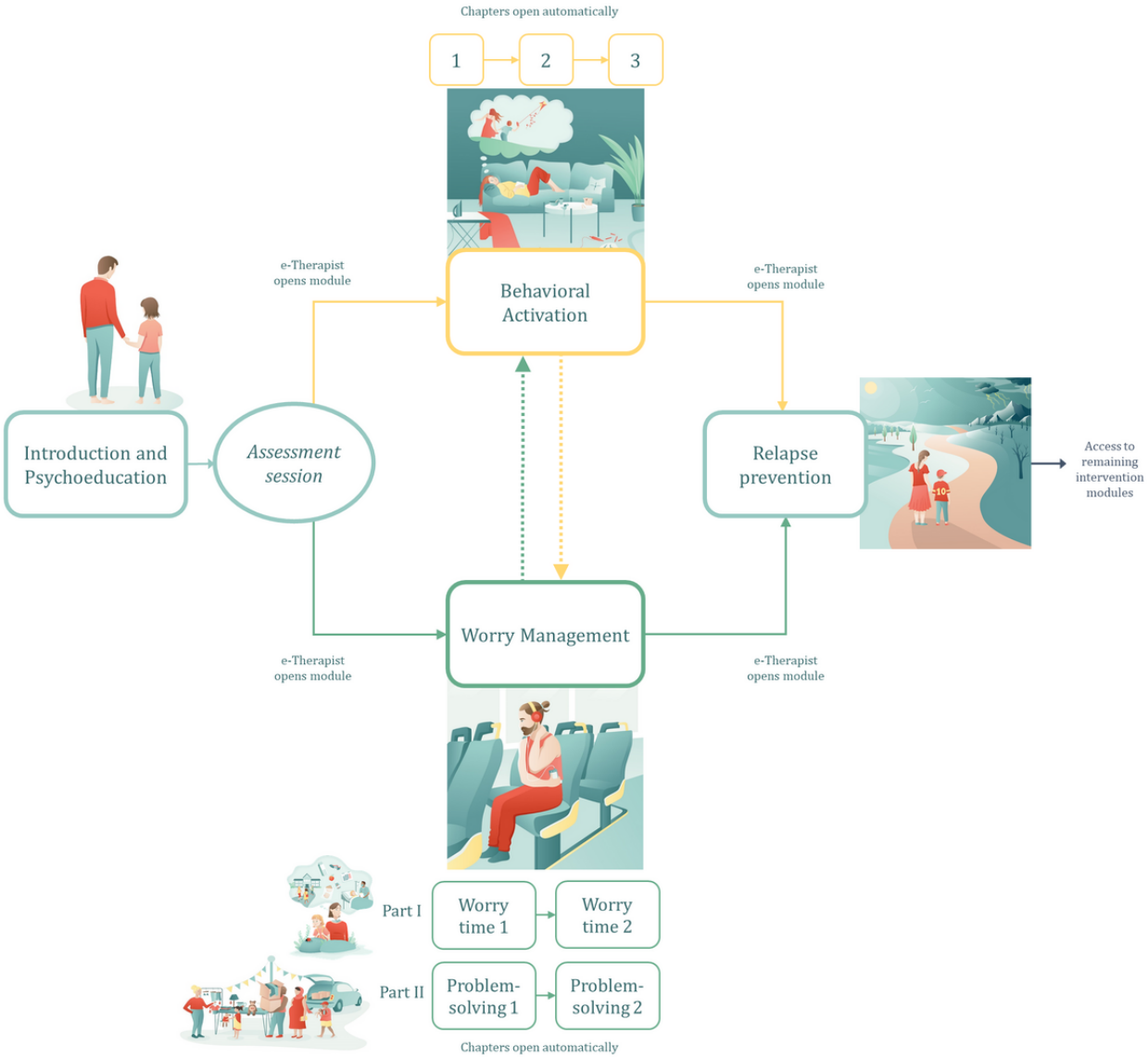
EJDeR is delivered on the portal and includes text, illustrations, film, audio files, and a frequently asked questions section. The About Us section presents photos and a brief biography of the EJDeR authors to verify author credibility, previously shown to be important when providing remote treatment [87]. Technical help texts are available throughout EJDeR to support parents to use all functions. To visually present how EJDeR appears to parents, sample screenshots from the intervention can be seen in Figure 3.

Figure 3. Sample screenshots of EJDeR. EJDeR: internetbaserad självhjälp för föräldrar till barn som avslutat en behandling mot cancer.



Parents initially complete the introduction and psychoeducation module, and after the initial assessment session, e-therapists provide access to the module containing the LICBT technique best suited to their main presenting difficulty (BA or worry management). After completion of BA or worry management, a collaborative decision between the e-therapist and parent may be reached to progress to the other LICBT technique; however, parents only work with a single LICBT technique at a time. A detailed description of the module content is found in TIDieR item 4, and an overview of the structure of EJDeR is shown in Figure 4.

Figure 4. An overview of the structure of EJDeR. EJDeR: internetbaserad självhjälp för föräldrar till barn som avslutat en behandling mot cancer.



Consistent with the LICBT approach, participant engagement with the techniques is facilitated through in-module exercises and weekly homework exercises completed on the portal and submitted to the e-therapist (see Figure 5 for an example). To provide choice, homework exercises can also be printed and completed offline, and parents subsequently complete a weekly homework review on exercise on the portal. Parents can access copies of all weekly homework exercises and audio files in a web-based library in the portal.

Figure 5. Sample exercise worksheet from EJDeR. EJDeR: internetbaserad självhjälp för föräldrar till barn som avslutat en behandling mot cancer.

Intervention Training

e-Therapists are provided with a portal handbook, with instructions on how to use EJDeR and training videos on the delivery of the BA and worry management techniques. e-Therapists review parent progress through the modules and any completed in-module exercises and homework exercises on the portal.

TIDieR Checklist Item 4: Procedures, Activities, and Processes Used in the Intervention

Module: Introduction and Psychoeducation

Parents are provided with a brief introduction of how to use EJDeR. Psychoeducation about psychological distress in the context of being a parent of a child treated for cancer is also provided. Parents are introduced to two case vignettes that are used throughout EJDeR based on the Five Areas CBT model [88,89] to facilitate an understanding of the CBT rationale. To enhance engagement, case vignettes were informed by our previous research [5,51]. Parents (1) complete their own Five Areas CBT model; (2) identify areas of importance and value in their life; and (3) set three goals that are specific, positive, and realistically achievable. Parents are presented with the two case vignettes briefly outlining the techniques parents will work with during EJDeR.

Alongside completion of this module, parents take part in an initial assessment session with an e-therapist (see *TIDieR checklist Item 6*) to determine the parent's main presenting difficulty. The e-therapist provides access to the BA module for parents experiencing depression and the worry management module for parents experiencing GAD.

Module: BA

The full clinical protocol for BA has been described elsewhere [67-69]. Activities that make up a normal life routine are categorized into three types: (1) routine (providing life structure and typically repeated during the week, such as housework and cooking); (2) pleasurable activities that provide a sense of pleasure or enjoyment that are determined by the parent; and (3) necessary activities that are recognized as having the potential for serious negative consequences if not done (eg, attending hospital appointments, taking medication, or paying a bill). Parents are gradually supported to re-engage with activities they have stopped, aiming to re-establish a balance of routine and pleasurable activities, and where required, include necessary activities. The clinical protocol includes four main steps (identifying current activities, identifying stopped activities, organizing activities, and planning activities). As an adaptation, an additional step entitled Prioritizing Activities was added, recognizing that parents commonly experience difficulties trying to balance their home, work, and family life after cancer treatment has ended [5]. Parents may need to reprioritize routine activities to gain opportunities to re-engage with neglected pleasurable activities. A case vignette is used to guide parents through BA, including examples of completed exercises and occasions where setbacks are experienced, and to provide guidance and feedback on the use of BA [60,61]. Parents are encouraged to work with BA, with the exact number of weeks required decided collaboratively between the parent and e-therapist.

Module: Worry Management

The clinical protocol for worry management has been described elsewhere [54,70,71]. Parents capture worries over a week in a worry diary and categorize worries into two types: (1) practical (eg, important and can be solved) and (2) hypothetical (eg,

important but have no way of being solved, such as worries relating to past events, things that might happen in the future, or things that cannot be controlled). Parents review the types of worries they have captured and determine whether a particular type (eg, practical or hypothetical) has a greater impact and is more distressing. Parents are encouraged to use problem solving for practical worries and worry time for hypothetical worries. A case vignette is also used to guide parents through worry management. Parents continue to work with worry management, with the number of weeks decided collaboratively between the parent and the e-therapist. Parents may work with both worry time and problem solving.

Module: Relapse Prevention

This module is based on a relapse prevention protocol for LICBT [54,68] and is completed at the end of the 12-week intervention period or before if a collaborative decision is made between the parent and the e-therapist. Parents identify warning signs that may indicate relapse using the Five Areas CBT model [88,89] completed in the introduction and psychoeducation module. Next, parents identify what activities, skills, and techniques they have learned and found helpful during EJDeR to inform a staying-well toolkit. Parents are encouraged to make a written commitment to check-in with themselves, initially on a weekly basis, to consider what warning signs they may be experiencing. If parents find themselves experiencing warning signs, they should use their staying-well toolkit to identify how to address these.

TIDieR Checklist Item 5: Expertise, Background, and Specific Training Given to Intervention Providers

EJDeR is designed to be guided by e-therapists trained in the competencies required to support LICBT [90]. Within the IAPT program [27], guidance is provided by a psychological well-being practitioner workforce, where practitioners receive 9 months of graduate or postgraduate level training and are not required to have a core health or mental health professional qualification [34]. In Sweden, there is no psychological well-being practitioner workforce. Therefore, e-therapists are intended to be psychology program students, in at least their fourth year of study, including a term of advanced studies in CBT and those who have not yet gained an accredited mental health professional qualification.

A 2-day training program for EJDeR was provided to e-therapists by intervention authors PF (IAPT program LICBT national expert advisor and clinical lead, accredited cognitive behavioral psychotherapist and chartered psychologist) and JW (research psychologist, expert in LICBT, and teacher on educational programs to train mental health professionals using LICBT), a Swedish licensed psychologist, and 2 research assistants (MSc level). Training focuses on developing an understanding of (1) LICBT, (2) BA, (3) worry management, (4) difficulties commonly experienced by parents of children treated for cancer, (5) the structure of EJDeR, (6) support protocols, and (7) using the portal.

e-Therapists receive weekly group clinical supervision via videoconferencing or face-to-face with a licensed psychologist with expertise in the population and internet-administered CBT. On-demand individual supervision with a licensed psychologist is provided, if required.

TIDieR Checklist Item 6: Modes of Delivery

The Portal

The portal [64,65] incorporates security and safety features to ensure sensitive information management, including (1) user log-in via bank ID (a citizen authentication system used in Sweden); (2) access through an encrypted connection using an HTTPS protocol; (3) protection of the webserver via Uppsala University's secure firewall, allowing only http secure traffic; and (4) storage of study data on a separate database to personal data (eg, the parent's identity and contact details) with both databases encrypted using 256-bit transparent data encryption. User action logging is enabled via action metadata management to allow user behavior analysis, including (1) log-ins; (2) log-outs; (3) opened modules; (4) section views (eg, the library); (5) opening PDFs; (6) homework entries, (7) multimedia (eg, audio and video) file consumption (including play, pause, and stop); and (8) time-stamp data. Message logging is also enabled, for example, the number of automated reminders sent via SMS text messaging or email, and the number of written messages sent between the e-therapist and the parent within the portal. A number of persuasive system design elements [91,92] are integrated to improve intervention adherence: (1) tunneling (eg, intervention content delivered in a predefined step-wise order to guide users through the intervention); (2) tailoring (eg, intervention content is personalized to user needs, ie, their main presenting mental health difficulty); (3) personalization (eg, reminder messages include the parent's first name); (4) self-monitoring (eg, mood monitoring via a visual analog scale); (5) rehearsal (eg, exercises are repeated); (6) reminders (eg, automated messages to remind parents to perform specific actions); (7) similarity (eg, use of case vignettes); and (8) liking (eg, use of professional illustrations).

e-Therapist Guidance

Guidance is provided to parents by a secure inbuilt videoconferencing system, written messages via the portal, and over the telephone. e-Therapists hold an initial assessment session with the parent informed by existing protocols [68] via videoconferencing or telephone. At the end of the assessment, a decision is made concerning which LICBT technique is best suited to the parent depending on their main difficulty (eg, depression or GAD). Thereafter, e-therapists provide weekly guidance via written messages within the portal, informed by evidence suggesting frequent support is associated with adherence [93]. Weekly written messages are informed by an existing brief check-in support protocol [68] and include (1) reviewing and providing feedback on weekly homework exercises; (2) reinforcement of progress made; (3) normalization of any difficulties encountered; (4) assistance with problem solving difficulties and directing the parent to advice in the EJDeR intervention; (5) setting a plan for the use of EJDeR over the coming week; and (6) encouragement to support continued motivation and engagement. The brief check-in support protocol [68] is informed by the ICBT Therapist Rating Scale [94] and designed to minimize the use of undesirable e-therapist behaviors [95]. e-Therapists may provide at-need

written support via the portal if requested and are required to respond to parents within 1 working day. Parents receive a booster session via videoconferencing or telephone halfway through EJDeR to review and assess progress, identify and provide assistance for problem solving any difficulties experienced, and provide continued encouragement and motivation.

TIDieR Checklist Item 7: Location

e-Therapists were located at Uppsala University, Sweden. EJDeR can be assessed on PCs, smartphones, and tablets.

TIDieR Checklist Item 8: Timing, Duration, and Intensity

EJDeR is designed to be delivered over 12 weeks. The initial assessment session lasts approximately 45 minutes and the booster session lasts for 30 minutes. e-Therapists are expected to spend 20-30 minutes per parent each week, providing weekly written messages via the portal. Parents are expected to complete the introduction and psychoeducation module and one LICBT intervention module (eg, BA or worry management).

TIDieR Checklist Item 9: Tailoring the Intervention

Content has been closely developed alongside PRPs and has been informed by research identifying the experiences, distress, needs, and preferences for support of parents of children treated for cancer [5,6,49-52]. Examples of tailoring for the population include (1) the use of case vignettes of parents using the intervention, which were informed by our previous research to enhance realism and relevancy [5,51]; (2) professional illustrations depicting parents throughout the intervention; (3) the inclusion of psychoeducation in the context of the situation of being a parent of a child treated for cancer (eg, fear of cancer reoccurrence); (4) the choice between attending the initial assessment session via telephone or videoconference [51]; and (5) the inclusion of a midintervention booster session [51].

TIDieR Checklist Item 10: Modifications of the Intervention

EJDeR is currently being tested in a single-arm feasibility study, ENGAGE [96,97] (ISRCTN 57233429), with a baseline, posttreatment (12 weeks), and 6-month follow-up, with an embedded qualitative and quantitative process evaluation to inform a future phase III definitive randomized controlled trial. Findings from the embedded qualitative process evaluation will inform future potential modifications to the intervention. Any intervention modifications during the course of the study will be reported in the ENGAGE study results.

TIDieR Checklist Item 11: Assessing Intervention Adherence (Planned)

Videoconference and telephone guidance sessions are audio-recorded with informed consent. Overall, 15% of written communication and 15% of video or telephone communication between parents and e-therapists are reviewed by a member of the research team to assess e-therapist fidelity to the clinical protocol. Parent activity on the portal is logged to examine parent adherence, including the number of log-ins, opened modules, completed in-module and homework exercises via the portal, and the number of written messages via the portal sent to e-therapists.

TIDieR Checklist Item 12: Assessing Intervention Adherence (Actual)

Actual adherence to EJDeR will be reported in the results of the ongoing single-arm feasibility study ENGAGE [96].

Discussion

Principal Findings

The detailed description of EJDeR, in line with the TIDieR checklist, can help facilitate e-therapist fidelity to the EJDeR protocol during the ENGAGE study [98]. Furthermore, if EJDeR is implemented later, clinical delivery will be replicable.

Limitations and Strengths

Although public involvement was embedded within intervention development and resulted in valuable feedback and intervention changes, involvement was at a consultation level, with feedback provided on materials already developed by the research team. Involvement may have been enhanced by the greater engagement of PRPs earlier in the process. For example, holding in-depth discussion groups, involvement in writing the intervention, and development of case vignettes to add extra authenticity. PRPs only provided feedback on a written version of EJDeR and not when EJDeR was uploaded onto the portal, and was, therefore, reviewed outside of its intended context. However, an important objective of the ongoing study ENGAGE is to examine the acceptability and feasibility of EJDeR in more depth.

EJDeR does not include the collection of routine weekly clinical outcome measurements for clinical purposes, for example, to help inform treatment decisions. Instead, weekly clinical outcome measurements (depression, Patient Health Questionnaire-9; GAD, GAD-7; posttraumatic stress symptoms, PTSD Checklist for *DSM-5*, and PTSD Checklist-Civilian Version) were collected via the portal to inform a process evaluation for research purposes only [96]. Collection of clinical outcome measurements on a session-by-session basis is a core feature of the stepped care model to inform the treatment planning [27] and a core feature of the successful implementation of internet-administered CBT in routine health care [99].

Consistent with the single-strand LICBT interventions developed in England as part of the IAPT program, EJDeR was adapted to enhance the acceptability for the Swedish population. Adopting a more structured framework to inform the cultural adaptation of evidence-based psychological interventions may improve acceptability and relevance [100]. Finally, to ensure consistency with the LICBT approach, EJDeR targets depression and GAD. Therefore, EJDeR does not target all mental health difficulties commonly experienced by parents of children treated for cancer, such as PTSD [50]. Future psychological interventions developed for parents of children treated for cancer may target other difficulties.

Notwithstanding these limitations, the development of EJDeR was informed by a series of iterative research studies, including

evidence synthesis, conceptualization of distress, participatory action research, and a cross-sectional web-based survey, and therefore, it is strongly grounded in research on the population. Public involvement was embedded within the intervention development process, resulting in invaluable feedback and intervention changes. Development included translation by native Swedish speakers and subsequent back-translation by a professional translation company.

Comparison With Prior Work

To the best of our knowledge, this is the first LICBT intervention to be described in detail and in accordance with the TIDieR checklist [47]. Although LICBT clinical protocols have been published [68], the TIDieR checklist represents a systematic and structured approach to facilitating detailed intervention descriptions. The provision of a systematic and structured clinical protocol may be of particular importance, given that therapeutic drift [101] in supporting LICBT is commonly reported [102]. In addition, the content of LICBT interventions differs significantly [34,103] and is poorly described [104]. Furthermore, the use of the TIDieR checklist, alongside the application of further intervention fidelity measures, will facilitate determining the extent to which EJDeR is delivered as planned in the ENGAGE study, thereby increasing confidence in the results of any subsequent effectiveness trial [98].

Conclusions

Informed by phase I (development) of the Medical Research Council guidance for the development and evaluation of complex interventions [46], an overview of the development process is provided, along with a detailed description of the EJDeR intervention informed by the TIDieR checklist. The provision of a detailed and structured intervention protocol is of particular importance for the implementation of evidence-based treatments and reduction of research waste [48], providing procedures to maximize fidelity to protocols [98]. Reducing therapist drift is a core feature associated with the successful implementation of internet-administered LICBT [99].

Acknowledgments

This work was supported by the Swedish Research Council (grant numbers VR521-2010-3042, VR521-2014-3337, K2015-99X-20836-08-4, and 2018-02578), the Swedish Cancer Society (grant numbers 2007/1015, 2010/27, 2013/580; 2014/613, 140790, 150673, and 180589), and the Swedish Childhood Cancer Foundation (grant numbers PROJ08/010, PRO12/028, and PR2017-0005). The funders had no role in the study design, data collection and analysis, decision to publish, or preparation of the manuscript.

The authors would like to thank Anna Mautner and Nathalie Petersén (licensed psychologists), Laura Kukkola (doctoral student), and Kajsa Norbäck (MSc; project coordinator and intervention translation) for their work on the previous drafts of EJDeR. The authors are very grateful to the PRPs and e-therapists Agnes Hellgren and Caroline Sandström for sharing their expertise and time to work with the research team to develop EJDeR and enhance its suitability and relevance for parents of children treated for cancer.

The techniques used in the EJDeR program were derived from the Managing Your Worries LICBT intervention authored by PF, JW, and Ms Faye Small. Copyright University of Exeter (2019; acting through Clinical Education, Development, and Research (CEDAR); Psychology Department). Certain specific factors are derived from the BA protocol developed by Professor David Richards and Dr Mark Whyte (2011) and the problem-solving protocol developed by Professor Pim Cuijpers (2004). Graphic design was provided by ETC Communications, Stockholm, and all illustrations used in the EJDeR intervention were designed by Rebecka Porse Schalin.

Conflicts of Interest

None declared.

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Abbreviations

BA: behavioral activation
CBT: cognitive behavioral therapy
EJDeR: internetbaserad självhjälp för föräldrar till barn som avslutat en behandling mot cancer
GAD: generalized anxiety disorder
HICBT: high-intensity cognitive behavioral therapy
IAPT: Improving Access to Psychological Therapies
LICBT: low-intensity cognitive behavioral therapy
PRP: parent research partner
PTSD: posttraumatic stress disorder
SOC: selection, optimization, and compensation
TIDieR: Template for Intervention Description and Replication
U-CARE: Uppsala University Psychosocial Care Programme

Edited by G Eysenbach; submitted 18.08.20; peer-reviewed by M Vander Haegen, X Wang, D Collins; comments to author 18.11.20; revised version received 08.01.21; accepted 17.06.21; published 22.07.21.

Please cite as:
Woodford J, Farrand P, Hagström J, Hedenmalm L, von Essen L
Internet-Administered Cognitive Behavioral Therapy for Common Mental Health Difficulties in Parents of Children Treated for Cancer: Intervention Development and Description Study
JMIR Form Res 2021;5(7):e22709
URL: https://formative.jmir.org/2021/7/e22709
doi:10.2196/22709
PMID:34142662

Original Paper

Experience of Peer Bloggers Using a Social Media Website for Adolescents With Depression or Anxiety: Proof-of-Concept Study

Sana Karim[1], MS; Kimberly Hsiung[2], MS, MD; Maria Symonds[3], BS; Ana Radovic[4], MSc, MD

[1]Children's Hospital of Pittsburgh, University of Pittsburgh, Pittsburgh, PA, United States

[2]University of Pittsburgh School of Medicine, Pittsburgh, PA, United States

[3]McLean-Franciscan Child and Adolescent Inpatient Program, Franciscan Children's, Brighton, MA, United States

[4]Division of Adolescent and Young Adult Medicine, University of Pittsburgh School of Medicine, UPMC Children's Hospital of Pittsburgh, Pittsburgh, PA, United States

Corresponding Author:
Sana Karim, MS
Children's Hospital of Pittsburgh
University of Pittsburgh
120 Lytton Ave
Pittsburgh, PA
United States
Phone: 1 4126247000
Email: sana.karim3@chp.edu

Abstract

Background: Supporting Our Valued Adolescents (SOVA) is a moderated and anonymous social media website intervention. SOVA ambassadors are adolescents and young adults (AYA) asked to write monthly blog posts and comments on others' posts on topics surrounding mental health.

Objective: This study aims to understand the feasibility and acceptability of peer blogging for a moderated mental health intervention website and explore whether bloggers—AYA who self-report symptoms of depression and anxiety—experience potential benefits.

Methods: AYA aged 14 to 26 years with a self-reported history of depression or anxiety were recruited to the SOVA Peer Ambassador Program. Participants were asked to write one blog post a month and comment at least four times a month on other blog posts, for which they were compensated for up to US $15 monthly. Outcome variables measured at baseline and 3 months after intervention included website usability and feasibility, depressive symptoms, anxiety symptoms, mental health treatment history, cybercoping, personal blogging style, self-esteem, loneliness, mental health stigma, social support, and positive youth development characteristics. Open-ended questions were asked about their blogging acceptability and usability.

Results: Of 66 AYA showing interest and completing onboarding, 71% (47/66) wrote at least one blog post, with an average of 3 posts per person. A sample of 51% (34/66) of participants completed a 3-month survey for the full analysis. Almost all 34 participants were satisfied with the experience of blogging (32/34, 94%) and rated the website usability as good (80.1, SD 14.9). At 3 months, self-esteem scores increased by 2.1, with a small-medium effect size (P=.01; Cohen d=0.45), and youth competence and confidence increased by 0.7 (P=.002) and 1.3 (P=.002), with medium effect sizes (Cohen d=0.62 and 0.60), respectively.

Conclusions: A blogging intervention for AYA with a history of depression or anxiety was feasible with regular and active engagement and shows evidence in a one-sample design for positive changes in strength-based assets—self-esteem, competence, and confidence—which map onto resilience.

(JMIR Form Res 2021;5(7):e26183) doi:10.2196/26183

KEYWORDS

adolescent; social media; blogging; depression; anxiety

Introduction

Background

Almost 12% of adolescents have depression and up to one-third have anxiety [1]. Suicidality contributes to US $12 billion in hospital costs [2], with one-third depressed adolescents experiencing suicidality and 11% having attempted suicide [3]. Less than half of the patients receive treatment [4], with initial treatment delayed by 10 years [5]. Less than one-fifth of adolescents with anxiety use mental health services [6].

Some of the most important barriers preventing adolescents from seeking help are a lack of mental health knowledge [7] and negative beliefs about treatment [8]. Despite these barriers, youth actively talk about experiences with depression and anxiety in web-based social environments [9-12], often seeking support [13,14]. A web-based environment may be best suited to reconsider negative health beliefs, as adolescents discuss their depressive symptoms on web [15,16], use social media for identity exploration [17], and for social norms setting [18]. This suggests that the web-based environment is a point of entry to begin talking about mental health symptoms, find support, and consider help-seeking.

Supporting Our Valued Adolescents (SOVA) is a moderated web-based intervention designed to increase mental health knowledge, address negative health beliefs, and grow an anonymous web-based social support community for adolescents (Figure 1). The SOVA Blogging Ambassador Program is an accompanying intervention to SOVA, where participating adolescents and young adults (AYA) contribute authentic article content as a more interactive opportunity to offer peer support. Several observational studies found that individuals who write on web about their health experience improvement in social connectedness [19] related to self-disclosure [20] and an increase in meaning making [21], including making sense of illness [22]. Adolescents writing about peer difficulties as part of an experimental study had a decrease in their social-emotional difficulties when they wrote in a web blog open to reader commenting versus one that was closed [23]. The theory of change for the intervention can be viewed in Figure 2; a preview of the intervention can be viewed in Figure 3.

Figure 1. Supporting Our Valued Adolescents (SOVA) intervention design.

Figure 2. Supporting Our Valued Adolescents (SOVA) theory of change.

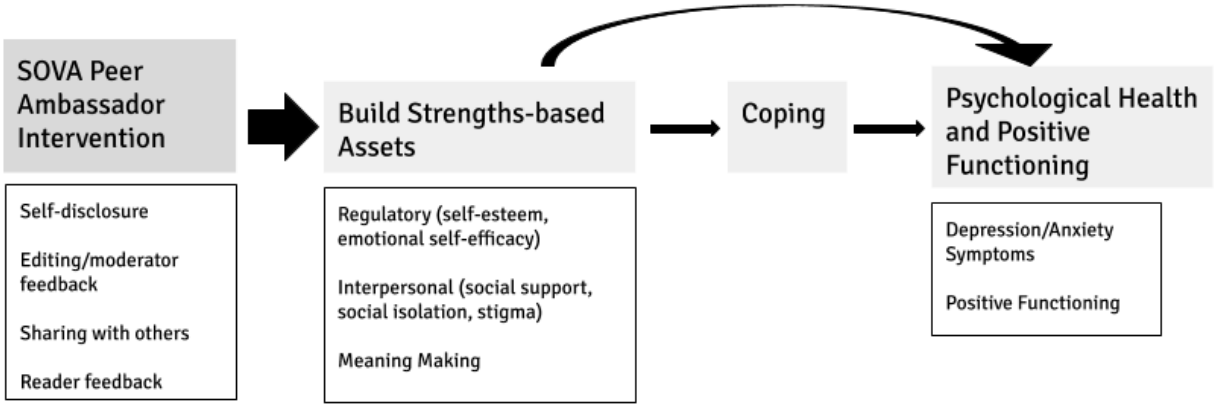
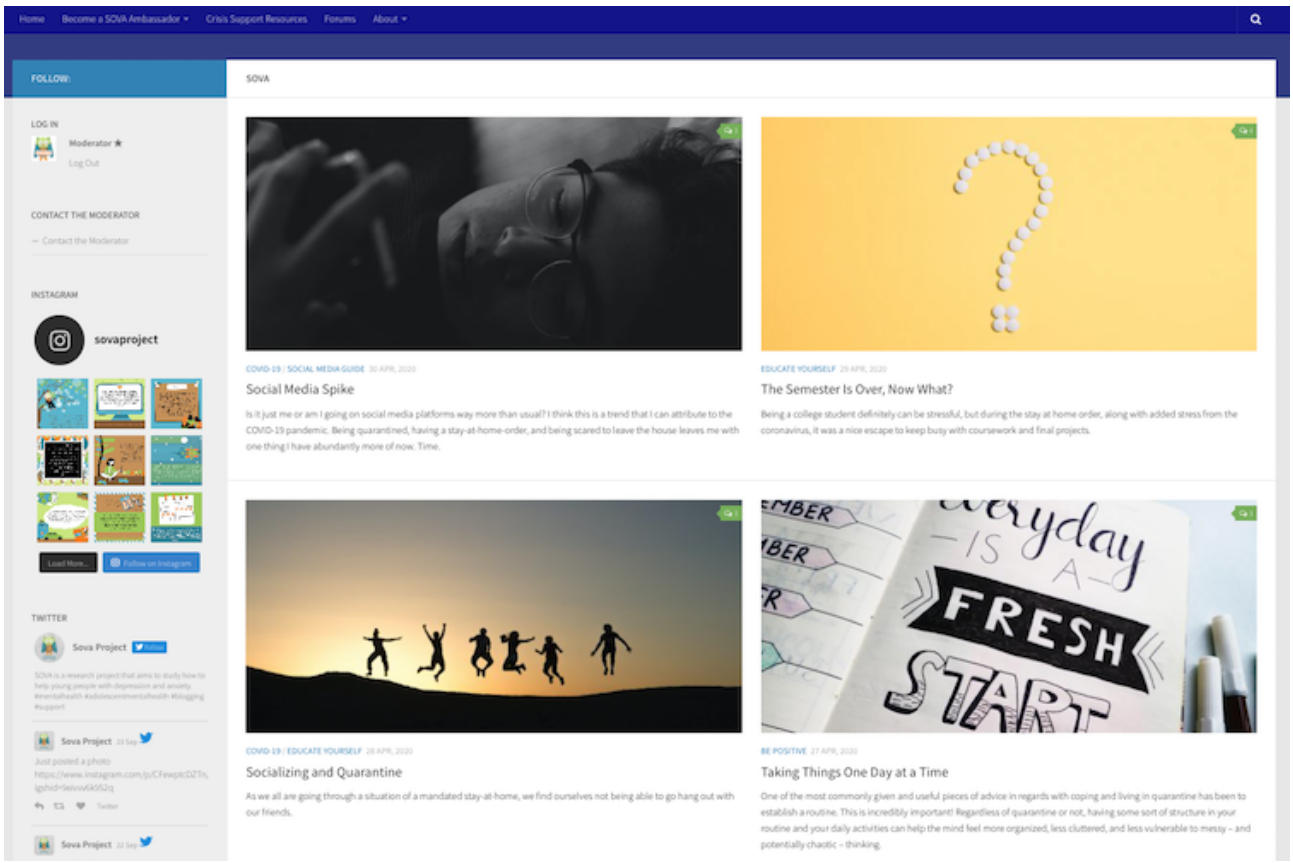


Figure 3. Preview of Supporting Our Valued Adolescents intervention (captured November 2020).



Objectives

The SOVA Blogging Ambassador intervention offers opportunities for self-disclosure, sharing with others, and reader feedback. Reflecting on how to self-disclose a highly emotionally charged event in a readable way that is not self-defeating may help with regulatory strengths. Writing a post for readership or commenting on others' posts may involve fostering web-based connections. Composing a post may involve making meaning of a lived experience to share with a reader audience and the capacity to find meaning, especially in difficult life events, can promote positive mental health [24]. This is especially relevant as many AYAs are experiencing multiple hardships because of the COVID-19 pandemic, including disruptions to their educational and career pursuits, increased rates of depression and anxiety, and social isolation [25].

This paper describes a single-arm exploratory trial of the SOVA Peer Ambassador Program to understand the feasibility and acceptability of monthly blogging for the SOVA sites, and to understand the initial benefits AYA with depression or anxiety may experience blogging. We specifically desired to understand the feasibility of engaging users to blog on the SOVA site, measured by blogging frequency; learn what prompted AYA to blog, and whether there were differences between those who showed interest but did not write blog posts and those who did write blog posts; and explore whether SOVA ambassadors experience psychological benefits or resilience, specifically examining depressive symptoms, anxiety symptoms, self-esteem, emotional self-efficacy, social support, social isolation, and stigma.

Methods

Recruitment

Approval for the study was obtained from the University of Pittsburgh Institutional Review Board. Participants were recruited using various methods, including fliers and posted advertisements at an academic medical center AYA clinic and local college campuses and the University of Pittsburgh's web-based recruitment database Pitt+Me. Study advertisements were posted on the Instagram page (@sovaproject) and distributed during community mental health conferences and presentations.

Once participants emailed confirming an interest in the study, they created an anonymous username on SOVA and completed a screening survey to determine eligibility. Potential participants were included if they were between the ages of 14 and 26 (inclusive), capable of reading and writing English, completed the sixth grade, had internet and email access, and self-reported current or prior symptoms of anxiety or depression. Those with severe social isolation scores and depressive symptoms indicated on the Patient Health Questionnaire-9 (PHQ-9) were allowed to participate, but those who endorsed suicidality with the intention to act or had a history of a suicide attempt with no subsequent follow-up treatment were excluded from the study and provided crisis resources.

Those who qualified for the study completed a web-based consent form and confirmed that they were interested in continuing. Parental permission was waived by the Institutional Review Board to allow those between 14 and 17 to easily participate because of minimal risk and because some parents may be unaware of their child's mental health symptoms. Participants were then sent a web-based baseline survey through Qualtrics.

After completing the baseline survey, the SOVA Peer Ambassador Advisor arranged a meeting time to explain the blogging process over the phone to complete onboarding. The 10-minute call provided an opportunity for participants to ask questions, reminded the participant that blogging was not a replacement for therapy, and covered the study protocol as detailed below.

Participants were encouraged to write one blog post a month on any mental health topic. These posts were classified into four categories: *Be Positive, Educate Yourself, Social Media Guide, and Links.* When participants began writing for the website, there were already about 160 articles published by the research team to help set a standard for writing style and web-based community norms. All blog posts were reviewed for factual accuracy, sensitive content, and grammar. Feedback was provided via email from the advisor. The advisor and site moderators of the SOVA website were all trained to address blog posts or comments posted by participants, which suggested that they were at risk for harming themselves or others.

Participants were encouraged to leave comments on other blog posts on SOVA. These could be in response to the questions at the end of the blog post by the moderator to elicit comments, or about whatever they wished to respond to another participant's blog post. Participant blog posts were uploaded to the SOVA website on weekdays, excluding major holidays, along with posts written by the research team. Participants were sent a postsurvey via email, 3 months after the phone call. Participants received compensation on a prepaid debit card based on how frequently they contributed to the website. They received US $10 if they wrote a blog post a month and an additional US $5 if 4 comments were left on the website in the same month. Participants were paid US $10 upon completion of the 3-month postsurvey. There was no official duration; participants could withdraw at any time and when they turned 27 and aged out of the study.

Measures

Demographics

The baseline survey included questions about age, gender identity, sexual orientation, socioeconomic status [26], race, and ethnicity. Demographics were not initially recorded to ensure full anonymity for the study but were added in July 2019. Because this sample included participants who joined before July 2019, they will not be included in the analysis for this study.

Usability

The System Usability Scale [27] (Cronbach α=.88) is a robust and versatile tool used to assess users' subjective ratings of product usability. Ten items are rated on a 5-point Likert scale (1=strongly disagree to 5=strongly agree), and scores were scaled to a range of 0-100 [28]. The scale demonstrated strong structural validity and reliability using over 2000 surveys compiled from 206 studies. The mean usability score of the pool was 70.

Additional single-item questions were asked to assess feasibility. User-friendliness was assessed through the question, "Overall you would rate the user-friendliness of this site as:" followed by 7 response options (1=worst imaginable; 7=best imaginable). Dichotomous items include, "Were you satisfied with the experience of blogging for this project?," "Did you access the website?," and "Did you gain something from blogging?" All feasibility questions were asked at 3 months.

Depressive Symptoms

The PHQ-9 (Cronbach α=.86), modified for adolescents, is a 9-item diagnostic tool used to assess depression severity [29,30]. Each item of the questionnaire is scored on a 4-point Likert scale (0=not at all; 3=nearly every day) with different scores indicating different levels of depression (5-9: mild, 10-14: moderate, 15-19: moderately severe, and ≥20: severe). A score of ≥11 was considered a positive screen for clinically significant depression. The scale included 2 additional questions: "In the past year have you felt depressed or sad most days, even if you felt okay sometimes?" that had dichotomous response choices and "If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?" The second question was scored on a 4-point Likert scale (1=not difficult at all; 4=extremely difficult). The PHQ-9 has been found to be a reliable and valid measure of depression severity [29], and the

PHQ-9 has been validated for diagnostic accuracy in this age group [30].

Anxiety Symptoms

Anxiety symptoms were assessed using the Screen for Child Anxiety Related Emotional Disorders—Child Version—5 (Cronbach α=.52), a 5-item short-form self-report screening tool for childhood anxiety disorders [31]. Items were rated on a 0-2 point rating scale, with 0=not true or hardly ever true, 1=somewhat true or sometimes true, and 2=very true or often true. Total scores of ≥3 were considered as a positive screen for clinically significant anxiety with 74% sensitivity and 73% specificity. The Screen for Child Anxiety Related Emotional Disorders—Child Version—5 has demonstrated adequate validity for use in screening anxiety disorders in community settings [31].

Personal Blogging Style

The Personal Blogging Style Scale [32] is a 25-item scale used to characterize individuals' blogging styles as therapeutic (Cronbach α=.58; directed to concerns of bloggers than blog readers), substitution (Cronbach α=.62; focus on interaction with others as a substitute for social networks), self-censoring (Cronbach α=.13; focus on positive portrayal and self-presentation over open communication), and connected (Cronbach α=.29; focusing on connecting and communicating with others rather than solving emotional problems). Only participants who reported having written blogs before completed this scale. Response options used a 5-point Likert scale (1=completely disagree; 5=completely agree). Scores were calculated by summing the relevant item ratings. The Personal Blogging Style Scale has been found to have good validity and reliability in identifying blogging styles [32].

Cybercoping

Cybercoping, or the act of problem solving in cyberspace, was assessed using items from the Developing Coping Skills Online scale, a 30-item scale used to assess web-based coping skills of those with chronic diseases [33]. As mental health conditions are highly comorbid with chronic physical illnesses [34,35], carry a heavy global burden of disease [36], and are considered to be a chronic condition by the Centers for Medicare and Medicaid Services [37], this scale was determined to be suitable for the study. Only patients who reported having read blogs before completed this scale. Domains deemed relevant by the study authors include enhancement of emotion-focused coping (6 items; Cronbach α=.92), enhancement of problem-focused coping (5 items; Cronbach α=.71), and affective coping outcome (4 items; Cronbach α=.93); domains that were not included were those that pertained to physical diseases. Response options used a 7-point scale (1=not at all; 7=very much). Scores were summed, with higher scores indicating higher coping capabilities and outcomes. The original 30-item scale demonstrated adequate structural and construct validity among individuals with chronic conditions, including depression [33].

Self-esteem

The 10-item Rosenberg Self-Esteem Scale (RSES) [38] (Cronbach α=.89) was administered to assess participants' self-esteem. Items on the RSES ask about self-worth and self-acceptance and are scored using a 4-point scale (1=strongly disagree; 4=strongly agree). The scores on each question were summed together, with higher scores indicating greater self-esteem. The RSES is the most widely used measure of global self-esteem in the literature [39] and demonstrates concurrent, predictive, and construct validity with significant correlations with other measures of self-esteem and predictive measures of depression and anxiety [40].

Emotional Self-efficacy

Emotional self-efficacy was assessed using the Mental Health Self-Efficacy Scale (MHSES; Cronbach α=.74). The MHSES was developed according to Bandura guidelines to create self-efficacy questionnaires [41]. The questionnaire contains 5 items asking about the participants' confidence level in performing mental health self-care behaviors. Scoring of the MHSES is based on a 5-point Likert scale (0=disagree very much; 5=agree very much).

Social Isolation

The revised University of California, Los Angeles Loneliness Scale was administered to all participants to measure social isolation (Cronbach α=.93). This 20-item scale measures one's feelings of social isolation and is scored using a 4-point scale (1=never; 4=often) [42]. The revised measure was updated to counter the possible effects of response bias and was shown to have evidence of concurrent and discriminant validity among college students [42].

Perceived Stigma

Perceived stigma was assessed using the 9-item Depression Stigma Scale and perceived stigma factor [43] (Cronbach α=.93). Items of the scale touch on different themes about depression, such as the extent to which depression is an illness, how much control people have over their depression, and the degree to which depression is seen as a character flaw or something that should not be discussed. Using a 5-point Likert scale (0=strongly disagree; 4=strongly agree), perceived stigma was measured by asking participants to rate their agreement with the statements based on what they think other people believe. The higher the score on the scale, the greater the stigma that a person has. The measure has been shown to have adequate internal consistency (Cronbach α=.82) and test-retest reliability in a population of individuals with depressive symptoms [43].

Social Support

The eight-item emotional and informational support subscale from the Medical Outcomes Study Social Support Survey [44] (Cronbach α=.93) was administered to participants to assess social support. This scale measures the level of emotional and informational support available to the participants. Each item is rated using a 5-point scale (1=none of the time; 5=all of the time). The Medical Outcomes Study Social Support Survey demonstrates reliability among a population of chronically ill patients and has been found to be fairly stable over time [44].

Positive Youth Development

Positive youth development was assessed using the Positive Youth Development Very Short Form (PYD-VSF) [45]. The PYD-VSF is a questionnaire that measures adolescent strengths

based on the Lerner and Lerner Five Cs of PYD [46]: competence (3 items, total score ranging from 3-12), connection (4 items, total score ranging from 4 to 20), confidence (3 items, total score ranging from 3 to 13), caring (3 items, total score ranging from 3 to 15), and character (4 items, total score ranging from 4 to 19). Items were heterogeneous in their response formats (ie, a mix of 4-point and 5-point scales). The PYD-VSF was shown to have structural validity evidence that ran parallel with its derivative, the PYD-Short Form, among a population of adolescents [45].

Participant History

Two additional questions were asked at both baseline and after 3 months regarding treatment history ("Have you ever received help from a professional psychologist or counselor for any personal or emotional problems you have experienced?" and "Have you ever used medication like an antidepressant for any personal or emotional problems you have experienced?") with dichotomous response options. At baseline, two additional questions were asked regarding blogging history ("Have you read a blog to help you understand your mental illness?" and "Have you ever written a blog? (y or n) Please describe below").

Open-ended Responses

Participants were invited to answer three open-ended questions at the baseline. All participants were asked, "Why are you interested in blogging." The other two open-ended questions asked participants about their experience in reading blogs to understand mental illness and write blogs if they answered "yes" to these questions about blogging history, as mentioned in the previous section.

In the 3-month survey, participants were invited to respond to eight open-ended questions about their experience with the website and if they had any feedback. Questions included the following: what prompted you to log on, why were you satisfied with the website, why were you not satisfied with the website, what were your reasons for continuing with the study, what worries did you have, what did you gain from the website, what did you like about the website, and what would you change about the website?

Having a space for participants to provide open-ended responses in their own words gave researchers a more detailed opportunity to review participant background and interest in both blogging and SOVA, as well as a space to give candid feedback.

Analysis

Baseline descriptive statistics were reported using means (SD) for continuous outcomes and frequencies (%) for dichotomous outcomes. The following comparisons were made: preintervention (baseline) and postintervention (3 months), baseline comparisons between bloggers who completed the 3-month survey and those who did not, baseline comparisons between those who blogged and those who did not, and baseline data between those who completed the 3-month survey and those who did not. These were performed using paired two-tailed *t* tests for continuous variables and McNemar test for dichotomous variables. Effect sizes were calculated using: Cohen *d*=mean of the difference/SD of difference [47]. To detect the actual blogging impact, a sensitivity analysis was performed by removing participants who did not blog (ie, nonbloggers) and then rerunning the paired comparisons. Model diagnostics showed no need for transformation of any variables. Missing data were not included in the *t* test. *P* values represent two-sided tests; results were statistically significant at $P<.05$.

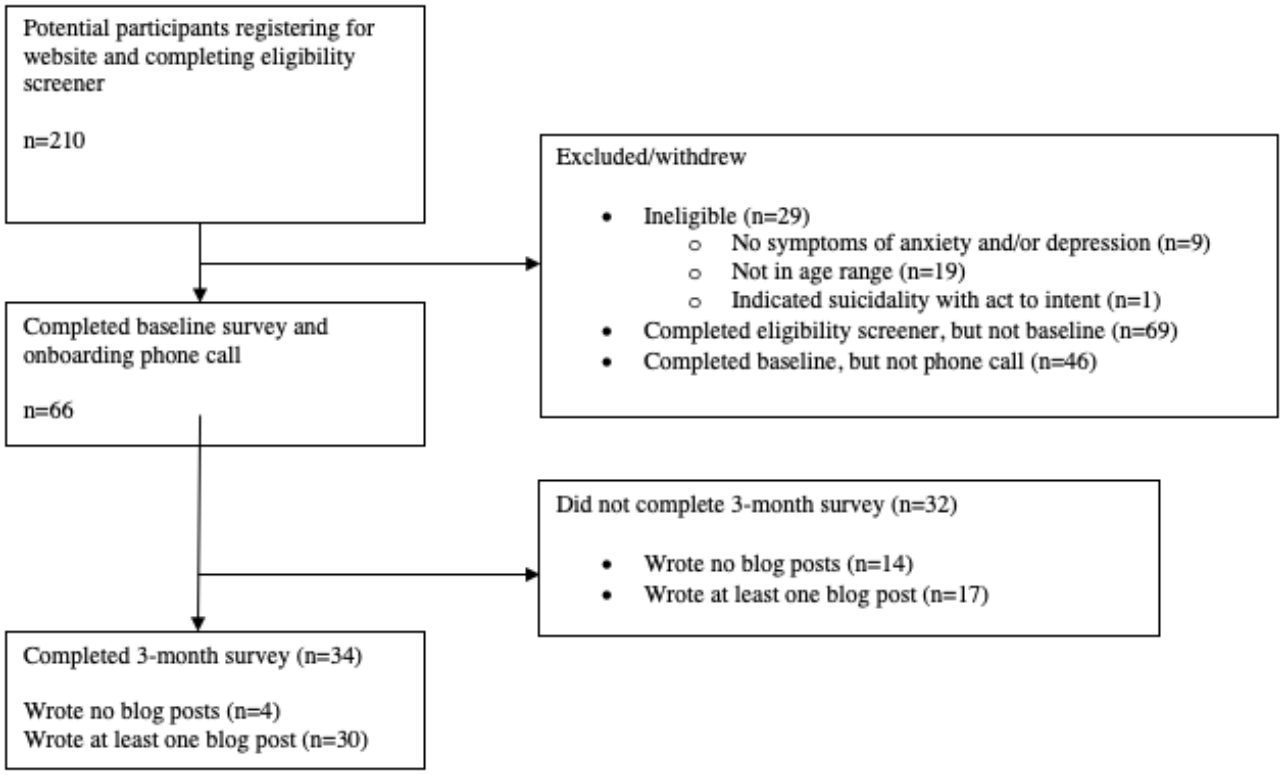
Text-based responses to open-ended questions were manually and individually reviewed and coded once to find any common themes by the first and third authors using content analysis and the approach of qualitative description as proposed by Sandelowski [48]. After reviewing both sets of codes, the first author developed a codebook for both baseline and 3-month free-text responses. These codes were then reviewed and discussed with the remaining authors to increase their validity. None of the authors reported any discrepancies, and there were no disagreements.

Results

Blogger Information and Participation

Overall, 66 AYA completed the onboarding process between April 2018 and July 2020, which included completing the baseline survey (full recruitment numbers are available in Figure 4). In this sample, 71% (47/66) of participants completed at least one blog post. In addition, 52% (34/66) completed the full 3-month survey. Participants were categorized into bloggers (ie, participants who wrote at least one blog post during the study) and nonbloggers (ie, those who did not contribute to any blog posts). There were no significant differences at baseline between bloggers and nonbloggers (Table 1), between completers and noncompleters of the 3-month survey, or between bloggers who completed the 3-month survey and those bloggers who did not, although data missingness greatly limits our interpretation of any differences.

Figure 4. Strengthening the reporting of observational studies in epidemiology recruitment diagram.



Participants who blogged had an average age of 20 years (SD 3.2); 40% (19/47) had a PHQ-9 score consistent with depression, whereas 87% (41/47) had a SCARED-C score consistent with anxiety. Most bloggers (40/47, 85%) had previously been seen by a professional psychologist or counselor, and 60% (28/47) had taken medications such as antidepressants.

No concerning blog posts or comments during the studied time period required reaching out to emergency contacts and sending crisis resources. There was only one blog post that was not posted; this was because of applying misinterpretations of bipolar disorder onto themselves. The participant was contacted and a moderator explained that the post had factually incorrect information, directing them to more information about bipolar disorder. The participants wrote a new post for that month instead.

Table 1. Comparison of baseline data between bloggers and nonbloggers.

Outcome	Bloggers (n=47)		Nonbloggers (n=18)		*P* value
	Value, mean (SE)	Participant, n (%)[a]	Value, mean (SEM)	Participant, n (%)[a]	
Depressive symptoms					
PHQ-9[b] score (range 0-27)	9.8 (0.8)	N/A[c]	12.8 (1.4)	N/A	.06
PHQ-9 score consistent with depression (range≥11)	N/A	19 (40)	N/A	9 (50)	.53
Anxious symptoms					
SCARED-C[d] score (range 0-15)	4.4 (0.3)	N/A	4.8 (0.7)	N/A	.62
SCARED score consistent with anxiety (range≥3)	N/A	41 (87)	N/A	13 (72)	.09
Treatment history (having ever received)					
Ever seen professional psychologist or counselor	N/A	40 (85)	N/A	17 (94)	.39
Ever taken medication like antidepressants	N/A	28 (60)	N/A	12 (67)	.67
Cybercoping (range 15-105)[e]	58.2 (4.4)	N/A	68.1 (6.6)	N/A	.22
Self-esteem (range 10-40)	25.6 (0.8)	N/A	26.1 (1.4)	N/A	.73
Mental health self-efficacy (range 0-20)	16.0 (0.4)	N/A	16.5 (0.8)	N/A	.56
Social isolation (range 20-80)	43.2 (1.6)	N/A	46.2 (2.5)	N/A	.32
Perceived stigma (range 0-36)	22.7 (1.2)	N/A	21.2 (1.9)	N/A	.54
Social support (range 8-40)	31.0 (0.9)	N/A	28.7 (1.7)	N/A	.19
Positive youth development					
Competence (range 3-12)	7.6 (0.2)	N/A	7.6 (0.4)	N/A	.88
Confidence (range 3-13)	7.0 (0.4)	N/A	7.7 (0.6)	N/A	.34
Character (range 3-19)	14.7 (0.6)	N/A	15.7 (0.8)	N/A	.47
Caring (range 3-15)	14.0 (0.2)	N/A	14.2 (0.3)	N/A	.68
Connection (range 4-20)	14.0 (0.5)	N/A	13.1 (0.6)	N/A	.28

[a]Calculations used exact sample sizes so that missing data were not included.

[b]PHQ-9: Patient Health Questionnaire-9.

[c]N/A: not applicable.

[d]SCARED-C: Screen for Child Anxiety Related Disorders-Child.

[e]Sample size is out of those who reported having read blogs before (ie, n=19 for bloggers, n=9 for nonbloggers).

Feasibility

Between April 2018 and July 2020, 31.8% (188/591) of the published blog posts were written by participants. There were no examples of technical difficulties from the participants regarding website use.

In the 3-month survey, 68% (23/34) reported logging on less than once per week, and 32% (11/34) logged on at least weekly. We analyzed and coded 272 free-response responses in the 3-month survey. The codebook for free-response questions in the 3-month survey is presented in Table 2. Participants were primarily prompted to log onto the website to engage with the website by reading the blogs, writing and responding to comments, and writing their blog. Others were prompted to fulfill the study requirements. No one was prompted because of external triggers, except for one participant who had set up calendar reminders to go on the website. Reasons provided for why they continued to blog included out of enjoyment for writing and being a part of and helping the website community. Other frequent reasons included having a space to vent and write to cope and for the monetary compensation.

Table 2. Three-month free-response codebook.

Category and code	Definition	Example
Community		
Not feeling alone	Participant mentions that the intervention has them relating to blog posts and feeling that what they are going through is not just happening to them	"I liked that I was able to connect with people similar to me." [ID 41]
Rejection from others	Participant worries that other participants will not enjoy, comment, or will judge their posts	"I worried whether or not people would appreciate what I had to say or if they would just brush it off as if I didn't know what I was talking about." [ID 63]
Helping others	Participant mentions using, continuing, or enjoy the intervention because they use their experience and posts to support others	"I want to help other people like me who suffer from mental illnesses" [ID 51]
Community support	Participant explicitly mentioned feeling a sense of community with other participants using intervention	"I gained a sense of community and support from people from all backgrounds. It is nice to be able to be vulnerable without the fear of being invalidated." [ID 44]
Writing	Participants indicated an interest in writing and writing skills, whether it was writing in general or the process of writing for the intervention	"I was able to improve my writing by blogging." [ID 69]
Barriers to blogging		
Time	Participant did not have enough time to use the intervention	"My primary worry is time, I am an incredibly busy college student and I was not sure I would have time to make comments and write blogs." [ID 106]
Ideas	Participant expressed worries about not having something to write about	"Maybe that I would run out of ideas." [ID 64]
Benefits to self		
Self-reflection	Participant enjoyed using the platform because it gave them an opportunity to reflect on their experiences	"Insight to my own strengths and weaknesses, tips from others, a sense of community." [ID 67]
Education and resources	Participant learned something by reading other blog posts or mentioned access to resources listed on website	"I've learned a LOT of information from reading other people's posts, including multiple apps/websites that I now use, which is just really cool and something that I didn't initially expect to get out of this experience." [ID 47]
Outlet	Participant mentioned that the intervention served as a place for them to openly talk about what they were going through	"It may be because of covid, but my mental health has been a rollercoaster, so I needed this blog to feel sane. The blogs have really helped me have a space to let out how I feel, and also learn from others." [ID 96]
Anonymity		
Benefit	Participant stated that they enjoyed the anonymity or confidentiality of the intervention	"I could be anonymous if I wanted to and I could speak my mind and see others who felt the same way." [ID 66]
Fear of losing anonymity	Participant expressed worry that someone could trace their blogs back to them	"I was worried that my blogs would be traced back to me. I would prefer to stay anonymous." [ID 73]
Mental health effect	Participant mentions any impact that the intervention had on their mental health	"I've gained better a perspective about mental health and the work that I am doing with my therapist." [ID 103]
Critiques	Criticisms, feedback, and recommendations that participants had about the intervention	"It took me a while to figure out how to blog as well as navigate the site." [ID 90]

The primary concerns that participants had about continuing to blog were time constraints and busyness that at times prevented them from contributing and feeling pressured to blog in addition to these constraints. Some were also concerned with running out of ideas and whether other users would like their content. A few participants mentioned worries about the website itself, with several mentioning that they were afraid of the risk of losing their anonymity.

Almost all (32/34, 94%) of the participants at 3 months were satisfied with their blogging experience. The reasons included the simplicity of the website, having a place to express themselves, receiving support from moderators and other users, and helping others. One user stated as follows:

> *If I were in high school again and I was able to see where I'd be five or ten years from that age, I would be amazed at my progress and would feel so hopeful about my future. This blog is successful in making that connection, and I fully support it's mission.* [ID 63]

A total of 82% (28/34) of participants reported having gained something from blogging. The overall mean usability score was 80.1(SD 14.9), 13% higher than that of the initial usability study [49]. The overall mean user-friendliness rating was 5.3(SD 0.8), consistent with good or excellent. When asked about what they gained, the majority of participants felt more comfortable, confident, and reassured about their writing abilities and feelings. Participants felt that they had gained considerable new information from the website.

Participants provided feedback on the design and function of the website. Many were satisfied with the variety of articles and the website's organization, navigability, and accessibility. Although 21% (7/34) said that they would not change anything about the website, the most common critique was that the website was difficult to navigate at first and wanted the site to be more interactive. Suggestions for site changes included a discussion board, a suggestion box for blog topics, and weekly polls.

Pre- and Postintervention Comparison

Baseline and 3-month outcome comparisons are presented in Table 3. For the full sample, self-esteem scores increased at 3 months by 2.2, with a small-medium effect size (P=.01; Cohen d=0.45), and youth competence and confidence increased by 0.7 (P=.002) and 1.3 (P=.002), with medium effect sizes (Cohen d=0.62 and 0.6), respectively.

Table 3. Baseline and 3-month outcome comparison.

Outcome	Baseline (N=34)		3 months (N=34)		Difference[a]		*P* value
	Value, mean (SE)	Participant, n (%)[b]	Value, mean (SE)	Participant, n (%)[b]	Value, mean (SE)	Participants, n	
Depressive symptoms							
PHQ-9[c] score (range 0-27)	9.8 (1.1)	N/A[d]	9.0 (0.7)	N/A	0.8 (0.9)	N/A	.41
PHQ-9 score consistent with depression (range≥11)	N/A	11 (32)	N/A	10 (29)	N/A	–1	.99
Anxious symptoms							
SCARED-C[e] score (range 0-15)	4.5 (0.4)	N/A	4.1 (0.4)	N/A	–0.4 (0.3)	N/A	.22
SCARED score consistent with anxiety (range≥3)	N/A	28 (82)	N/A	25 (74)	N/A	–3	.45
Treatment history (having ever received)							
Ever seen professional psychologist or counselor	N/A	29 (86)	N/A	28 (82)	N/A	–1	.99
Ever taken medication like antidepressant	N/A	17 (50)	N/A	19 (56)	N/A	2	.50
Cybercoping (range 15-105)	63.3 (6.6)	N/A	59.7 (6.4)	N/A	–3.6 (5.1)	N/A	.50
Self-esteem (range 10-40)	25.9 (1.0)	N/A	28.0 (0.9)	N/A	2.1 (0.8)	N/A	.01
Mental health self-efficacy (range 0-20)	15.8 (0.5)	N/A	16.1 (0.5)	N/A	0.3 (0.5)	N/A	.58
Social isolation (range 20-80)	43.5 (2.1)	N/A	40.0 (2.1)	N/A	–3.5 (1.8)	N/A	.06
Perceived stigma (range 0-36)	23.3 (1.6)	N/A	21.1 (1.5)	N/A	–2.2 (1.2)	N/A	.08
Social support (range 8-40)	30.9 (1.1)	N/A	31.9 (1.1)	N/A	1.0 (1.0)	N/A	.35
Positive youth development							
Competence (range 3-12)	7.6 (0.3)	N/A	8.3 (0.3)	N/A	0.7 (0.2)	N/A	.002
Confidence (range 3-13)	7.0 (0.5)	N/A	8.3 (0.4)	N/A	1.3 (0.4)	N/A	.002
Character (range 3-19)	14.4 (0.8)	N/A	15.6 (0.4)	N/A	–0.5 (0.4)	N/A	.19
Caring (range 3-15)	14.0 (0.2)	N/A	14.2 (0.2)	N/A	0.2 (0.3)	N/A	.52
Connection (range 4-20)	14.2 (0.6)	N/A	13.8 (0.5)	N/A	–0.5 (0.5)	N/A	.40

[a]Difference is expressed as the difference in mean (SE of the mean) for continuous variables and the difference in quantity for dichotomous variables.

[b]Calculations used exact sample sizes so that missing data were not included.

[c]PHQ-9: Patient Health Questionnaire-9.

[d]N/A: not applicable.

[e]SCARED-C: Screen for Child Anxiety Related Disorders-Child.

Discussion

Principal Findings

The SOVA intervention was designed to provide adolescents with mental illness symptoms an opportunity to blog and comment about mental health in an anonymous, peer-supported, and moderated space. The results of the surveys taken at baseline and at 3 months answered some of the initial research questions designed before the study, including the website's feasibility and usability, reasons to initially blog and continue to blog, and the effects on bloggers' mental health. First, the website had favorable feasibility and usability ratings. Second, participants primarily answered that they enjoyed writing and wanting to help others when asked why they continued to blog and participate in the intervention. This did not change after 3 months. In fact, after using the website, participants reported that they were satisfied with the blog and continued to do so because of the sense of community and they were able to help others and share their own experiences through their writing. Additionally, participants continued to use SOVA because they gained a place for self-reflection about their mental health. Third, bloggers found benefits for their mental health in areas of self-esteem, youth competence, and confidence.

Website Feasibility and Usability

The intervention's favorable feasibility and usability ratings, combined with the positive feedback in the 3-month surveys, suggest that peer blogging for SOVA is a feasible intervention for AYA who self-reported symptoms of mental illnesses such as anxiety and depression, even without any prior experience in blogging in general or about mental health topics. The site also proved to be usable and acceptable, particularly because of its simplicity and organization and, importantly, its anonymity.

The most common reason participants gave for barriers from blogging was that they were too busy and did not have enough time to go on SOVA, though there were comments that participants wanted to and did use the website when they had free time. Although busyness was a barrier from participants blogging on the website, SOVA can be an outlet for adolescents to manage their stress in their busy schedules, find coping mechanisms, and read articles by peers who may be going through similar stressors. However, because participants are not obligated to blog on the website, they may lose priority in their otherwise busy schedules. Older adolescents and AYA who experience emotional and mental struggles have also been shown to have negative adherence to treatment [50], which may apply to mental health interventions such as SOVA. Our intervention used compensation to show appreciation for content creation, and we found that submissions increased closer to the monthly deadline.

Reasons for SOVA Blogging

In text-based comments, participants indicated that enjoyment in writing motivated them to continue blogging at the site. In addition, most felt comfortable contributing to the SOVA website because of the anonymity of the website and its moderated nature. Although adolescents are largely on social media, the lack of anonymity on most platforms may prevent them from wanting to open up about their mental health in fear of others judging them because of stigma. Social media platforms that allow anonymity, but do not have moderation, have their own risks, such as cyberbullying [51] and spreading misinformation [52].

SOVA offers a middle ground between sharing information openly and staying anonymous. It does not allow users to have their usernames, blog posts, or comments to include personal information, thereby preventing exposing users to harm by having their content traced back to them. For safety purposes, users' contact information is collected but stored on a secure university server that is separate from the website. The intervention with the SOVA Peer Ambassador Advisor and moderators still allows users to be open and vocal enough to share openly in a welcoming, safe community.

The results of the intervention also suggest that SOVA serves more than a space for adolescents to discuss their mental health safely and anonymously. On the basis of their reasons for joining and continuing, there is a desire for advocacy and to be a source of peer support for others who may be struggling with their mental health. Participants genuinely wanted to help others because of their own experiences in dealing with problems with their mental health. This corresponds with findings about how younger generations today have a desire to help others and advocate for social justice issues and believe that social media is an effective outlet [53,54].

Given participants' reasons for blogging, SOVA seems to serve as a platform of social support as well as an outlet of therapeutic writing as a way to manage AYA stressors and symptoms. Interventions such as SOVA find a balance in anonymity and moderation that give users a space to open up without the fear of pushback, cyberbullying, being *exposed* to others they know, and misinformation.

Effects on Participant Mental Health

Participants had increased self-esteem, competence, and confidence. These findings are similar to other studies that have also found that users participating in adolescent forums to discuss mental health saw an increase in their confidence [55]. There are several reasons that may specifically explain the increase in these three domains in the SOVA intervention.

As previously discussed, participants joined and continued the study because of a desire to help others. Previous research has found similar results in the relationship between helping others and an increase in adolescents' self-esteem [56]. By helping others, adolescents have a more positive view of themselves, and this positive self-image can lead to increased confidence [56]. In our study, participants were motivated to blog to help their peers, felt that they did so in their responses in the 3-month survey, and thus had an increased positive view of themselves. This may additionally explain the nonsignificant results of the scores measured by the Positive Youth Development Scale. Participants already showed high scores and may have been the reason why they chose to participate in the study. There was little room for these participants to improve.

Most posts written by participants were of a psychoeducational nature. The ability to use their lived experience in the context of psychoeducation to support others—as evidenced to users by affirming comments received to posts they have written—may have changed prior beliefs that their mental illness is a character flaw into the belief that their experiences have provided them with competence in mental wellness.

Limitations

This study had several limitations. The major limitation is the small sample size and the lack of a control group. Although there were participants who joined and did not blog, nor did they use the website, the low number was not enough for us to make even comparisons between bloggers and nonbloggers at 3 months. There may be limited clinical significance for small to medium effect sizes, which is limited by the small sample size. Another limitation is that multiple comparisons were made using a small sample size. Due to the pilot nature of this exploratory study, we did not want to use methods that were too stringent to erase potentially significant results [57]. Instead, we interpret our findings as a signal to inform measures for future fully powered trials. A larger, more definitive study with a control arm is needed to further examine these findings.

In addition, selection and response bias likely accounted for the low response rate of 72% (34/47) of participants who blogged and completed the 3-month survey. We did not identify any significant differences between those who took the 3-month survey and those who did not. However, because the study is solely web-based with the goal of increasing blogger comfort by sharing personal stories on the internet, this may limit retention as the research team never comes face-to-face with participants. The intervention also had considerable flexibility. For example, the study did not require participants to blog every month. This flexibility may make adherence to the intervention more difficult, albeit more feasible for bloggers who cited a lack of time as a reason they may not blog. As a pilot feasibility study, this study provides groundwork for future studies that include more active recruitment and retention efforts while also including a control group that may reveal increasing severity of symptoms of depression or anxiety in the group not participating in blogging, as symptom severity was maintained at low levels throughout the study, and we cannot ascertain whether this is comparable with a comparison group. The participants were followed for only 3 months. This may be too little time to observe if there are any long-term changes in participants' mental health. Including additional surveys every 3 months for the first year of participation may be a stronger measure.

Recruitment methods and geographical location may have accounted for the lack of diversity in the study. Adolescents using the Pitt+Me database primarily consist of students attending a predominantly White institution; most of the participants being recruited from the database reflect these demographics. Future recruitment and similar interventions may need to consider more direct community outreach and utilizing outlets such as other social media platforms to find a more diverse sample, as well as a specific implementation intervention to enhance recruitment.

Due to its exploratory nature, this study did not have a complex study design, but the signal in the findings suggests that larger controlled studies with multiple time points and a more diverse sample are warranted.

Future Directions

Participants used SOVA to help others by sharing their experiences, while also having an outlet for themselves, and a place to write. The aim of the initial work was to understand the feasibility of involving participants in making a substantial contribution to the intervention. Future directions include recruiting a larger, more heterogeneous sample, especially as future studies to examine potential benefits require a larger sample. In particular, future implementation should work to understand how to bring blogging and its potential benefits to those who may not be as comfortable or as enthusiastic about writing as our own sample.

The beneficial effects of this exploratory study included an increase in confidence, self-esteem, and competence. Given these results, blogging of the SOVA websites may be a useful supportive intervention for AYA who have prior experience with mental health treatment and are seeking to maintain the skills and knowledge they have gained while providing peer-based psychoeducation to younger AYA who may have not yet sought help for depression or anxiety. Peer blogging ambassadors can act in a peer support role and provide informal advice through their experiences in their blog posts and responses in comments to others' blog posts. As SOVA attracted those who enjoyed writing, similar interventions can be used as a volunteering or job opportunity for aspiring young journalists to gain writing experience as well as competence in emotional wellness. Other future developments of SOVA can include a discussion board and more organizational tools to make the variety of topics on the website more accessible. In addition, future interventions can explore ways to increase website activity from participants in a manageable way that does not increase stress on busy schedules.

Conclusions

SOVA is a web-based intervention designed to create a space for AYA to access mental health information, share their own experiences with mental illness, and interact with others who share their own advice and experiences. The intervention serves as a middle ground between sharing anonymously and sharing openly in a welcoming in-person community. In this process of sharing, AYA seem to show a signal of experiencing benefits to increase their resilience and take something that was a perceived handicap and turn that into a strength. The need for virtual mental health interventions has increased because of COVID-19, particularly in AYA. SOVA has shown that carving out a space on the web for AYA to discuss their mental health journeys and needs not only gives them a community with others they can relate to but can improve their morale and confidence by helping others and themselves.

Acknowledgments

This project was supported by a career development award (NIMH 1K23MH111922-01A1). This research was also supported by the Pitt+Me Research Recruitment Program through the National Institute of Health Clinical and Translational Science Award (UL1 TR001857), by the Fine Foundation and by the Beckwith Institute, in part, by University of Pittsburgh Medical Center Children's Hospital of Pittsburgh. The authors thank Alyssa Davidson for website maintenance, and Kayla Odenthal, MSW, for recruitment assistance and site moderation. The authors thank and acknowledge the SOVA blogging ambassadors, community members, and stakeholders for informing this study and making it possible.

Conflicts of Interest

None declared.

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Abbreviations

AYA: adolescents and young adults
MHSES: Mental Health Self-Efficacy Scale
PHQ-9: Patient Health Questionnaire-9
PYD-VSF: Positive Youth Development Very Short Form
RSES: Rosenberg Self-Esteem Scale
SOVA: Supporting Our Valued Adolescents

Edited by G Eysenbach; submitted 01.12.20; peer-reviewed by M Ranney, M Bryan; comments to author 19.01.21; revised version received 14.04.21; accepted 20.05.21; published 22.07.21.

Please cite as:
Karim S, Hsiung K, Symonds M, Radovic A
Experience of Peer Bloggers Using a Social Media Website for Adolescents With Depression or Anxiety: Proof-of-Concept Study
JMIR Form Res 2021;5(7):e26183
URL: https://formative.jmir.org/2021/7/e26183
doi:10.2196/26183
PMID:34292161

Original Paper

Experiences of an Online Treatment for Adolescents With Nonsuicidal Self-injury and Their Caregivers: Qualitative Study

Olivia Simonsson[1], MSc; Hedvig Engberg[2,3], MD, PhD; Johan Bjureberg[1], PhD; Brjánn Ljótsson[4], PhD; Julia Stensils[1], MSc; Hanna Sahlin[1], PhD; Clara Hellner[1], MD, PhD

[1]Centre for Psychiatry Research, Department of Clinical Neuroscience, Karolinska Institutet, & Stockholm Health Care Services, Region Stockholm, Stockholm, Sweden

[2]Department of Women's and Children's Health, Karolinska Institutet, Stockholm, Sweden

[3]Medical Unit of Gynecology and Reproductive Medicine, Karolinska University Hospital, Stockholm, Sweden

[4]Department of Clinical Neuroscience, Division of Psychology, Karolinska Institutet, Stockholm, Sweden

Corresponding Author:
Olivia Simonsson, MSc
Centre for Psychiatry Research
Department of Clinical Neuroscience
Karolinska Institutet, & Stockholm Health Care Services, Region Stockholm
Norra Stationsgatan 69, 7th Fl
Stockholm, SE-113 64
Sweden
Phone: 46 76 142 65 65
Email: olivia.simonsson@ki.se

Abstract

Background: Nonsuicidal self-injury (NSSI) is common in adolescence and is associated with several adverse outcomes. Despite this, few established treatment options exist. Online treatment seems promising for several conditions; however, knowledge on NSSI is scarce. It is important to explore how online treatment for NSSI is experienced to improve such interventions and learn more about factors that are important in the treatment of adolescents with NSSI.

Objective: This study aims to explore the experiences of a novel online treatment for adolescents with NSSI and their caregivers.

Methods: A qualitative study using thematic analysis was conducted through semistructured interviews with 9 adolescents and 11 caregivers at treatment termination or at the 6-month follow-up of the online emotion regulation individual therapy for adolescents.

Results: A total of 3 overarching themes were identified. The theme *support can come in different shapes* showed how support could be attained through both interaction with the therapist as well as through the format itself (such as through the fictional characters in the material and the mobile app). Caregivers found it helpful to have their own online course, and adolescents accepted their involvement. The theme *self-responsibility can be empowering as well as distressing* showed that self-responsibility was highly appreciated (such as deciding when and how to engage in treatment) but also challenging; it caused occasional distress for some. The theme *acquiring new skills and treatment effects* showed the advantages and challenges of learning several different emotion regulation skills and that decreased emotion regulation difficulties were important treatment outcomes for adolescents. In addition, several different skills seemed to facilitate emotion regulation, and having access to such skills could hinder NSSI.

Conclusions: Online emotion regulation individual therapy for adolescents seems to offer an accepted way to deliver family interventions for this target group; facilitate skills training with several means of support, including support from both the mobile app and the therapist; contribute to decreasing emotion regulation difficulties and teaching skills that could hinder NSSI; and cause (in some individuals) distress because of the self-responsibility that is inherent to online formats, which needs to be addressed.

(JMIR Form Res 2021;5(7):e17910) doi:10.2196/17910

KEYWORDS

nonsuicidal self-injury; self-injurious behavior; online treatment; internet; digital health; emotion regulation; emotion regulation individual therapy for adolescents; adolescent; qualitative; experience

Introduction

Background

Nonsuicidal self-injury (NSSI) is common in adolescence and associated with several long-term risks. NSSI refers to the "direct and deliberate destruction of body tissue in the absence of any observable intent to die" [1]. NSSI is a symptom of borderline personality disorder but is also present in the absence of borderline personality disorder [2,3], together with several other disorders [4,5], and in nonclinical populations [6]. NSSI is common, especially in midadolescence [7], with a pooled prevalence of approximately 17% [8]. In fact, the prevalence rate seems to have increased in recent years [9,10]. NSSI in adolescence is worrying, as it is associated with an increased risk of incidence of other psychopathology in youth [11] and several adverse outcomes in adulthood [12-14]. Even though there is an overlap between NSSI and suicide attempts [4,15-17], there are some key differences between the two, concerning intention, repetition, and medical lethality [1,17-19]. In addition, NSSI is one of the strongest risk factors for future suicide attempts [20], and cessation of self-injury in adolescence can potentially decrease the risk of future suicidal behavior [21].

Therefore, NSSI is serious and requires urgent treatment. Treatments that target NSSI specifically are needed because NSSI is a transdiagnostic phenomenon [2-5], and targeting NSSI can potentially prevent suicides [21,22]. Focusing on the maintenance factors of NSSI in treatment could be useful; the emotion regulation function (ie, that one engages in NSSI to decrease or escape aversive emotions) has been identified as the most common function of NSSI [23], and treatment for NSSI that targets emotion regulation difficulties seems to have beneficial effects on other health outcomes as well [24]. At present, no well-established treatment is available for treating NSSI [25-29], but dialectical behavior therapy (DBT) is probably efficacious for adolescents [25]. Nevertheless, challenges with accessibility and costs connected to DBT have been highlighted and briefer interventions have been called for [22].

Our research group has previously developed a brief emotion regulation individual therapy for adolescents (ERITA) [30] derived from emotion regulation group therapy (ERGT) [24,31] drawing from the principles of DBT and acceptance and commitment therapy. The aim of ERITA and ERGT is to decrease NSSI through learning and using new skills to regulate emotions. In contrast to ERGT, ERITA is a 12-week individual therapy that is specifically for adolescents and includes a parallel online course for caregivers. As ERITA seems promising [30], and as online treatment has several advantages, such as (1) the possibility of frequent contact with the therapist [32], (2) seems effective for several conditions among adolescents [33], and (3) can facilitate help-seeking as fear of stigmatization can be a barrier [34] and individuals with perceived stigmatized problems may prefer online treatment [35], our research group has further adapted ERITA [30] to an online version (ie, online ERITA). The quantitative results from the pilot trial indicate that online ERITA seems acceptable, feasible, and useful [36]. Online ERITA was, in a recent systematic review, the only online treatment tested for adolescents with NSSI [37].

Consequently, as research on online treatment for adolescents with NSSI is scarce, our knowledge of the experience of online treatment is limited [38]. Collaboration with patients has been suggested to be important when developing novel interventions for self-injury [29]. One way to engage patients in the development of interventions is through qualitative research methods. Qualitative evaluations of interventions allow for individual experiences, positive and negative feedback, and could together with quantitative evaluations contribute to a richer understanding of an intervention [38]. Regarding adolescents with self-injury, there is only 1 previous qualitative study investigating the experience of online interventions, specifically the experience of a mobile app as an adjunct to face-to-face treatment [39]. To our knowledge, no study has investigated the experiences of online treatment for adolescents with NSSI nor have the experiences of caregivers been explored. Involving caregivers in treatment for self-injury has been suggested [40], and increased knowledge of the experience of such involvement, also from the caregivers' perspective, could help to further develop successful treatment for adolescents with NSSI. Overall, exploring individual experiences of novel treatments can potentially help improve existing treatments as well as increase our understanding of factors that are important in the treatment of adolescents with NSSI.

Objective

This study aims to explore the experiences of online ERITA for those with NSSI and their caregivers.

Methods

Overview

This qualitative study was part of a pilot trial of online ERITA [36]. This study was approved by the regional ethical review board of Sweden in November 2015 (reference number: 2015/1895-31/5). Furthermore, it is presented according to the Consolidated Criteria for Reporting Qualitative Research standards [41] for reporting qualitative research.

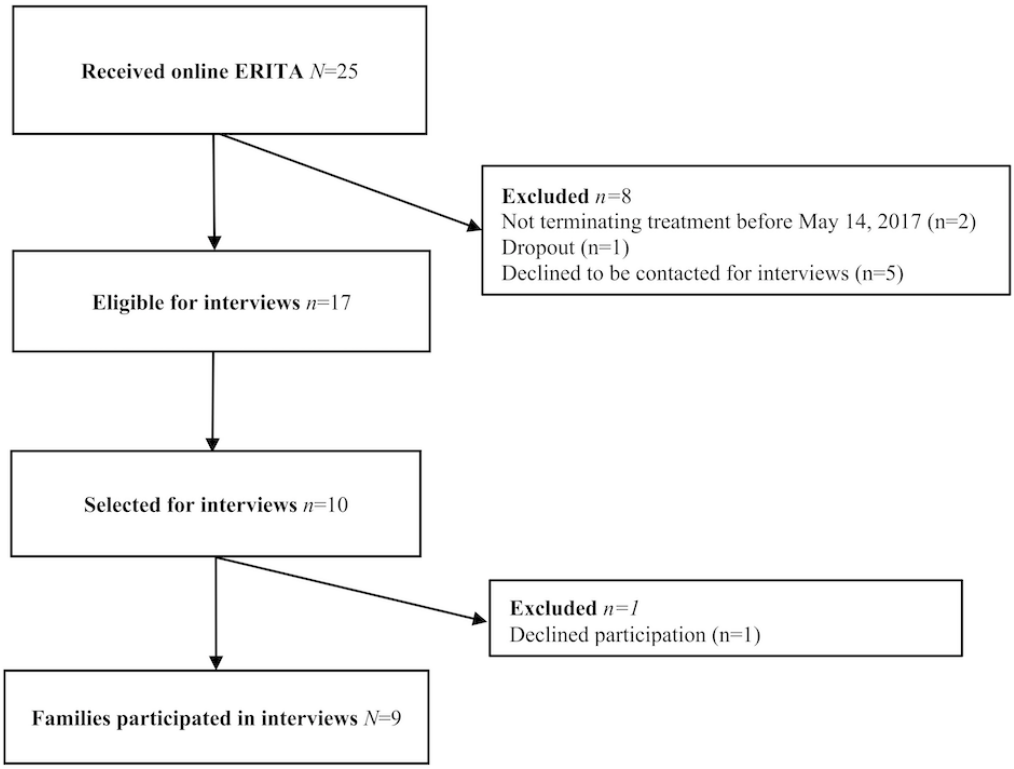
Participants

Families who had participated in the quantitative part of the pilot trial of online ERITA [36] were the population of interest. Inclusion criteria for adolescents in the pilot trial [36] were as follows: (1) being 13-17 years old; (2) fulfilling criteria for the proposed NSSI disorder [42]; (3) having engaged in ≥1 NSSI episode during the past month at the preassessment; (4) having stability of psychotropic medications (if any) for at least 2 months; and (5) having at least one caregiver committed to participate in the caregiver course. Exclusion criteria for adolescents in the pilot trial [36] were as follows: (1) severe suicidal ideation; (2) diagnosis of psychotic or bipolar I disorder, or substance dependence; (3) ongoing dialectical behavioral or mentalization-based therapy; and (4) insufficient understanding of the Swedish language. To participate in the qualitative part of the pilot trial, participants had to accept participation in interviews and terminate treatment before May 14, 2017.

Potentially eligible families were informed and prompted to participate in the interviews, either when meeting their therapist at posttreatment follow-up or by telephone. From the 17 eligible families, families were continuously selected for interviews as the data collection proceeded based on maximum variation sampling [43]; the target was to reach variability in the sample regarding age, gender, and past month NSSI frequency before and after treatment. One family was selected for interviews but later declined.

Information power [44] was assessed continuously by analyzing the amount of new information from the interviews and the quality of data. From previous research, 6 to 12 interviews have shown to capture all themes and concepts needed to answer the research question [44-47]. We expected that more than 6 interviews per group (ie, separating adolescents and caregivers) were needed based on the variability within the adolescent group and the scope of the study. Conversely, sample specificity was good in relation to the research question. After interviews with 9 families (ie, 9 adolescents and 11 caregivers), there was redundancy in interview data; therefore, it was deemed that a data saturation point was reached [48]. The participant flow is shown in Figure 1.

Figure 1. Flowchart of the participating families. ERITA: emotion regulation individual therapy for adolescents.



In total, 9 adolescents and 11 caregivers participated (ie, 20 interviews in total); 7 families completed the interview in conjunction with the posttreatment follow-up, and 2 families completed the interview in conjunction with the 6-month follow-up. Participating adolescents were 14-17 years old (median 16; IQR 16-17), and 6 adolescents identified as female and 3 adolescents as nonbinary. Before the initiation of the treatment, past month NSSI frequency varied between 3 and 22 (median 10; IQR 9-15), and after the treatment, the past month NSSI frequency varied between 0 and 14 (median 2; IQR 1-8). All adolescents had completed all the 11 modules in the treatment, and all caregivers had completed all 6 modules in the caregiver course. Of the participating caregivers, 9 were mothers and 2 were fathers. Their ages ranged from 43-55 years (median 50; IQR 46-53).

Intervention

Overview

Online ERITA is developed by a diverse group, with experts in both online and self-injury treatment, in close collaboration with the developers of ERGT, and with help from a user experience design consultant. Furthermore, the content and online interface has been additionally reviewed by clinicians working with adolescent self-injury and patient representatives from an association specifically for self-injury.

The aim of ERITA is to decrease NSSI through learning and using new skills to regulate emotions. The treatment includes skills training in emotional awareness, acceptance, impulse control, validation, and valued direction. Online ERITA comprises 11 modules delivered over 12 weeks. In each module, participants read texts (ie, both psychoeducation and examples

from how fictive characters practiced skills), listen to audio files, watch short films, and get assignments for the upcoming week. In addition, the adolescents have access to a supplementary mobile app where they can (1) register NSSI acts or impulses, (2) register and engage in their skills practice, and (3) access their individual crisis list. Screenshots of the online treatment and mobile app are presented in Figure 2 and Figure 3, respectively.

Figure 2. Screenshots of interactive worksheets from online emotion regulation individual therapy for adolescents [36].

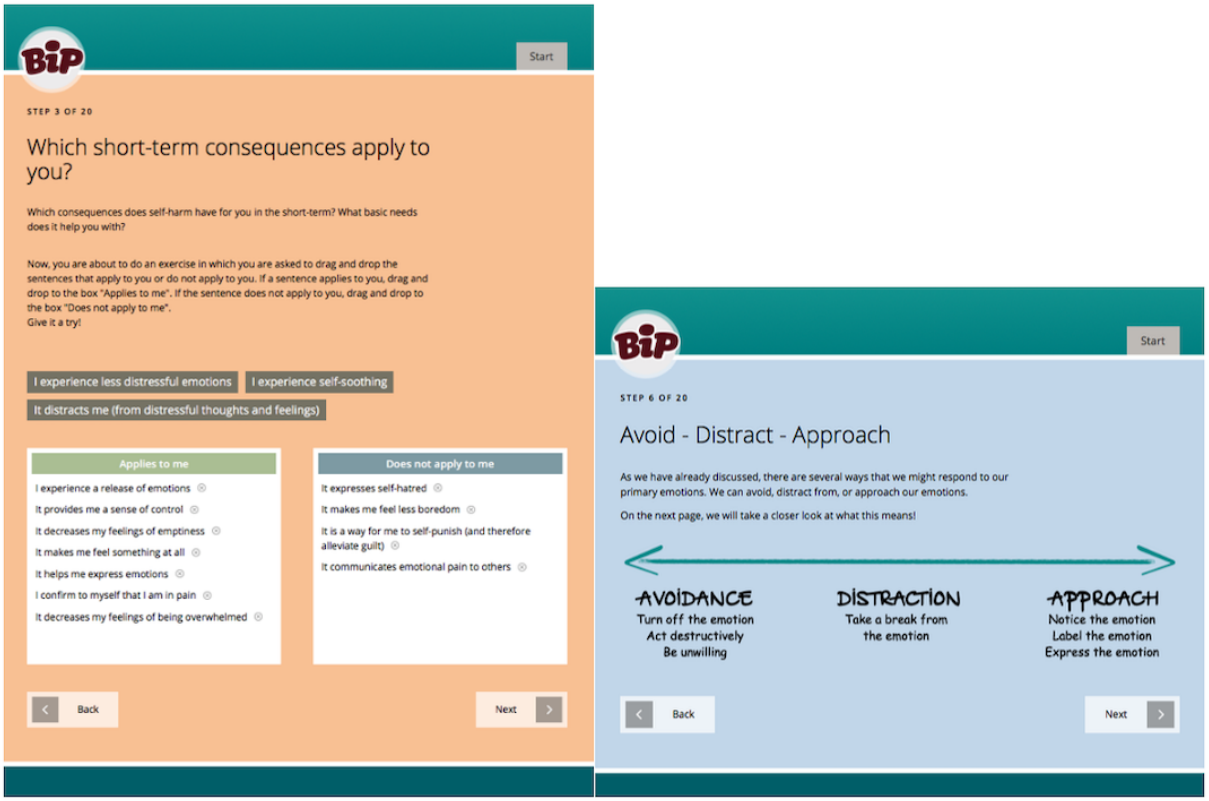
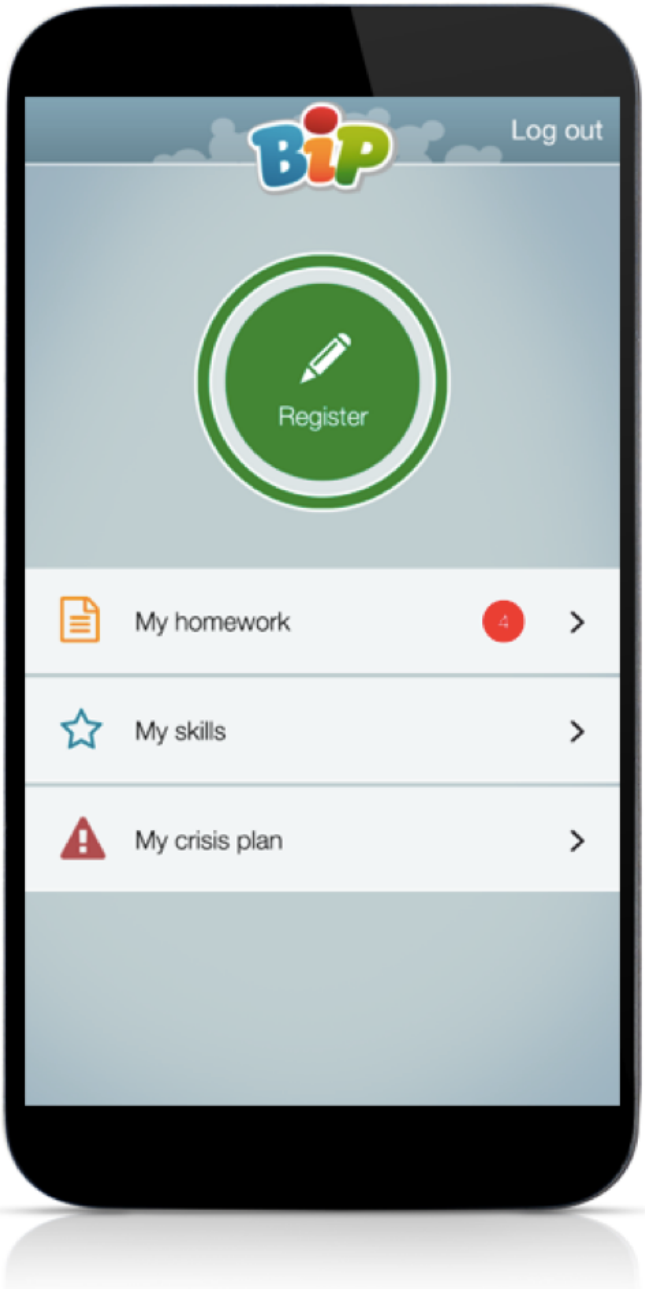


Figure 3. Screenshot of the mobile app from online emotion regulation individual therapy for adolescents [36].



Moreover, online ERITA includes a parallel online course for the caregivers, which consists of 6 modules, with the aim to teach the caregivers emotion regulation strategies to better support and understand adolescents. The caregiver course includes skills training in validation, emotional awareness, and behavioral activation. The caregivers also have access to the module texts from the adolescent's treatment, to learn what the adolescent is taught and encouraged to assist in their skills practice. The family meets their assigned online therapist for a face-to-face assessment before starting the treatment. During the treatment, both adolescents and caregivers have regular contact with the therapist on the online platform as well as by telephone if needed. In the secure online platform, the therapist has access to all interactions by adolescents and caregivers with the online system (eg, answered worksheets, registrations, and reflections on content, video, or audio) and data from the mobile app from adolescents (eg, daily registrations on destructive behavior and number of skills training sessions). The information is used by the therapist to assist in skills training, explain content if needed, monitor symptoms, and contact the family immediately in case any information indicates that the safety or well-being of adolescents is at risk.

Participant Safety and Confidentiality

Both adolescents and caregivers received information on how confidentiality would be handled in case any information indicated that the safety or well-being of adolescents was at risk (ie, contacting adolescents and/or caregivers) before consenting, and this was also discussed when developing the individual crisis list. Furthermore, the online platform was on a secure server, and log-in required 2-factor authentication (ie, both password and mobile code) for both the therapist and the participants. The mobile app was password-protected and locked to 1 phone. Adolescents were automatically logged out of the

mobile app in case of inactivity, and data from the mobile app were saved on a secure server. The mobile app was designed to be discrete; the mobile app icon is neutral and cannot be associated with mental health. Moreover, participants could have initiated or did initiate treatment contacts outside of online ERITA based on their needs.

Data Collection

Interviews were conducted between February and September 2017. The interviewers were 2 female psychology master students (OS and JS) educated in the theory and method of online ERITA, but they had no prior relation to the participants before the interviews. The interviews were conducted either at a child and adolescent mental health clinic (9 interviews), in the home of the families (6 interviews), or over telephone (5 interviews).

The interviews were conducted with the adolescents and caregivers in separate rooms, without nonparticipants. Before starting the interviews, the participants were informed about the purpose of the study; the occupation and experience of the interviewer; their right to terminate at any time; and how the material would be processed, stored, anonymized, and presented. Written informed consent (ie, caregivers and adolescents aged ≥15 years provided own written consent, and caregivers provided written consent on behalf of adolescents aged ≤14 years, according to Swedish law) was obtained before the interviews started. The duration of the interviews ranged from 13-41 minutes. To decrease the potential risk of the negative impact from talking about mental health issues and experiences of treatment, participants could choose the location of the interview, and all participants were asked before and after the interview if the situation induced distress. Interviewers were prepared to assist in case of reported or observed adverse events. However, no adverse events were reported before, during, or after the interviews.

Semistructured interviews were chosen based on the research questions and allowed for diverse experiences [49]. A total of 2 interview guides, 1 for the adolescents and 1 for the caregivers (Multimedia Appendices 1 and 2), were developed based on previous research (ie, on structure [49] and content [25,26,37,40]) and clinical experience and reviewed by the authors. The interview guide was pilot-tested on the first participant and evaluated with the supervisor (HE); no changes were deemed necessary. All interviews were audio recorded and later transcribed verbatim by the interviewers. The audio recording was erased immediately after the completion of the transcription.

Data Analysis

Thematic analysis was used for data analysis, according to the steps recommended by Braun and Clarke [50]. Data analysis included a constant movement back and forth between the steps described below. In the first step, all transcripts were reread to gain familiarity with the data. In the second step, initial codes were generated; OS and JS coded 5 interviews together, and HE reviewed the coding as a verification step. After the verification step, OS coded the rest of the interviews and consulted HE throughout the process. All codes were reviewed several times by HE and OS. Examples of codes are listed in Table 1. In the third step, possible themes were investigated. Codes were clustered into categories and possible themes, and OS and HE reviewed different clustering opportunities and looked for negative cases. Data were split between adolescents and caregivers and compared in terms of both content and structure. In the fourth step, the themes were reviewed until they were deemed exclusive and fit the material. In the final step, the themes were labeled and the materials belonging to each theme were summarized. Discussions were ongoing in the research group throughout the process, and the final results were approved by all authors. Original quotes from the transcripts were chosen to show the relationship between the data and themes. For the qualitative analysis, the data program Open Code version 4.03 was used [51].

Table 1. Illustration of the resulting model.

Overarching themes and subthemes	Example of codes
Support can come in different shapes	
Support from the therapist despite distance	• Free in what one could say to the therapist • Lonelier without the therapist • Therapist cared
Finding support within the family	• Work separately • Caregivers more aware now • Better communication
Finding support in the format	• Could relate to the fictional characters • Good to know you are not alone • The app contributes with control
Self-responsibility can be empowering as well as distressing	
Flexibility and empowerment	• Treatment was no big deal • According to your needs • Helped myself
Distress as a consequence of treatment	• Hard to manage to support • Pressure of constant accessibility • Guilt when not following the treatment
Acquiring new skills and treatment effects	
Learning and using new skills	• Use the skill that works in the situation • Difficult to manage during emotional distress • Too much to think about
Benefits in everyday life	• Increased awareness • Can use skills in everyday life • Dare to express emotions

Results

A total of 3 overarching themes were identified. Each theme, their respective subthemes, and examples of codes in the themes are presented in Table 1.

Support Can Come in Different Shapes

Overview

The overarching theme *support can come in different shapes* describes the diversity of how support can be attained, as defined by the separate subthemes. Although adolescents experienced support from several sources, caregivers focused more on support from the therapist.

Support From the Therapist Despite Distance

There was consensus that therapist support was an essential part of the treatment, among both adolescents and caregivers. The therapist was perceived as available, caring, supportive, personal, helpful, and pedagogical:

> *You could just ask anything, also questions that I thought were stupid, but still. Otherwise [without the therapist] it would have felt lonelier, as if you were just doing it by yourself, like nobody cared. Now there was someone who was there that wrote to you, after all. You got the response quickly when you sent a message, it felt good.* [Adolescent #5]

In addition, caregivers stressed the need for an initial face-to-face meeting to build trust. The initial meeting was also important as it decreased some caregivers' worries about a somewhat lower level of caretaking in the online format compared with face-to-face treatment. Several caregivers wished for a face-to-face meeting halfway through the treatment period to assure the therapist was still there and to discuss problems that had emerged as treatment had progressed. According to most caregivers, the therapist was crucial—it felt as if somebody would take them on and wanted to help them:

> *It has been very important to have the therapist there, so you don't feel that this is just digital. You need to have a real person there. The therapist has been very generous with the amount of contact. Both me and my adolescent have felt that the therapist aspect has been very important.* [Caregiver #11]

Adolescents appreciated the online communication with the therapist, and many preferred it to talking face-to-face. Nevertheless, telephone calls were appreciated as problem solving went quicker and the therapist could explain the treatment material that was hard to understand. For adolescents, the physical distance to the therapist seemed to increase their willingness to share sensitive personal information:

> *I simply find it easier to write, to get more time to think about exactly how to formulate myself...it can*

be easier to say things I don't like to say aloud. [Adolescent #5]

Finding Support Within the Family

Adolescents experienced the involvement of caregivers as reasonable and relevant, and some saw the advantages of caregivers getting their own support. Caregivers' awareness of what the adolescent was going through (ie, through reading the adolescent's material) facilitated communication and increased support. However, a few families expressed that they did not talk among each other about what they were going through:

> *They are more aware of what I do, that is, what assignments I get. And they can solve situations, kind of. But we haven't talked so much about it. We have rather done it individually.... But now they have helped themselves and I have helped myself and it is like, I have not had to push them away in the same way [as before].* [Adolescent #3]

Caregivers were appreciative that they were more involved in online ERITA compared with previous treatments. Some requested more interactive parts with the adolescent for a natural starting point to communicate around the treatment material. Both adolescents and caregivers stated a better and more supportive relationship exemplified as talking more, having a common language, being more honest with each other, and having fewer arguments:

> *It feels like we've come closer. Before, she was in her room and you didn't get any contact. And it may well happen that she does that now too, but it's not that often. She is seeking much more social contact.* [Caregiver #8]

Finding Support in the Format

Adolescents found the treatment format and content to be supportive. The fictional characters in the modules were perceived as relatable and created a sense of normalization for some:

> *There were always examples of four people, and I could always recognize myself in at least one of them. Sometimes you might not recognize yourself up to a hundred percent, but there was always something you could recognize that made you feel less alone and "all right, it's not just me who has this problem."* [Adolescent #4]

Moreover, adolescents who used the supplementary mobile app appreciated it. Practicing skills in the mobile app and getting suggestions of what to do made the treatment more present and supported everyday skills training. The reasons mentioned for not using the mobile app were not experiencing the need or technical issues (eg, not being able to log in):

> *I think the app was the best. I probably logged in to it more times than I really needed. More as a reminder to me.... Sometimes it was hard to remember what to do in a situation when I was feeling very, very bad. If I logged in to the app, I had more control. Otherwise, I find it very difficult to come up with it [strategies] myself.* [Adolescent #9]

Self-Responsibility Can Be Empowering as Well as Distressing

Overview

The overarching theme *self-responsibility can be empowering as well as distressing* describes the positive and negative aspects of the perceived self-responsibility of initiating and following through with the treatment. The subthemes reflect the positive aspects, such as you could engage in treatment according to your preferences and attribute accomplishments to your own ability, and the possible negative aspects, such as feeling distressed and insecure.

Flexibility and Empowerment

Adolescents and caregivers appreciated that the material was always accessible and that one could engage in treatment wherever it felt comfortable. Furthermore, flexibility in how to engage with the material (eg, text, audio files, videos, and mobile app) and freedom to write to the therapist whenever you have a question were similarly mentioned as positive consequences of self-responsibility:

> *It didn't become such a big deal as to go somewhere, meet someone and talk. Rather it was more like sitting at home on the couch, just filling out some questions.... You could get a question, feeling it was tough, get up and go and grab a sandwich, talk it through with a parent and then go back and work on an answer.* [Adolescent #1]

Other positive aspects of self-responsibility, mentioned by adolescents, were connected to empowerment; feeling that you have the treatment to yourself and help yourself (rather than just receive help) and to not burden anyone else:

> *It didn't feel like I was troubling anyone else in any way with my mental health problems. It was just me trying to get better.* [Adolescent #3]

Distress as a Consequence of Treatment

Engaging in and experiencing the responsibility of the treatment was, at times, connected to aversive emotions and unhelpful behaviors. The sense of failing assignments and expectations was associated with elevated levels of shame and guilt and decreased self-confidence. Being aware of one's problems (ie, NSSI and difficulties in regulating emotions) was difficult for some, and the treatment was a reminder of those problems. When adolescents felt that they did not meet expectations, some ended up procrastinating and avoiding treatment; still, it was hard to mentally let go of the treatment. However, such aversive emotions were also described by some as manageable, transient, and acceptable because the treatment was important:

> *When I felt that I would not be able to do as many homework assignments as I wanted to do, then I did nothing instead, and finally I felt more stressed because I did nothing.... It wasn't just a meeting; it was all the time. And sometimes it felt good because then it was like, you helped yourself all the time and you got help all the time. But at the same time, it was really hard because a meeting with a psychologist is usually really exhausting. And now it was like it went*

> *on all the time, that you had to think about all the stuff and all the questions, so it was just as hard, but good.* [Adolescent #3]

Both adolescents and caregivers experienced insecurities about what was *right* and *enough* in terms of how to answer homework assignments and what was expected of them. Rarely did adolescents or caregivers mention such concerns to their therapists:

> *One problem was that I had a hard time formulating answers to the questions in the module, so I don't really know if I...came through with all my thoughts to the therapist. I thought the messages worked well, but I was always unsure how much I should write in the questions in modules-How deep should I go?* [Adolescent #1]

Some caregivers expressed doubts about their own capabilities, especially trusting the adolescent with responsibility and encouraging independence. The responsibility to motivate and remind adolescents was challenging for some:

> *Some days we felt that the adolescent did not manage to do the assignments and she received quite a lot of reminders, and we got a lot of reminders to remind her and so on. And it was very difficult to push her.* [Caregiver #5]

Acquiring New Skills and Treatment Effects

Overview

The overarching theme *acquiring new skills and treatment effects* describes the outcome of participating in online ERITA. The subthemes reflect both learning skills and the positive effects of using such skills.

Learning and Using New Skills

Adolescents mentioned several different skills as helpful. The particular skills that were most helpful differed between adolescents and over time. Learning how to combine skills during this delimited time period was challenging for some, especially how to use the skill set in challenging situations:

> *I thought it was a little difficult in the moment, when I was feeling bad, to try to focus on all these different steps because there were so many different things you can do. So, it got a little confusing. I couldn't really use the whole thing as a package.* [Adolescent #6]

Regarding the less helpful skills, some mentioned mindfulness as unimportant. Others were unable to specify in retrospect if anything was less helpful. In cases where participants perceived specific content as nonrelevant, they did not indicate that this content had had an overall negative impact on the experience of the treatment. Moreover, some experienced that some skills (particularly distraction skills) were insufficient, not solving problems in life:

> *It felt more like all skills became like distractions to me, more like I was postponing problems, instead of...I mean, I understand that it is a way of handling one's problems, and that it is perhaps better than just ignoring it, but it didn't feel like it helped a lot at the time.* [Adolescent #2]

Caregivers appreciated the fact that they received their own skills training and discovered that they could benefit from the same skills as adolescents. Learning about primary and secondary emotions and validation was perceived as particularly useful. Validation was defined as a eureka moment and a breaking point. Furthermore, the caregivers did not perceive any treatment content as less helpful, and several caregivers made the spontaneous reflection that everyone should learn these types of skills.

Benefits in Everyday Life

The improvements reported were both overt behavioral changes as well as changes in attitude toward internal experiences. Specifically, the improvements expressed by adolescents were increased emotional awareness and acceptance, courage to be who you are, skillful communication of emotions, and reaching out for help before making the situation worse:

> *I have become very much more aware of how I really work and how emotions and thoughts work and...I don't know, just a lot of knowledge. It's been amazing! And can help friends a little bit too, so it's cool.* [Adolescent #1]

When discussing changes, the adolescents mentioned but were less focused on changes in the frequency of NSSI (although most of them had decreased their frequency of NSSI from before treatment to the time of the interview). Reasons for decreased or ceased NSSI described by adolescents were that they felt less trapped and dared to express their emotions and that they had other strategies to handle impulses/emotions now. Moreover, some adolescents reported that they did not experience positive changes until after several weeks after treatment termination.

The caregivers experienced similar improvements in adolescents. In addition, the caregivers observed that adolescents were more present in the family and forgiving toward oneself and easier to talk to and seemed happier. The caregivers perceived their own improvements as increased self-awareness and emotional awareness—being more aware of their adolescents' mood—and increased self-efficacy in handling possible setbacks. Moreover, they mentioned that they were teaching the skills to other people around them.

Discussion

Principal Findings

This study conveys the experiences of online ERITA for those with NSSI and their caregivers. The main findings were that online ERITA is experienced as offering several means of support (eg therapist, the mobile app) and that the caregiver involvement in this format is acceptable and beneficial. The perceived self-responsibility in online ERITA had both positive (ie, sense of empowerment) and negative aspects (ie, increased distress) connected to it. Several different skills seem to facilitate emotion regulation ability, and having access to such skills could hinder NSSI. Finally, decreased emotion regulation difficulties seemed to be an important treatment outcome for adolescents.

Interestingly, although several treatment effects were described, the most important changes identified by adolescents were improvements in emotion regulation and how that affected functions in daily life. This may not be surprising, given that NSSI per se is seldom the main concern for the individual but rather the emotional distress triggering NSSI [52]. Access to emotion regulation skills was mentioned as a reason for decreased NSSI, illustrating the potential mediating role that emotion regulation has in decreasing NSSI [30,36,53]. Furthermore, the results are in line with those of previous studies [24,30,36], indicating that interventions that are designed specifically for NSSI and target emotion regulation difficulties can affect other symptoms and the overall function. This is expected, as emotion regulation deficits seem to be important to a wide range of psychopathologies [54]. Altogether, these results highlight the importance of measuring several outcomes when evaluating treatment for NSSI to capture the processes through which the treatment works and the changes that are connected to decreased distress and increased function.

Our results indicate that adolescents used several different skills to regulate their emotions. Given that several different subscales of difficulties in emotion regulation have been strongly connected to NSSI (eg, nonacceptance of emotional responses, impulse control difficulties, and difficulties engaging goal-directed behavior) [23], several different emotion regulation skills could be useful to target these different difficulties. Therefore, it does not need to be concerning that no single emotion regulation skill was identified as of certain importance from the interviews with adolecents. Investigating whether it is possible to predict what skills the individual would benefit the most from, based on reports of difficulties in different emotion regulation subscales, could be an important next step to identify potent skills and components and further tailor the treatment to the individual. Online treatment could provide a useful framework for dismantling studies (eg, testing the effectiveness of a specific treatment component) [55] as treatment content could be controlled and modules can be easily added or removed.

In this study, therapist support was perceived as essential and therapeutic alliance was continually developed through the online format. The question has been raised if the online format can facilitate therapeutic alliance when treating self-injury [37]. Our results indicate that the online format facilitated self-disclosure, in line with the experiences of other pediatric clinical groups who have received online treatment [38]. In general, our results validate the importance of therapeutic alliance for this target group [26], which seems to be facilitated by both online, telephonic, and face-to-face contact in this context. The availability of frequent and flexible online and telephonic contact was important for the participants, in line with previous findings [25,27].

The importance of family involvement for this population [25,40] was also underscored from the results of this study. Involving caregivers in a parallel online course was highly appreciated by the caregivers and experienced as positive, or at least not negative, by the adolescents. Involving family members in this online format could be a valuable addition to traditional face-to-face family sessions. The importance of providing a sufficient dose of caregiver or family component has been emphasized [25], and the online format could be a time-efficient method for the therapist to increase such dose. Conversely, face-to-face meetings, as a complement to the online treatment, were requested by caregivers in this study, implying the importance of flexibility in format. Moreover, caregivers' own skills training in emotion regulation was appreciated and helpful, and this is important as youth NSSI could affect the well-being of caregivers negatively [56].

Several advantages of the supplementary mobile app were described by the adolescents, both as an easy and flexible way to engage in treatment and a means of support. These results, together with the previous promising results on the utility of mobile apps for self-injury [39], indicate the usefulness of supplementary add-on formats for both online and face-to-face treatments. However, not all adolescents used the mobile app, and the reasons mentioned involved not needing it and technical issues. The technical issues are unfortunate but are difficult to avoid in complex apps. The report from some of the adolescents that the technical issues prevented them from using the app underline the need for thorough pretesting of the app and also conducting pilot trials, such as this study, before the app is used in a large-scale clinical trial or implemented within health care. Nevertheless, whenever an app is used, continuous efforts should be made to detect and handle any issues because technical problems could have negative consequences on treatment credibility, adherence, and effectiveness.

Furthermore, difficulties in fulfilling assignments and adhering to treatment [57] and feeling worse on occasions [38] have been stated as possible negative effects of online treatment before. Such distress can be challenging for individuals with NSSI, as difficulties in regulating emotions are especially prominent within this group [23]. Detecting participants experiencing distress because of the self-responsibility inherent in the online format and offer support is therefore important. The findings could be interpreted as a need for more individual tailoring in online treatments for NSSI to facilitate successful treatment outcomes and identify patients in need of adaptions or potentially more extensive treatment first hand. This means of treatment may not be suitable for the most severely affected; although online treatment offers frequent contact that could facilitate detection of deterioration in some cases, there may be dimensions of a face-to-face contact (eg, nonverbal communication) that are lost in online treatment, which could possibly make it more difficult to detect deterioration in other cases. Nevertheless, online treatment could serve important functions; the results from this study indicate that some prefer online contact, and a third of the adolescents in this study (and a fifth in the overall pilot trial [36]) identified as nonbinary, which could indicate that the online format may facilitate treatment-seeking among gender minority groups.

Strengths and Limitations

Although our study provides important information on how skills training, caregiver involvement, and the online format can be experienced, it is not without limitations. Irrespective of sample size, sampling from a single pilot study limits the transferability of the results [58]. Nevertheless, by including

adolescents of different ages, genders, and NSSI frequencies, we could collect rich data, hopefully making the findings transferable in the sense that they speak for more than the individuals interviewed. However, although we strived for variability in the sample, we have no adolescents who identified themselves as male, and none of them were aged 13 years. Moreover, some families were interviewed months after ending the treatment, possibly introducing recall bias but also introducing the possibility of capturing late effects.

Future Work

Our results indicate the potential development of online ERITA. Primarily, it is important to systematically detect those at risk of distress because of the self-responsibility inherent in the online format. As online treatment generally offers structured treatment content, questions regarding treatment engagement and feelings of increased distress can easily be incorporated into the treatment modules. Accordingly, modifying and evaluating the efficacy of online ERITA is warranted, and a randomized controlled trial is currently being conducted and is registered at ClinicalTrials.gov (trial number: NCT03353961).

If online ERITA is proven to be efficacious, steps have already been taken to prepare for a large-scale implementation trial within Swedish child and adolescent mental health services. In this phase, we will not only monitor treatment effectiveness and potential adverse events but also study patient as well as caregiver experiences and evaluate the intervention from an organizational perspective.

Conclusions

The findings from this qualitative study exploring the experiences of online ERITA for those with NSSI and their caregivers provide some important insights. First, decreased emotion regulation difficulties were an important outcome for adolescents, implying the importance of targeting emotion regulation and measuring several outcomes when evaluating treatment for NSSI. In addition, several different skills seem to facilitate emotion regulation ability and having access to such skills could hinder NSSI. Second, involving caregivers through a parallel online course seems to be an accepted and beneficial format to deliver family interventions for this patient group. Third, it is possible to learn and practice skills training in online format, with several means of support, from both the mobile app and the therapist. Finally, although online treatment could be empowering, there is a risk of distress because of the self-responsibility inherent in the online format that needs to be addressed.

Acknowledgments

The authors would like to thank the participants for their willingness and bravery to share their experiences. This project was supported by the National Self Injury Project in Sweden and the Swedish Research Council under grant 2014-1008. The funder had no role in the study design or the writing of the manuscript.

Authors' Contributions

All authors were involved in designing the study. JB and HS served as therapists. OS and JS interviewed participants. All authors were involved in the data analysis at different steps (as described in the *Methods* section). OS drafted the initial manuscript, and all authors revised it critically for important intellectual content. All authors read and approved the final manuscript.

Conflicts of Interest

CH, JB, HS, and BL were involved in the development of online ERITA but declare no financial interests. JB receives book royalties from Natur & Kultur. BL is a shareholder of DahliaQomit AB, a company specializing in online psychiatric symptom assessment, and Hedman-Lagerlöf och Ljótsson psykologi AB, a company that licenses cognitive behavior therapy manuals. The other authors report no conflicts of interest.

Multimedia Appendix 1
Interview guide for adolescents.
[PDF File (Adobe PDF File), 45 KB - formative_v5i7e17910_app1.pdf]

Multimedia Appendix 2
Interview guide for caregivers.
[PDF File (Adobe PDF File), 44 KB - formative_v5i7e17910_app2.pdf]

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Abbreviations

DBT: dialectical behavior therapy
ERGT: emotion regulation group therapy
ERITA: emotion regulation individual therapy for adolescents
NSSI: nonsuicidal self-injury

Edited by G Eysenbach; submitted 18.06.20; peer-reviewed by L McCann, S Thomas; comments to author 06.08.20; revised version received 01.10.20; accepted 16.03.21; published 23.07.21.

Please cite as:
Simonsson O, Engberg H, Bjureberg J, Ljótsson B, Stensils J, Sahlin H, Hellner C
Experiences of an Online Treatment for Adolescents With Nonsuicidal Self-injury and Their Caregivers: Qualitative Study
JMIR Form Res 2021;5(7):e17910
URL: https://formative.jmir.org/2021/7/e17910
doi:10.2196/17910
PMID:34297001

Original Paper

Mobile Delivery of Mindfulness-Based Smoking Cessation Treatment Among Low-Income Adults During the COVID-19 Pandemic: Pilot Randomized Controlled Trial

Josephine Mhende[1], MPH; Sharrill A Bell[1], MPH; Cherell Cottrell-Daniels[1], MPH; Jackie Luong[1], BS; Micah Streiff[1], MPH; Mark Dannenfelser[2], MA; Matthew J Hayat[1], PhD; Claire Adams Spears[1], PhD

[1]Georgia State University, Atlanta, GA, United States

[2]Mindfulness Center of Atlanta, Atlanta, GA, United States

Corresponding Author:
Claire Adams Spears, PhD
Georgia State University
140 Decatur Street, Suite 400
Atlanta, GA, 30303
United States
Phone: 1 404 413 9335
Email: cspears@gsu.edu

Abstract

Background: Smoking is the leading cause of premature death, and low-income adults experience disproportionate burden from tobacco. Mindfulness interventions show promise for improving smoking cessation. A text messaging program "iQuit Mindfully" was developed to deliver just-in-time support for quitting smoking among low-income adults. A pilot study of iQuit Mindfully was conducted in spring 2020, during the COVID-19 pandemic, among low-income and predominantly African American smokers.

Objective: This pilot study examined the acceptability and feasibility of delivering Mindfulness-Based Addiction Treatment via mHealth during the COVID-19 pandemic.

Methods: Participants were adult cigarette smokers (n=23), of whom 8 (34.8%) were female, 19 (82.6%) were African American, and 18 (78.3%) had an annual income of <US $24,000. They were randomly assigned to either 8 weeks of iQuit Mindfully as a fully automated standalone intervention or iQuit Mindfully in combination with therapist-led in-person group treatment. For participant safety, in-person mindfulness groups were transitioned to the internet and assessments also took place over the internet. Survey questions asked participants about changes in their stress, smoking habits and quit attempts, and their perceptions of the mindfulness and text messaging intervention in the context of the pandemic.

Results: Most participants (n=15 of 21, 71.4%) indicated a change in stress due to the pandemic, of whom 14 (93.3%) indicated higher stress. Participants shared concerns about finances, homelessness, health, and social isolation. Most (n=17 of 21, 80.9%) believed that smoking increases the risk of contracting COVID-19, and although that was motivating for some, others expressed lower motivation to quit smoking because of higher stress. Most (n=18 of 21, 85.7%) stated that practicing mindfulness was helpful during the pandemic. Mean ratings of the helpfulness of text messages and the extent to which they would recommend the program to others were 7.1 (median 8 on a 10-point scale, SD 2.9) and 8.2 (median 9, SD 2.5), respectively. Through open-ended program evaluations, participants shared details about how mindfulness practices and the text messages helped them manage stress and feel a sense of social support during the pandemic. Moreover, 10 of 19 (52.6%) of participants achieved 7-day abstinence from smoking, with no differences between conditions.

Conclusions: This study supports the promise of text messaging and the use of teleconferencing to provide mindfulness and smoking cessation services to underserved populations during a pandemic.

(JMIR Form Res 2021;5(7):e25926) doi:10.2196/25926

KEYWORDS

acceptability; addiction; African American; cessation; COVID-19; feasibility; income; low socioeconomic status; mHealth; mindfulness; minority; smoking; SMS; text messaging; treatment

Introduction

Background

Smoking continues to be the leading cause of premature death in the United States [1]. In 2015, two-thirds of cigarette smokers were motivated to quit smoking, and over half had attempted to quit in the past year [2]. However, only 7.4% of adult smokers were able to quit successfully [2]. Moreover, low-income adults and members of certain racial and ethnic minority groups (eg, African American individuals) are less likely to quit compared to those with a higher socioeconomic status (SES) and White individuals [2,3]. These priority populations also experience a higher prevalence of tobacco-related illnesses and associated mortality [3]. Barriers to quitting smoking among low-SES populations include high stress as well as low social support and self-efficacy [3-5]. Accessible interventions that directly target these barriers among underserved populations are critically needed, and mindfulness-based approaches might be useful in this regard.

Mindfulness-Based Interventions for Diverse Populations

Mindfulness is defined as "paying attention in a particular way: on purpose, in the present moment, and nonjudgmentally" [6]. A meta-analysis of randomized controlled trials reported that 25.2% of participants receiving mindfulness interventions for smoking cessation were abstinent 4 months after the intervention as compared to 13.6% of participants who received usual care [7]. Mindfulness interventions have been shown to reduce stress [8], improve social relationship functioning [9], and promote self-efficacy for coping with negative emotions without smoking [10]. Furthermore, mindfulness appears to target addiction by weakening associations of stress and cravings with addictive behavior [11-14]. That is, through mindfulness training, people learn to purposefully respond to stress, cravings, and other unpleasant sensations rather than impulsively reacting by smoking. Mindfulness is also speculated to buffer the negative mental and physical health consequences of stress [15]. This is particularly relevant for marginalized populations who disproportionately experience both acute and chronic stressors [16].

Although the majority of mindfulness studies have included relatively affluent and non-Latino White individuals [17], recent studies support the use of mindfulness-based smoking cessation for socioeconomically and racially or ethnically diverse populations [18-20]. There is still much work to be done to extend the reach and cost-effectiveness of mindfulness interventions. For example, Mindfulness-Based Stress Reduction [21], Mindfulness-Based Cognitive Therapy [22], and Mindfulness-Based Addiction Treatment (MBAT) [20] involve 8 weekly in-person group sessions, each lasting at least 2 hours. mHealth could be useful for increasing access to mindfulness interventions. In particular, text messaging can provide tailored, just-in-time interventions at relatively low cost. Hence, a mindfulness intervention for smoking cessation "iQuit Mindfully" was implemented with strong feasibility and acceptability among low-income, predominantly African American adults [23]. Text messages were developed and iteratively refined on the basis of feedback from the target population [24]. They were designed to be personalized and interactive and could be implemented as a standalone program or as a between-session enhancement to in-person MBAT.

Our team conducted an additional pilot study of iQuit Mindfully, both as a standalone intervention and as an enhancement to MBAT, in spring 2020 to further improve the program. Participants were enrolled in January and February 2020 and began the 8-week treatment intervention on February 13, 2020, in Atlanta, Georgia. During this time, the COVID-19 pandemic began to significantly impact the United States. By mid-March 2020, all 50 states reported confirmed COVID-19 cases [25]. At that time, the governor of Georgia declared a Public Health State of Emergency due to COVID-19 and a few weeks thereafter, a mandatory shelter-in-place order was issued statewide. For participant safety, the in-person mindfulness group sessions transitioned on the internet (via WebEx, although participants chose to join via audio only), and all assessments were conducted on the internet.

Health Disparities During the COVID-19 Pandemic

Although the pandemic has impacted people worldwide in countless ways, it introduced public health concerns that uniquely affected our participants, who were predominantly African American smokers from low-SES backgrounds. For example, smoking increases the severity of respiratory illnesses, and the World Health Organization summarized the current evidence by stating that "smokers are more likely to develop severe disease with COVID-19, compared to non-smokers" [26]. Furthermore, low-SES and African American populations have experienced disproportionate burden from COVID-19. African American people have contracted COVID-19 at higher rates and had higher rates of COVID-19–related mortality [27]. For example, African American people with COVID-19 in Chicago were 6-fold more likely to die than their White counterparts [28]. The majority (68%) of COVID-19–related deaths in Chicago were of African American individuals, although they comprised only 30% of Chicago's population [28]. Louisiana reported similar numbers, with African American people representing 70.5% of COVID-19 deaths, although they only accounted for 32.2% of the state's population [29]. In New York City, the initial epicenter in the United States, The Bronx (which had the highest percentage of racial and ethnic minorities and lowest SES of all 5 of the New York City boroughs) had the highest rates of hospitalization (634 per 100,000 population) and COVID-19 deaths (224 per 100,000 population) [30].

The impact of the COVID-19 pandemic on smoking behavior is still unclear. On one hand, smokers might be more likely to quit owing to concerns of an increased risk of illness with COVID-19. On the other hand, increased stress related to the pandemic could present serious barriers to quitting. For many, the shelter-in-place order meant unemployment, home-schooling, and social isolation. Based on an April 2020 nationally representative survey in the United States, 52% of lower-income adults indicated that they or someone in their household experienced unemployment or a pay reduction because of the outbreak (compared to 32% of those with a higher

income) [31]. Only 23% of lower-income adults had an emergency fund to cover illness, loss of employment, or an economic recession, compared to 48% of middle-income adults and 75% of higher-income adults [31]. Women, African American adults, Hispanic adults, those under 65 years of age, and those without a bachelor's degree were more likely to report financial concerns as a result of the COVID-19 pandemic [31]. Yancy [27] noted that the pandemic will end, but the associated health disparities will continue to be a public health priority.

The Current Study

In efforts to understand participants' experiences with the pandemic (and with the iQuit Mindfully intervention during this time), we added measures to assess their experiences specifically during the COVID-19 pandemic. Survey questions asked participants about changes in their smoking habits and quit attempts as well as their perceptions of the mindfulness and text messaging intervention in the context of the pandemic. Given that mindfulness training has been shown to promote more adaptive responses to stress, and that treatment could be offered through mobile technology during shelter-in-place orders, iQuit Mindfully was expected to be acceptable and feasible during the COVID-19 pandemic. Although this was not the original purpose of the study, the timing of our study and COVID-19–specific assessments provide insights into the experiences of low-income, racial and ethnic minority smokers during this time and could inform future intervention efforts.

Methods

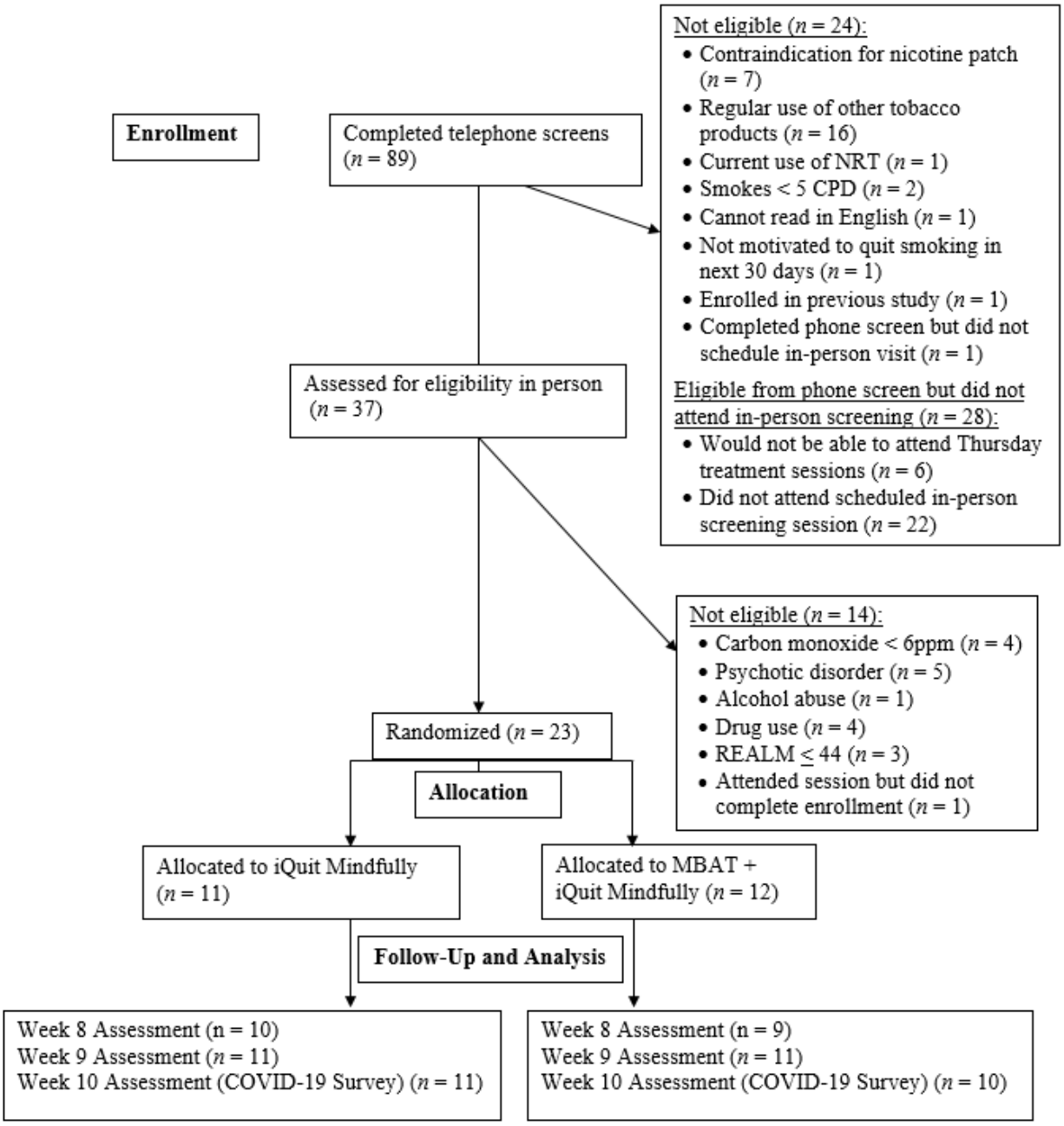
Participants

This study aimed to recruit a racially and ethnically diverse sample of predominantly low-income adult cigarette smokers who were interested in quitting smoking and lived in Greater Atlanta, Georgia. Inclusion criteria were the following: ages 18-65 years; able to speak, read and write in English; smoking at least 5 cigarettes per day; expired carbon monoxide >6 ppm; motivated to quit smoking within 30 days; and at least sixth-grade health literacy (Rapid Estimate of Adult Literacy in Medicine) [32]. Exclusion criteria were as follows: contraindication for nicotine patches, which were provided to them during the study; problematic substance use (Severity of Dependence Scale score >4) [33,34] or a positive response on at least 2 of the 5 Patient Health Questionnaire Alcohol Abuse/Dependence Scale items [35]; clinically significant depressive symptoms (a 2-item Patient Health Questionnaire score of >3 [36,37]; self-reported diagnosis of schizophrenia or bipolar disorder or the use of antipsychotic medications; and pregnancy or lactation. Individuals currently using tobacco cessation medications and regular (at least weekly) users of tobacco products other than cigarettes were also excluded, although participants were not excluded for the use of e-cigarettes. Individuals did not have to own a mobile phone to participate; they were provided the choice of using their own mobile phone or the one provided to them during the study. This study was approved by the institutional review board of Georgia State University (H19243), and all participants provided written informed consent. This pilot feasibility study was funded by the US National Institutes of Health and is not considered a clinical trial in accordance with the National Institutes of Health's definition [38].

Procedures

Recruitment involved the distribution of study flyers in the metro-Atlanta area (eg, downtown Atlanta, near train and bus stops, in the local community health centers) and posted on the internet (eg, Craigslist and neighborhood listservs). Although eligibility was not determined on the basis of income, low-income adults were targeted for recruitment in the study. Interested individuals completed an initial telephone screening, followed by in-person screening (expired CO and assessment of health literacy, mental health, and alcohol or drug use). After informed consent was obtained and baseline assessment was carried out, participants were randomized into 1 of 2 treatment groups (in-person MBAT treatment + iQuit Mindfully text messages [n=12] or iQuit Mindfully alone [n=11]). Figure 1 shows the CONSORT (Consolidated Standards of Reporting Trials) flow diagram. Stratified block randomization was implemented with block sizes of 4 and stratification by race and poverty status. Coauthor MJH generated the random allocation sequence, using SAS software system (version 9.4, SAS Institute). A research staff member (blinded to the size of the blocks) assigned participants to interventions with opaque sealed envelopes marked in accordance with the allocation schedule. Apart from members of the research team who were unmasked to handle randomization and delivery of the interventions, other study personnel were blinded to the treatment conditions. Participants completed in-person assessments at baseline. Remote assessments were carried out on the internet at weeks 8 (end of treatment), 9 (follow-up), and 10 (COVID-19 survey) owing to shelter-in-place restrictions.

Figure 1. CONSORT flow diagram for recruitment, enrollment, and follow-up assessments. CONSORT: Consolidated Standards of Reporting Trials, CPD: cigarettes per day, MBAT: Mindfulness-Based Addiction Treatment, NRT: nicotine replacement therapy, REALM: Rapid Estimate of Adult Literacy in Medicine.



Interventions

All participants received self-help material, nicotine patch therapy, and the iQuit Mindfully text messaging program. Participants assigned to the MBAT + iQuit Mindfully condition also received MBAT treatment for 8 weeks. All participants were asked to set a quit date between 7 and 30 days from the start of treatment. Participants were recruited to begin the interventions all at once (rather than on a rolling basis), and the 8-week treatment began on February 13, 2020.

Self-help Material

All participants received the National Cancer Institute's "Clearing the Air" smoking cessation booklet, including the recommendation to call the Tobacco Cessation Quitline (1-800-QUIT-NOW).

Nicotine Patch Therapy

In accordance with the original MBAT protocol [20], all participants were provided nicotine patch therapy for 6 weeks, regardless of treatment condition. Patch therapy for participants who smoked more than 10 cigarettes per day consisted of 21-mg patches for 4 weeks, 14-mg patches for 1 week, and 7-mg patches for 1 week. Patch therapy for participants who smoked 5-10 cigarettes per day consisted of 14-mg patches for 4 weeks and 7-mg patches for 2 weeks. Patch dispensation occurred upon in-person assessment visits. Participants were instructed to apply a new patch each day when they woke up, starting on

their quit date, and they were provided detailed paper-based and verbal instructions on the proper use of the nicotine patch. At week 8, 11 of 18 (61%) participants with complete data reported having used nicotine patches in the past week (6 of 9 [67%] of those in the MBAT + iQuit Mindfully intervention and 5 of 9 [56%] in the iQuit Mindfully intervention alone).

iQuit Mindfully

iQuit Mindfully text messages [23,24] were sent to all participants each day during the 8-week treatment and 1 week of follow-up. The Upland Mobile Messaging platform was used to generate the automated text message system and send and receive text messages. Text messages were based on the MBAT protocol described below and encouraged participants to practice mindfulness (eg, reminders for informal practice, such as awareness of breath throughout the day, and reminders for formal practice such as the body scan and sitting meditation). They also reminded participants to use specific strategies to aid in cessation (eg, removing cues to smoke, reaching out for social support, and trying other coping techniques from the MBAT protocol [20]). The messages were designed to be interactive; that is, participants were asked questions through a series of flow logic, and they could also text the keywords "CRAVE," "STRESS," "SLIP," or "FACT" at any point to receive an immediate response. Participants could also text keywords (including "MIND," "BODY," and "3MIN") to receive a phone call with a short recording of a mindfulness practice.

Messages were personalized on the basis of first names, personal reasons for quitting, and the amount of money to be saved based on individual smoking habits and price paid per pack. Based on feedback from our previous message testing, participants were able to choose the timing and frequency of text messages. Participants chose from several frequency options (ranging from 1-2 to 5-6 per day) as well as a 12-hour time slot of their choice (either 7 AM to 7 PM or 10 AM to 10 PM). Participants were able to change both the frequency and timing at any point throughout the study. Messages were also personalized on the basis of participants' chosen quit dates. Each week they were asked whether they had smoked; if they had smoked and their quit date had passed, participants were encouraged to set a new quit date, which was then updated in the text messaging platform. After the initial set-up on the Upland Mobile Messaging platform, the text message intervention was fully automated.

MBAT

Participants in the MBAT + iQuit Mindfully condition also received 8 weekly 2-hour group sessions, by a certified Mindfulness-Based Stress Reduction instructor and licensed professional counselor. The MBAT protocol closely follows Mindfulness-Based Cognitive Therapy procedures but replaces depression material with information on nicotine dependence and quitting smoking [20]. MBAT emphasizes personal mindfulness practice in several forms, including sitting meditation, body scan meditation, walking meditation, eating meditation, and gentle yoga or stretching. The program teaches present-focused awareness of moment-to-moment experiences and promotes the ability to purposefully respond to thoughts, feelings, and situations rather than automatically reacting by smoking. For example, MBAT enables mindful awareness of stress, craving, and challenging situations so that participants can more skillfully respond to unpleasant sensations. The first 5 weekly sessions were delivered in person. Because of shelter-in-place orders due to COVID-19, sessions 6, 7, and 8 were delivered through the WebEx teleconference platform.

Measures

The a priori outcomes for this feasibility study were treatment attendance, retention, and participant feedback on the interventions. Because of the onset of the COVID-19 pandemic and our shift to remote intervention and assessment, this study also focuses on participants' experiences specifically in the context of the COVID-19 pandemic.

Program Evaluations

At week 8, participants completed program evaluations to provide their feedback and suggestions for improving the iQuit Mindfully intervention. They were asked the following: "Of all of the text messages that you received as part of this program, how many did you read?" (response options were "None," "Some," "Most," or "All"); "Overall, how helpful were the text messages in getting you to try to quit smoking?" (rated from 1="Not at all helpful" to 10="Extremely helpful"); and "On the scale below, please circle the number that best represents whether you would recommend that other people receive the text messages that you received in this program (or similar texts) as a way to help them quit smoking" (rated from 1="Would not recommend" to 10="Would definitely recommend"). MBAT participants were similarly asked about the extent to which they would recommend the MBAT group sessions to others.

Smoking Abstinence

At weeks 8 and 9, participants were asked, "In the last 7 days, have you smoked even a puff?" Although biochemical confirmation of smoking behavior had been planned for in-person assessments, this was self-reported owing to web-based or telephone surveys. Missing data were not coded as smoking because of the bias often associated with this "missing=smoking" assumption [39].

COVID-19 Survey

At week 10, participants completed a survey of their experiences with stress, smoking, mindfulness practice, and iQuit Mindfully text messages during the COVID-19 pandemic. Participants were asked whether (and how) their level of stress had changed because of the pandemic, with an open-ended follow-up question, "Why do you think your stress level changed?" They were also asked whether their motivation to quit smoking had changed, with a follow-up question of "Why do you think your motivation changed?" Similarly, they were asked about changes in their smoking behavior specifically because of the pandemic, and if so, why. They then answered the following question with a "yes" or "no" response: "Do you think that smoking cigarettes increases a person's chances of getting sick with coronavirus?" The survey also asked whether mindfulness practice was helpful during the pandemic (and if so, how), whether their mindfulness practice had changed since the pandemic, and which mindfulness practices (if any) they had implemented in the past week. Finally, they were asked whether the text messages were helpful

during the pandemic (with responses of “yes” or “no”), and, if so, how.

Data Analysis

Descriptive statistics were used to characterize the study sample as well as indicators of feasibility, acceptability, and experiences during the COVID-19 pandemic. Illustrative participant quotes were selected from open-ended responses on the program evaluations and the COVID-19 survey.

Results

Participant Characteristics

As shown in Table 1, participants were 23 adult cigarette smokers with a mean age of 52 (SD 9.3) years. Slightly over one-third (n=8, 34.8%) were female, and the majority (n=19, 82.6%) were African American. Most (n=18, 78.3%) reported an annual household income of <US $24,000, and 12 (52.2%) were living below the federal poverty level. At baseline, participants smoked 20.7 (SD 12.2) cigarettes per day, and 10 (43.5%) reported smoking their first cigarette within 5 minutes of waking.

Table 1. Characteristics of the study participant in the 2 intervention groups (N=23).

Characteristics	Overall	MBAT[a] + iQuit Mindfully (n=12)	iQuit Mindfully (n=11)
Age (years), mean (SD)	52.0 (9.3)	51.3 (12.0)	52.7 (5.4)
Females, n (%)	8 (34.8)	6 (50.0)	2 (18.2)
Race, n (%)			
African American or Black	19 (82.6)	10 (83.3)	9 (81.8)
White	3 (13.0)	2 (16.7)	1 (9.1)
Other	1 (4.3)	0 (0.0)	1 (9.1)
Ethnicity (Hispanic or Latino), n (%)	1 (4.3)	0 (0.0)	1 (9.1)
Annual income (US $), n (%)			
0-2400	4 (17.4)	3 (25.0)	1 (9.1)
2401-12,000	9 (39.1)	4 (33.3)	5 (45.5)
12,001-18,000	3 (13.0)	1 (8.3)	2 (18.2)
18,001-24,000	2 (8.7)	0 (0.0)	2 (18.2)
24,001-36,000	2 (8.7)	2 (16.7)	0 (0.0)
36,001-54,000	3 (13.0)	2 (16.7)	1 (9.1)
Below the US federal poverty level, n (%)	12 (52.2)	7 (58.3)	5 (45.5)
Education level, n (%)			
Less than a high school degree	5 (21.7)	2 (16.7)	3 (27.3)
High school degree or GED[b]	2 (8.7)	1 (8.3)	1 (9.1)
Some college or technical school	7 (30.4)	4 (33.3)	3 (27.3)
Associate degree	3 (13.0)	1 (8.3)	2 (18.2)
Bachelor's degree	5 (21.7)	4 (33.3)	1 (9.1)
Some graduate school	1 (4.3)	0 (0.0)	1 (9.1)
Employment status, n (%)			
Regular full-time work (≥40 hours/week)	3 (13.0)	3 (25.0)	0 (0.0)
Regular part-time work	2 (8.7)	1 (8.3)	1 (9.1)
Student	1 (4.3)	0 (0.0)	1 (9.1)
Unemployed	6 (26.1)	4 (33.3)	2 (18.2)
Retired	4 (17.4)	1 (8.3)	3 (27.3)
Unable to work or disabled	6 (26.1)	3 (25.0)	3 (27.3)
Other (self-employed)	1 (4.3)	0 (0.0)	1 (9.1)
Cigarettes smoked per day, mean (SD)	20.6 (12.2)	23.2 (15.5)	17.9 (6.8)
Past experience with meditation or yoga, n (%)			
Yes	11 (47.8)	7 (58.3)	4 (36.4)
Missing	1 (4.3)	0 (0.0)	1 (9.1)

[a]MBAT: Mindfulness-Based Addiction Treatment.

[b]GED: General Educational Development.

Retention and Treatment Attendance

Assessment completion rates for the week 8, week 9, and week 10 surveys (all conducted remotely) were 82.6% (n=19), 95.6% (n=22), and 91.3% (n=21), respectively. Among those in the MBAT + iQuit Mindfully intervention, on average participants attended 75% of the first 5 in-person sessions. The median number of in-person sessions attended was 4 of 5. Once treatment transitioned to the internet, participants attended 67% of virtual MBAT sessions (median 2 of 3 virtual sessions attended). Although participants were invited to turn on video mode during the live WebEx sessions, all participants joined via audio only. Participants reported benefits to meeting in this

format, particularly in terms of continued social support and community practice time.

Experiences With Stress in the Context of the COVID-19 Pandemic

Most (n=15 of 21, 71.4%) participants indicated a change in stress because of the pandemic, 14 (93.3%) of whom indicated increased stress. Participants stated that heightened stress was related to concerns about finances, housing, health, and social isolation. One participant reported feeling "isolated and worried about the future" [Participant #214, male], and 2 others stated the following:

> *I became unemployed, uninsured, and homeless. Moving into homelessness with everything shutting down. Needing to find a place to stay.* [Participant #215, female]

> *I was very concerned about catching the virus and how it would [affect] me economically.* [Participant #220, male]

Smoking Cessation in the Context of the COVID-19 Pandemic

At week 8, 10 of 19 (52.6%) participants reported that they had not smoked for the past 7 days (7 of 10 [70.0%] in the MBAT + iQuit Mindfully group and 3 of 9 [33.3%] in the iQuit Mindfully group). At week 9, 11 of 21 (52%) participants reported past 7-day abstinence (6 of 11 [54.5%] in the MBAT + iQuit Mindfully group and 5 of 10 [50.0%] in the iQuit Mindfully group). The majority of participants (n=17 of 21, 80.9%) indicated that they believed that smoking increases the risk of contracting COVID-19.

When asked about their motivation to quit smoking, 8 of 21 (38.1%) participants reported that their motivation had changed specifically because of the pandemic. Of them, 4 (50.0%) indicated higher motivation and 4 (50.0%) indicated lower motivation to quit smoking. The other 13 respondents indicated that they were still motivated to quit but had not done so because of COVID-19. For those whose motivation increased, reasons included the following: "my risk of catching the virus. Smoking weakens my immune system" [Participant #203, female] and "because I am concerned about my health…. Smoking in a stressful situation will make it worse" [Participant #212, male]. Among those who indicated lower motivation to quit because of the pandemic, reasons included the following: "the stress has caused me to buy cigarettes" [Participant #220, male] and "my focus needs to be directed to other things first" [Participant #215, female].

Similarly, 8 of 21 (38.1%) participants indicated that their smoking behavior had changed because of the pandemic. Of them, 2 (25%) reported they "quit smoking because of the virus outbreak" [Participant #219, female; Participant #210, male], 4 (50%) reported that they smoked less, and 2 (25%) reported that they smoked more. Reasons for quitting or reducing their smoking because of the pandemic included "money reasons and health reasons" [Participant #201, male] and the following:

> *Looking at the larger picture, there is a blessing. Smoking will make the virus worse. I have a positive mindset that I will overcome any adversity.* [Participant #212, male]

> *It played into quitting. Being sick, not being able to socialize, stress, and coronavirus outbreak played into me wanting to quit smoking.* [Participant #210, male]

> *It's helping my immune system stay strong.* [Participant #203, female]

For those who reported smoking more or the same amount during the pandemic, explanations included "stress" [Participant #218, female; Participant #221, female; Participant #220, male] and the following:

> *I'm trying to quit because I can't keep going out like this. I don't trust this virus. I can't smoke with my asthma, it is dangerous. But when I was not stressed I [did] good with not smoking.* [Participant #221, female]

> *In the past I was able to channel my energy with work. Once the work was gone I was left with no distraction for my efforts to quit smoking.* [Participant #220, male]

> *I'm still trying to slow down. With all that's going on it's not a big priority right now.* [Participant #214, male]

Experiences With Mindfulness in the Context of the COVID-19 Pandemic

The majority of participants (n=18 of 21, 85.7%) indicated that practicing mindfulness was helpful during the pandemic. Participants shared details about how mindfulness was helpful for them during the pandemic, including "taking a deep breath and thinking about what you want to do" [Participant #204, male] and the following:

> *It gives me a chance to be with myself. I can get away from what's going on in this house and focus just on me.* [Participant #208, male]

> *At first I did not know how that was going to fit into my everyday life. It has been extremely helpful. I have more time to think about it. The body scan and other mindfulness practices. That stuff is powerful.* [Participant #210, male]

> *Takes me to a quiet place where stress is alleviated. I feel calmer. I feel stronger and more peaceful. Even like my blood pressure has gone down.* [Participant #203, female]

> *Sometimes when I was having racing thoughts, I would take me a walk and some deep breaths.* [Participant #219, female]

> *I've smoked less per day and with more awareness. I've been able to better deal with stress than I thought I would have been able to by practicing breathing and meditation.* [Participant #215, female]

When asked about whether their frequency of mindfulness practice had changed since the pandemic, more than half (n=12 of 21, 57.1%) indicated that they practiced mindfulness more, while 5 (23.8%) and 4 (19.1%) practiced mindfulness less. At

the week 10 assessment, 21 of 23 (91.3%) participants indicated having practiced mindfulness in the past week. Of the specific practices, the most commonly used ones were sitting meditation (n=13 of 23, 56.5%) and awareness of breath (n=12 of 23, 52.2%). Among participants in the MBAT + iQuit Mindfully group, the average rating of whether they would recommend MBAT to others was 9.1 (median 10 on a 10-point scale, SD 2.0).

Experiences With the Text Messaging Intervention in the Context of the COVID-19 Pandemic

Based on the program evaluation, 15 of 19 (78.9%) participants indicated reading most or all the text messages. The average rating of the helpfulness of the text messages for quitting smoking was 7.1 (median 8.0 on a 10-point scale, SD 2.9), and the average rating of the extent to which people would recommend the text messaging program to others was 8.2 (median 9.0 on a 10-point scale, SD 2.5). When they were asked whether the text messages were helpful specifically during the COVID-19 pandemic, 14 of 20 (70.0%) replied with "yes." Example responses describing how the texts were helpful during this time include the following:

> *I felt like I wasn't alone. I still felt like you all were here to support me. The quick keyword responses helped a lot because I didn't have to wait for a response.* [Participant #203, female]
>
> *Reminded me not to pick up a cigarette early in the morning. I reach for my cigarette as soon as I wake up so that text was helpful.* [Participant #221, female]
>
> *Yes, I looked forward to them. It gave me something to look forward to. It helped me feel less stressed.* [Participant #202, male]
>
> *It was my inspiration that I could go another day without buying a pack of cigarettes. I have some of the messages.* [Participant #219, female]

In terms of engagement with the text messages over the course of the study, all participants interacted with the program by either replying to texts, using keywords, or both. Over the course of 9 weeks, the median number of times participants texted the system was 37 (range 10-261). In addition, 14 of 23 (60.9%) participants used at least 1 keyword (eg, "CRAVE," "STRESS," "SLIP," or "FACT") to interact with the program.

Discussion

Principal Findings

Lower-income and African American populations are faced with a disproportionate burden due to the COVID-19 pandemic [40,41]. Moreover, cigarette smoking is more common in low-income communities [3,42] and has been linked with an increased likelihood of contracting severe disease [26,43]. Low-income adults have already had lower health care access before the COVID-19 pandemic, and this is likely exacerbated during the pandemic owing to issues including loss of employment or health insurance; limited access to telemedicine, and other barriers. In this study on low-income, predominantly African American adult smokers, most participants reported heightened stress because of the pandemic. Specific stressors included homelessness, unemployment, financial concerns, isolation, and worry about the virus. Most participants believed that smoking increased their risk of becoming sick with COVID-19. While this increased motivation among some participants to quit smoking, others indicated lower motivation to quit because of heightened stress during the pandemic.

Our results support the acceptability and feasibility of remotely delivered mindfulness training to address stress and smoking during the pandemic. The retention rate of the web-based assessment time points ranged from 82.6% to 95.6%. Engagement with the mindfulness-based text messaging intervention was high. For those who were receiving group-based mindfulness treatment, attendance was slightly lower in web-based sessions than in the in-person sessions (67% vs 75%, respectively). In program evaluations, participants highlighted the benefits of both mindfulness practice and support from the text messaging intervention in their daily lives. Moreover, at least half of the participants in both treatment arms (mindfulness-based text messaging intervention with or without group treatment) reported achieving 7-day smoking abstinence. Overall, this study supports the promise of text messaging and the use of teleconferencing to provide mindfulness and smoking cessation services to underserved populations during the pandemic. These methods could increase access to evidence-based treatment for underserved populations regardless of pandemic circumstances.

Comparison With Prior Work

Several studies support the utility of both mindfulness and text messaging interventions for smoking cessation before the pandemic [7,44]. Evidence also supports the efficacy of smartphone apps that advocate mindful acceptance for smoking cessation [45]. Moreover, extant research suggests that mHealth smoking cessation interventions are promising among low- and middle-income countries [46,47], bolstering the notion that mHealth is a viable strategy for targeting smokers with lower socioeconomic resources. While our feasibility study is limited by its small sample size, the rates of self-reported smoking cessation were adequately high. Nine weeks after the start of treatment, 5 of 11 (45.5%) iQuit Mindfully participants and 6 of 11 (54.5%) MBAT participants (all of whom received the iQuit Mindfully text messaging intervention) reported complete abstinence from smoking for the past 7 days. Although not directly comparable because of methodological differences, self-reported 7-day abstinence rates for other text messaging smoking cessation programs have ranged from 20% to 33% [48,49]. For reference, approximately 7% of adult smokers in the United States successfully quit smoking in 2015 [2].

As with our study participants, other studies have reported high levels of stress and distress during the COVID-19 pandemic [50,51]. In particular, African American people have reported higher health concerns related to COVID-19 compared to White people [52]. Low-income and African American communities have already been experiencing a higher prevalence of financial strain, racism, discrimination, and numerous other stressors before the pandemic. Preexisting inequities including lower health care access, higher prevalence of chronic illnesses,

low-wage jobs with fewer opportunities to work from home, and lower access to telehealth services have increased during the COVID-19 pandemic [53,54]. Accordingly, community leaders in collaboration with other stakeholders are seeking solutions to help address and process trauma and stress for communities of color. For example, researchers in Michigan have implemented mindfulness and other wellness programs to reduce stress and promote resilience in African American communities during the COVID-19 pandemic [55].

Participants' descriptions of their experiences with mindfulness and text messaging dovetail with findings from qualitative studies conducted before the pandemic. In previous iterations of the iQuit Mindfully program, participants similarly noted that mindfulness helped them cope with stress, and that the text messages provided important reminders and social support [23,24]. In other text messaging programs for smoking cessation, participants have also highlighted a sense of emotional support [56,57]. In addition, several studies support the utility of mindfulness for addressing mental health among low-income and African American communities [58,59]. Such interventions could be especially relevant in the context of heightened stress during the pandemic.

Digital health interventions involving mindfulness are now being developed and evaluated to address mental health challenges during the pandemic. For example, a web-based intervention is being developed to include mindfulness and cognitive-behavioral skills for addressing COVID-19–related stress [60]. Another study aims to implement a web-based version of a breathing and yoga program for health care workers to reduce anxiety, depression, and insomnia as a result of the pandemic [61]. As this research area grows, it will be important to ensure that effective technologies are accessible to low-income and racial or ethnic minority populations.

Limitations

This pilot study is limited by its small sample size, lack of biochemical confirmation of smoking status, and short follow-up period (1 week after the end of the program or 9 weeks after the start of treatment). Subgroup analyses could not be conducted owing to the small sample size, but future larger studies might examine whether income or other sociodemographic variables moderate the effectiveness of the intervention. In-person expired carbon monoxide assessment was conducted at baseline but could not be conducted once all procedures became remote owing to the implemented social distancing measures. Nonetheless, this is a timely study on strategies to reach underserved populations when participants experienced heightened stress but were not able to access in-person services. This study could help inform clinicians and researchers working under similar circumstances.

Conclusions

This study supports the feasibility of a remotely delivered mindfulness intervention to address stress and smoking among low-income adults during the COVID-19 pandemic. This study adds to the relatively small but growing body of research supporting the utility of mindfulness training among low-income and racial or ethnic minority populations. Moreover, mHealth tools could greatly enhance the accessibility of mindfulness interventions for diverse populations. Well-established mindfulness programs typically involve substantial costs and resources (eg, 8 weekly 2-2.5–hour in-person sessions). Text messaging appears to be a low-cost way to provide in-the-moment support to promote well-being in high-stress contexts. This approach could increase treatment access among populations at a higher risk of experiencing adverse effects of the COVID-19 pandemic and other difficult contexts.

Acknowledgments

This study was supported by the National Cancer Center (R01CA237004442). The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health. The authors are grateful to the study participants for their time and feedback throughout the study.

Conflicts of Interest

None declared.

Editorial Notice

This randomized study was not registered; the study was funded by the US National Institutes of Health (National Cancer Institute), and NCI provided specific guidance for why this study does not fit the clinical trial definition (ie, the focus is on acceptability/feasibility). The editor granted an exception from ICMJE rules mandating prospective registration of randomized trials because the risk of bias appears low and the study was considered formative. However, readers are advised to carefully assess the validity of any potential explicit or implicit claims related to primary outcomes or effectiveness, as retrospective registration does not prevent authors from changing their outcome measures retrospectively.

Multimedia Appendix 1
CONSORT-EHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 3584 KB - formative_v5i7e25926_app1.pdf]

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Abbreviations

MBAT: Mindfulness-Based Addiction Treatment

SES: socioeconomic status

Edited by G Eysenbach; submitted 20.11.20; peer-reviewed by Y Liao, N Guo; comments to author 03.02.21; revised version received 24.02.21; accepted 19.05.21; published 23.07.21.

Please cite as:
Mhende J, Bell SA, Cottrell-Daniels C, Luong J, Streiff M, Dannenfelser M, Hayat MJ, Spears CA
Mobile Delivery of Mindfulness-Based Smoking Cessation Treatment Among Low-Income Adults During the COVID-19 Pandemic: Pilot Randomized Controlled Trial
JMIR Form Res 2021;5(7):e25926
URL: https://formative.jmir.org/2021/7/e25926
doi:10.2196/25926
PMID:34033580

Original Paper

Acceptability and Feasibility of the Transfer of Face-to-Face Group Therapy to Online Group Chats in a Psychiatric Outpatient Setting During the COVID-19 Pandemic: Longitudinal Observational Study

Julia Scholl[1]; Elisabeth Kohls[1,2], PhD; Frauke Görges[2], PhD; Marc Steinbrecher[2], MSc; Sabrina Baldofski[1], PhD; Markus Moessner[3], PhD; Christine Rummel-Kluge[1,2], MD

[1]Department of Psychiatry and Psychotherapy, Medical Faculty, Leipzig University, Leipzig, Germany

[2]Department of Psychiatry and Psychotherapy, Universitätsklinikum Leipzig, Leipzig, Germany

[3]Center for Psychotherapy Research, Universitätsklinikum Heidelberg, Heidelberg, Germany

Corresponding Author:
Christine Rummel-Kluge, MD
Department of Psychiatry and Psychotherapy
Universitätsklinikum Leipzig
Semmelweisstraße 10
Haus 13
Leipzig, 04103
Germany
Phone: 49 3419724464
Email: Christine.Rummel-Kluge@medizin.uni-leipzig.de

Abstract

Background: At the height of the COVID-19 pandemic, several mental health care providers were obliged to shut down outpatient services, including group therapy and psychoeducational sessions. The lockdown in many countries is a serious threat to people's mental well-being, especially for individuals with severe mental illnesses. Discontinued outpatient treatments and disruption of daily routines are considered to be risk factors for destabilization of patients with mental illness.

Objective: The aim of this study was to evaluate the acceptability, usability, and feasibility of a group chat program to replace cancelled face-to-face group sessions in an outpatient psychiatric department.

Methods: Participants (N=33) were recruited in the outpatient department of a large university medical center in Leipzig, Germany. Former face-to-face group participants were invited to take part in a therapist-guided group-chat for 4 weeks (8 sessions) and were asked to evaluate the program via self-administered standardized questionnaires at baseline (T0, preintervention), after every chat session (T1), and posttreatment (T2, after 4-6 weeks). The chat groups were specific to the following mental disorder diagnoses and based on the same therapeutic principles and techniques as the former face-to-face groups: anxiety, depression, obsessive-compulsive disorder, and adult attention-deficit/hyperactivity disorder (ADHD). Sociodemographic measures, attitudes toward the COVID-19 pandemic, depressive symptoms (Patient Health Questionnaire-9), quality of life (abbreviated World Health Organization Quality of Life assessment), treatment credibility/expectancy (Credibility Expectancy Questionnaire), and participants' satisfaction (Client Satisfaction Questionnaire-8 [ZUF-8]) were measured.

Results: Participants joined an average of 5 out of 8 offered chat sessions. Participation rates in the respective groups were highest in the ADHD group (8.6/11, 78%) and lowest in the anxiety group (3.7/9, 41%). The overall preintervention level of depressive symptoms was moderate and showed a slight, nonsignificant improvement at posttreatment (T0: mean 10.7, SD 5.5; T2: mean 10.2, SD 5.5). A similar result was observed regarding quality of life (T0: median 41.7-68.8; T2: median 50-70.3). Treatment credibility and expectancy scores were medium-high (T0: $mean_{credibility}$ 18.1, SD 3.8; $mean_{expectancy}$ 11.2, SD 5.1; T2: $mean_{credibility}$ 17.1, SD 4.8; $mean_{expectancy}$ 10.3, SD 5.8). Further, significant correlations were detected between posttreatment expectancy score and posttreatment PHQ-9 score (r=–0.41, P=.02), posttreatment physical quality of life (r=0.54, P=.001), and posttreatment psychological quality of life (r=0.53, P=.002). Overall, participants' satisfaction with the program was very high, both after chat sessions and at posttreatment (ZUF-8: mean score 20.6, SD 1.0). Of all participants, a majority (27/31, 87%) rated the program as excellent/good and indicated they would recommend the group chat program to a friend in need of similar help (23/31, 74%).

Conclusions: A therapist-guided group chat program to substitute outpatient group setting treatment during the COVID-19 lockdown was shown to be feasible, usable, and highly acceptable for participants. Web-based programs such as this one provide an easy-to-implement tool to successfully stabilize participants during a difficult time, such as the COVID-19 pandemic.

Trial Registration: German Clinical Trials Register DRKS00021527; https://tinyurl.com/3btyxc2r

(JMIR Form Res 2021;5(7):e27865) doi:10.2196/27865

KEYWORDS

online; group chats; COVID-19 pandemic; psychiatric outpatient setting; online interventions; e-mental health; COVID-19; pandemic; mental health; psychoeducation; online chat

Introduction

E-mental health and web-based interventions, as in, the provision of psychosocial or psychotherapeutic support through information and communication technologies, have emerged as an important area in psychotherapy service and research over the past decade [1-3]. The worldwide COVID-19 pandemic was an unexpected situation for most health care providers. In an attempt to reduce the risk of infections and due to governmental restrictions, many health care providers in afflicted countries drastically reduced outpatient treatment options for patients who were in need of outpatient face-to-face therapy, increasing the need to quickly implement other treatment options to support patients [4-6].

This need to find rapid solutions was further amplified by other problems caused by the pandemic and by government restrictions, such as fear and "lockdown loneliness," which may increase the likelihood of deterioration and crises among individuals with impaired mental health [7,8]. Lockdown loneliness occurs because of required physical distancing, social isolation, and quarantine. For individuals with mental illnesses, it was necessary to discontinue many stabilizing factors during the pandemic, such as social contacts, group therapy, and face-to-face psychotherapy, leaving this group particularly vulnerable.

To address these challenges, an urgent need arose for treatment options that incorporated both therapeutic interventions and social interaction. Due to the extensive government restrictions, e-mental health interventions appeared to be the most promising approach.

Various web-based solutions had already been developed and thoroughly researched before the pandemic; however, these solutions encountered certain barriers when being implemented in routine care [9,10], especially due to the lack of acceptance by health care professionals themselves [11]. Because professionals were now forced to apply web-based technologies, it was predicted that the COVID-19 pandemic could be a turning point for e-mental health care [5].

During the pandemic lockdown, the face-to-face therapist-guided self-management groups in our psychiatric outpatient department were transformed into online group chats, similar to online support groups. These groups have been shown to be accessible and popular [12,13] and have potential to provide valuable support to individuals with depression as well as other common mental disorders [14]. Recent studies suggest that such support groups may improve mental health outcomes [15,16] and increase users' sense of empowerment, self-esteem, and perceived quality of life [17].

The aim of this study is to investigate the acceptability, usability, feasibility, and user satisfaction of a therapist-guided online group-chat program as a substitute treatment during the COVID-19 pandemic. The mental state of the participants and their behavior regarding the use of support offers were assessed. The program was intended to stabilize patients' mental condition during the high-risk situation of the COVID-19 pandemic.

Methods

Study Design

This longitudinal, observational prospective study evaluates a therapist-guided group chat intervention that was developed to replace face-to-face therapist-guided self-management group sessions during the lockdown phase of the COVID-19 pandemic. Groups were diagnosis-specific for participants with anxiety, depression, obsessive-compulsive disorder (OCD), and adult attention-deficit/hyperactivity disorder (ADHD), respectively. The study was approved by the ethics committee of the Medical Faculty of the University of Leipzig (133/20-ek, 03/2020) and is registered in the German Clinical Trials Register (DRKS00021527).

Participants and Recruitment

Recruitment of participants started after the psychiatric outpatient department was forced to close and the face-to-face self-management group sessions could no longer take place due to governmental regulations in Germany during the COVID-19 pandemic in April and May 2020. Patients who were receiving treatment at the outpatient department and were part of the established diagnosis-specific psychoeducation and support groups were asked by their therapist whether they wanted to participate in online group chat sessions as a substitute treatment during the lockdown. The inclusion criteria were age 18 years or older, current treatment in the psychiatric outpatient department, former participation in group sessions, adequate understanding of the German language, sufficient sight and reading ability, internet access, and an e-mail address. There were no exclusion criteria. Participants were informed via telephone by their therapist about the group chat program and gave consent via telephone, followed by written informed consent. Paper-and-pencil questionnaires were sent as a small booklet via regular mail to all participants before the start of the intervention. After completing the intervention, participants sent back the questionnaires by prepaid return envelope. An

e-mail reminder system to ensure the return of the completed assessments was implemented.

Through this process, 38 participants were included in the study, with an age range of 19-66 years and a mean age of 39.44 years (SD 12.28). The sample comprised an even gender distribution (female: 20/38, 53%; male: 18/38, 47%). The data of N=33 participants was analyzed (n=3 missing data; n=2 dropouts). Additionally, the posttreatment evaluation of 2 participants was filled in insufficiently, and therefore their data could not be analyzed.

Chat Intervention

The intervention consisted of 8 chat sessions over a duration of 4 weeks. Sessions were scheduled twice a week at fixed times during April and May 2020 and lasted between 60 and 90 minutes. Sessions were moderated by psychotherapists from the outpatient department, who were experienced in administering group therapy and psychoeducation and who had also led the respective face-to-face group sessions before the lockdown. The website and general program for the chats already existed and was customized for our study. Participants needed to log in with a username and secure password to ensure data security. Screenshots of the interface can be seen in Multimedia Appendix 1. As the participants and therapists knew each other personally from the former face-to-face group sessions, chat sessions were (after agreement by all participants) not held anonymously. There were 4 chat groups by diagnosis: anxiety (n=9), depression (n=10), OCD (n=8), and ADHD (n=11). The same classification was used as in the preexisting groups. During chat sessions, participants and therapists were able to communicate by written messages and basic emojis. Therapists were asked to apply techniques equivalent to those they would apply in a face-to-face setting. There was a concrete and manualized psychoeducational theme schedule, although the therapists adapted the topics in the individual chats to participant suggestions or current problems. Additionally, the therapists moderated the exchanges between participants about their own experiences with their disorder as well as coping strategies for everyday life. The main objective of the chats was to stabilize and monitor participants' mental situation and behavior. In cases of severe crisis or suicidal ideation, therapists were asked to perform the standard operating procedure from the outpatient department, adapted to the remote situation. It was not mandatory to participate in all 8 chat sessions.

Measures

Outcomes were measured through self-report questionnaires (paper-and-pencil in a booklet) filled in by participants and sent back via regular mail. Assessments were conducted at baseline (T0, preintervention), after every chat session (T1), and posttreatment (T2, after 4-6 weeks).

Sociodemographic Measures

Participants were asked questions about basic sociodemographic characteristics, such as marital status, living situation, parenthood, employment status, and changes in employment due to the COVID-19 pandemic.

Satisfaction

After each chat session, the participants were asked to fill out an adapted 5-item version of the Client Satisfaction Questionnaire-8 (ZUF-8) [18,19] to measure their satisfaction with the sessions. A full 8-item version of the ZUF-8 was administered at the posttreatment evaluation. All items were measured on 4-point Likert scales. The total sum scores at the posttreatment evaluation ranged from 8 to 32, with higher scores indicating higher satisfaction. The reliability of the ZUF-8 is generally high, and its internal consistency is sufficient [18].

Depressive Symptoms

The Patient Health Questionnaire-9 (PHQ-9) [20-22] was administered at baseline evaluation and posttreatment to assess symptoms of depression. Symptoms were rated by 9 items on a 4-point Likert scale from 0, not at all, to 3, nearly every day. The total sum score ranges from 0 to 27, with higher scores indicating higher levels of depressive symptoms. The scores were categorized by levels of severity. Reliability and validity studies of the tool have indicated that it has sound psychometric properties. The internal consistency of the PHQ-9 has been shown to be high [20].

Quality of Life

The abbreviated World Health Organization Quality of Life assessment (WHOQOL-BREF) [23,24] was used to measure the participants' quality of life at baseline and posttreatment. The 26 items on satisfaction with certain areas of life were rated on 5-point Likert scales from 1, not at all, to 5, extremely. The questions were divided into 4 different domains of quality of life: physical, psychological, social, and environmental. For each of those domains, an index was calculated, ranging from 0 to 100, with higher index scores representing higher quality of life. The WHOQOL-BREF has shown good discriminant validity, content validity, test-retest reliability, and internal consistency [23].

Treatment Expectancy and Credibility

To measure treatment credibility, participants completed the Credibility Expectancy Questionnaire (CEQ) [25] at baseline and posttreatment. The CEQ was translated using a back-translation procedure, and the wording was adapted slightly to the online format of the intervention. The questionnaire includes a credibility factor (3 items) and an expectancy factor (3 items). For the credibility factor, all items were measured on a rating scale of 1 to 9. Items 1 and 3 of the expectancy factor used an 11-point scale, from 0% to 100%, and item 2 also used a 1-9 rating scale. After transforming the percentage scales, the total sums of the scores for credibility and expectancy ranged from 3 to 27, with higher scores indicating a higher credibility/expectancy. The CEQ has demonstrated high test-retest reliability and adequate internal consistency [25].

Use of Other Support Services

In the posttreatment questionnaire, several items were included to inquire as to which supportive offers were used by the participants other than the group chat sessions (eg, offers by the psychiatric outpatient department, social media, or other internet-based support forums). The outpatient department

additionally offered a hotline for patients with severe mental crises.

The primary outcome measure was defined as the participants' satisfaction measured by the ZUF-8 at posttreatment as well as after every chat session. Secondary outcome measures were defined as the participants' quality of life (WHOQOL-BREF), depressive symptoms (PHQ-9), and treatment credibility and expectancy (CEQ).

Statistical Analysis

First, descriptive statistics were determined for socioeconomic variables, changes in employment due to the COVID-19 pandemic, symptoms of depression, quality of life, treatment expectancy/credibility, and participants' satisfaction. Second, potential differences between depressive symptoms at baseline and posttreatment were tested with a *t* test for paired samples. For the different domains of quality of life (WHOQOL-BREF), Wilcoxon tests (nonparametric paired groups) were administered, because the tests for normal distribution (Shapiro-Wilks test) showed that the values of this outcome were not distributed normally. Finally, the correlations between treatment credibility/expectancy at baseline and posttreatment (credibility and expectancy factors of the CEQ) and posttreatment outcome (depressive symptoms of the PHQ-9 and quality of life of the WHOQOL-BREF) were analyzed using the Pearson correlation coefficient. All statistical testing was two-tailed at an level of .05. Analyses were performed using SPSS, version 25.0 (IBM Corporation).

Results

Sample Characteristics

A total of 33 participants were included in the final sample. Half of the 33 participants (n=16, 49%) were single, and 42% (n=14) were either married or in a relationship. A majority of the 33 participants (n=22, 67%) lived with other people (partner, children, roommates, etc). Approximately three-quarters were childless (24/33, 73%) and lived without children in their household (n=25, 76%). Only 39% (13/33) of the participants were currently employed, approximately 20% (6/33, 18%) were retired, and 15% (5/33) were unemployed. Due to the COVID-19 pandemic, more than half (9/16, 56%) of the working participants indicated that their work time had not changed, while one-quarter (4/16, 25%) indicated that their work time had decreased. Only 13% (2/16) lost their job due to the pandemic. A majority of 67% of the working participants (8/12) were working from home during the pandemic, and approximately one-quarter (3/12, 25%) were still working at their regular workplace.

Participation

Participants joined an average of 5 of the scheduled 8 chat sessions (anxiety, mean 3.7; depression, mean 3.4; OCD, mean 5.3; ADHD, mean 6.2). The participation rates were highest in the ADHD group, with an average of 8.6 out of 11 participants (78%) joining the chat sessions. The lowest participation rates were detected in the anxiety group, with only 40% participation on average (3.7/9, 41%). In the depression group, approximately half of the participants joined on average (4.25/8, 53%), and in the OCD group, around 60% joined (5.3/8, 66%; see Table 1).

Table 1. Chat participation for each chat session per group; data are based on log-ins to the chatroom from n=36 participants.

Group	Participants in each chat, n							
	1 (mean 7)	2 (mean 4.5)	3 (mean (7)	4 (mean 6.7)	5 (mean 6.5)	6 (mean 4.3)	7 (mean 5)	8 (mean 5)
Depression (n=8, mean 4.3)	7	1	5	5	4	3	5	4
ADHD[a] (n=11, mean 8.6)	11	9	9	9	9	8	7	7
Anxiety (n=9, mean 3.7)	2	4	7	5	5	4	2	4
OCD[b] (n=8, mean 5.4)	8	4	7	3	8	2	6	5

[a]ADHD: adult attention-deficit/hyperactivity disorder.

[b]OCD: obsessive compulsive disorder.

Satisfaction

In the postsession evaluations, a majority of participants (66%-87%) indicated that they thought the respective chat was excellent/good. Most of the participants received the support they wanted (59%-78%) and would recommend such a group chat program to a friend in need of similar help (70%-87%). The highest scores were achieved for the question of how the participants liked the therapeutic chat. A range of 81%-100% of participants indicated they thought it was excellent/good. The posttreatment evaluation showed a mean sum score of 20.6 (SD 1.0), which indicates a moderately high overall satisfaction with the program (see Table 2).

Table 2. Results of assessments at baseline (T0) and posttreatment (T2).

Variable	T0 (n=33)	T2 (n=31)	*P* value
Depressive symptoms (PHQ-9[a] score)			
0-4, n (%)	3 (9)	6 (19)	
5-9, n (%)	10 (30)	7 (23)	
10-14, n (%)	12 (36)	12 (39)	
15-19, n (%)	6 (18)	5 (16)	
20-27, n (%)	2 (6)	1 (3)	
Sum score, mean (SD)	10.7 (5.5)	10.2 (6)	.93
Quality of life (WHOQOL-BREF[b] score), median (IQR)			
Physical	55.4 (21.4)	57.1 (25.0)	.62
Psychological	41.7 (29.2)	50.0 (24.0)	.52
Social	58.3 (25.0)	58.3 (31.3)	.62
Environment	68.8 (20.3)	70.3 (14.8)	.14
Treatment credibility/expectancy (CEQ[c] score), mean (SD)			
Credibility factor	18.1 (3.8)	17.1 (4.8)	N/A[d]
Expectancy factor	11.2 (5.1)	10.3 (5.8)	N/A
Satisfaction (ZUF-8[e] sum score), mean (SD)	N/A	20.6 (1.0)	N/A

[a]PHQ-9: Patient Health Questionnaire-9.

[b]WHOQOL-BREF: abbreviated World Health Organization Quality of Life assessment.

[c]CEQ: Credibility/Expectancy Questionnaire.

[d]N/A: not applicable.

[e]ZUF-8: Client Satisfaction Questionnaire-8.

Depressive Symptoms and Quality of Life

In this sample, baseline and posttreatment evaluation of the PHQ-9 scores showed an average of moderate depressive symptoms (T0: mean 10.7, SD 5.5; T2: mean 10.2, SD 5.5). In a calculation of the respective categories, a majority of participants (T0: 20/33, 61%; T2: 18/31, 58%) showed moderate to severe symptoms (see Table 2). At the baseline evaluation of the WHOQOL-BREF for quality of life, participants reached the lowest index scores in psychological health (median 41.7, IQR 29.2) and the highest scores in environmental quality of life (median 68.8, IQR 20.3). Overall, scores showed a medium level of quality of life at baseline. In the posttreatment evaluation, the scores were slightly higher; again, psychological health received the lowest score (median 50.0, IQR 24.0) and environmental quality of life received the highest score (median 70.3, IQR 14.8; see Table 2). There was no statistically significant difference in depressive symptoms (PHQ-9 scores) before and after the intervention (t_{30}=.89, P=.93). There was also no statistically significant difference in the scores for quality of life on the WHOQOL-BREF (P_{phys}=.62; P_{psych}=.52; P_{soc}=.62; P_{env}=.14) (see Table 2).

Treatment Credibility and Expectancy

In the baseline evaluation, the participants achieved high credibility scores (mean 18.1, SD 3.8) but lower expectancy scores (mean 11.2, SD 5.1). In the posttreatment evaluation, both scores slightly decreased (credibility: mean 17.1, SD 4.8; expectancy: mean 10.3, SD 5.8) (see Table 2). A correlation analysis showed a significant negative correlation between the posttreatment expectancy factor of the CEQ and the posttreatment PHQ-9 sum score (r=–0.41, P=.02). In addition, a significant positive correlation was found between the posttreatment expectancy factor and the posttreatment physical quality of life score (r=0.54, P=.001), while the correlation between the posttreatment credibility score and the posttreatment physical quality of life score was not significant (r=0.35, P=.06). Lastly, significant correlations were shown between posttreatment psychological quality of life scores and expectancy factors at baseline as well as posttreatment (r=0.36, P=.046, and r=0.53, P=.002, respectively).

Use of Other Support Services

In the posttreatment evaluation, use of other support services was assessed. In this evaluation, we could also include one of the insufficiently completed posttreatment questionnaires; therefore, the percentages were calculated with n=32. A majority of these 32 participants (n=19, 59%) indicated having had contact via telephone with their treating psychiatrist, while one-third (n=9, 28%) had contact with their treating psychotherapist. One-fifth of the participants used other offers, such as contact with the department's social worker (6/32, 19%). Most of the participants (29/32, 91%) stated having had social contacts in the last few weeks, and approximately half (n=17, 53%) used social media on a daily basis. The most commonly

used social media platform by the participants was the messaging platform WhatsApp, with 82% (14/17), followed by Facebook, with 47% (8/17). On average, social media platforms were used for 2.5 hours per day (mean 2.4, SD 1.7). Around half (n = 9, 52.9%) of the participants also used other social media, like other messaging services (Telegram, Threema, Discord), Twitter or YouTube (see Table 3). Other offers that provided support to participants were indicated by 21.9% (n=7, going for a walk, reading, having company, etc).

Table 3. Use of other support services by the study participants (n=32).

Question and answer choices	Value, n (%)
Which offers by the psychiatric outpatient department helped you particularly well in the last few weeks?	
Telephone contact with treating psychiatrist	19 (59)
Telephone contact with treating psychotherapist	9 (28)
Contact in group chat	22 (69)
Others	6 (19)
Which other offers did you use in the last few weeks and thought to be especially helpful?	
Social contacts (eg, calls with friends and family)	29 (91)
Social media	
Instagram users, n (%)	5 (29)
Time spent on Instagram (hours/day), mean (SD)	0.5 (0.3)
WhatsApp users, n (%)	14 (82)
Time spent on WhatsApp (hours/day), mean (SD)	0.9 (0.5)
Facebook users, n (%)	8 (47)
Time spent on Facebook (hours/day), mean (SD)	1.1 (0.8)
Other social media platform users, n (%)	9 (3)
Time spent on other platforms (hours/day), mean (SD)	1.7 (1.5)
Total social media users, n (%)	17 (53)
Total time on social media (hours/day), mean (SD)	2.4 (1.7)
Other online offers	5 (16)
Contact with treating therapist (outside psychiatric outpatient department)	5 (16)
Other contacts	7 (2)

Discussion

Principal Findings

This study was conducted under the circumstances of the COVID-19 pandemic and its effects on individuals with mental health problems, which appear to be substantial [26]. During the lockdown in Germany in March and April 2020, psychiatric patients were confronted with the closure of outpatient departments and the suspension of support offers. Therefore, the program in this study was mainly designed to offer help and support to patients during this difficult time. The opportunity presented by this situation was used to investigate the acceptability and feasibility of the implementation of a therapist-guided group chat program in psychiatric outpatient care.

The transfer of face-to-face group therapies into online group chats in a psychiatric outpatient setting during the COVID-19 pandemic has been successful, as indicated by the results regarding the program feasibility, user satisfaction, and mental health status for all participants. First, the program was shown to be highly satisfactory for the participants, which indicates that the participants received the support that was intended to be given. Second, the program is feasible, as the depressive symptoms of the participants were successfully stabilized; these symptoms were initially at a moderate level and even showed a slight nonsignificant decrease at posttreatment. Similar results were observed regarding the participants' perceived quality of life, which was stable at a medium level in all domains. Although the increase in quality of life scores was not statistically significant, the stabilization and lack of a significant decrease can be seen as successes, especially during the pandemic. The results are comparable to those of previous studies [27,28]. Because only approximately 40% of participants were employed at the time, all others lost their structured daily appointments at the psychiatric outpatient department, which are important in the treatment of mental illnesses. This program was seemingly able to support patients and stabilize their mental health.

The high satisfaction rates with the program after every chat and posttreatment show that the program is highly acceptable for patients experiencing severe mental illnesses. A majority of participants stated they would recommend the program to a

friend in need of similar help, and the participants particularly liked the therapeutic chat. Compliance was good; on average, each participant joined 1 of 2 group chats per week, and more than half of the participants joined every chat.

Overall treatment credibility was medium-high; however, expectancy of improvement was rather low. Our results indicate that a high treatment expectancy correlates significantly with better outcome scores in posttreatment symptoms of depression and perceived quality of life, as patients with a higher treatment expectancy after the intervention had significantly lower PHQ-9 sum scores posttreatment. These findings are in line with previous research, which showed a strong association between treatment expectancy/credibility and outcome scores in different fields of research [29-32] as well as in mental health care [33].

In the last part of our evaluation, we observed that most participants used social contacts for support and found them to be the most helpful. Furthermore, a majority of participants were still in contact with their treating psychiatrist. In line with previous research [34], social media also proved to be an important part of participants' support during this phase of isolation in our study. It can be concluded that additional internet-based treatment offers seem to be a feasible treatment option for most patients, especially during this pandemic.

Limitations

It is important to emphasize that this is not a randomized controlled study and therefore should not be considered as a validation of the effectiveness of online group chat programs. However, preceding research has shown that online or web-based treatments are as effective as or even more effective than face-to-face interventions [35-43]. The aim of this study was to show that such programs are implementable if needed, and this is possible according to our results. Furthermore, online group chats seem to be highly acceptable for patients.

As this study was conducted during an exceptional situation for both patients and mental health care providers, this different environment must be considered when evaluating our results. Participants may have evaluated the program differently because they had no alternative therapy options for comparison at the time.

Participation notably differed between the diagnosis-specific groups, which may have been caused by different habits and behaviors that occur due to the respective illnesses. This finding may also have depended on how well the group members got along before the shift to online treatment.

Conclusion

Online chat programs as a substitute for face-to-face group therapy sessions for patients with severe mental illnesses are feasible, usable, and can be implemented in clinical routine care under pandemic circumstances. They are also highly satisfactory and may have a stabilizing influence on patients' symptom burden. Therefore, they can be considered as a substitute treatment for group therapy sessions during a pandemic, and they may be a helpful tool for future e-mental health offers in routine clinical care.

Acknowledgments

The authors acknowledge support from Leipzig University for Open Access Publishing.

Authors' Contributions

JS, EK, SB, MM, and CRK designed the study protocol. JS and EK performed the analysis; JS, EK, and CRK wrote this manuscript. FG and MS were the administrators of the chat groups. MM developed the implemented chat program. All authors approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Screenshots of the chat program.
[PPTX File , 359 KB - formative_v5i7e27865_app1.pptx]

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Abbreviations

ADHD: attention-deficit/hyperactivity disorder
OCD: obsessive-compulsive disorder
PHQ-9: Patient Health Questionnaire-9
ZUF-8: Client Satisfaction Questionnaire-8

Edited by J Torous; submitted 13.02.21; peer-reviewed by R Maatoug, A Sharma; comments to author 26.04.21; revised version received 17.05.21; accepted 08.06.21; published 23.07.21.

Please cite as:
Scholl J, Kohls E, Görges F, Steinbrecher M, Baldofski S, Moessner M, Rummel-Kluge C
Acceptability and Feasibility of the Transfer of Face-to-Face Group Therapy to Online Group Chats in a Psychiatric Outpatient Setting During the COVID-19 Pandemic: Longitudinal Observational Study
JMIR Form Res 2021;5(7):e27865
URL: https://formative.jmir.org/2021/7/e27865
doi:10.2196/27865
PMID:34161252

Original Paper

Development of a Mobile App for Ecological Momentary Assessment of Circadian Data: Design Considerations and Usability Testing

Thomas B Woolf[1], PhD; Attia Goheer[2], MHS, PhD; Katherine Holzhauer[3], BA; Jonathan Martinez[3], BSc; Janelle W Coughlin[4], PhD; Lindsay Martin[3], MSc; Di Zhao[5], MHS, PhD; Shanshan Song[6], PhD; Yanif Ahmad[7], PhD; Kostiantyn Sokolinskyi[8], BSc, MSc; Tetyana Remayeva[8], BSc, MSc; Jeanne M Clark[3], MD, MPH; Wendy Bennett[3], MD, MPH; Harold Lehmann[6], MD, PhD

[1]Department of Physiology, Johns Hopkins University School of Medicine, Baltimore, MD, United States
[2]Department of Health Policy and Management, Johns Hopkins University Bloomberg School of Public Health, Baltimore, MD, United States
[3]Division of General Internal Medicine, Johns Hopkins University School of Medicine, Baltimore, MD, United States
[4]Department of Psychiatry and Behavioral Sciences, Johns Hopkins University School of Medicine, Baltimore, MD, United States
[5]Department of Epidemiology, Johns Hopkins University Bloomberg School of Public Health, Baltimore, MD, United States
[6]Division of Health Sciences Informatics, Johns Hopkins University School of Medicine, Baltimore, MD, United States
[7]Department of Computer Science, Johns Hopkins University, Baltimore, MD, United States
[8]SROST, Toronto, ON, Canada

Corresponding Author:
Thomas B Woolf, PhD
Department of Physiology
Johns Hopkins University School of Medicine
725 N Wolfe St
Baltimore, MD, 21205
United States
Phone: 1 410 416 2643
Email: twoolf@jhu.edu

Abstract

Background: Collecting data on daily habits across a population of individuals is challenging. Mobile-based circadian ecological momentary assessment (cEMA) is a powerful frame for observing the impact of daily living on long-term health.

Objective: In this paper, we (1) describe the design, testing, and rationale for specifications of a mobile-based cEMA app to collect timing of eating and sleeping data and (2) compare cEMA and survey data collected as part of a 6-month observational cohort study. The ultimate goal of this paper is to summarize our experience and lessons learned with the Daily24 mobile app and to highlight the pros and cons of this data collection modality.

Methods: Design specifications for the Daily24 app were drafted by the study team based on the research questions and target audience for the cohort study. The associated backend was optimized to provide real-time data to the study team for participant monitoring and engagement. An external 8-member advisory board was consulted throughout the development process, and additional test users recruited as part of a qualitative study provided feedback through in-depth interviews.

Results: After ≥4 days of at-home use, 37 qualitative study participants provided feedback on the app. The app generally received positive feedback from test users for being fast and easy to use. Test users identified several bugs and areas where modifications were necessary to in-app text and instructions and also provided feedback on the engagement strategy. Data collected through the mobile app captured more variability in eating windows than data collected through a one-time survey, though at a significant cost.

Conclusions: Researchers should consider the potential uses of a mobile app beyond the initial data collection when deciding whether the time and monetary expenditure are advisable for their situation and goals.

(JMIR Form Res 2021;5(7):e26297) doi:10.2196/26297

KEYWORDS

mhealth; circadian; sleep; ecological momentary assessment; timing of eating; mobile applications; habits; body weight; surveys and questionnaires

Introduction

Establishing the impact of daily habits on long-term health is an important but challenging goal [1-3]. It is well-established that poor daily habits, continued over many years, can lead to adverse health outcomes [4-6]. Less clear is how to collect individuals' daily habits in a way that encourages accurate and comprehensive reporting. We present our experience in developing a research environment for collecting data to explore associations between sleep and eating patterns (the daily habits) and weight (the health outcome) [4,7-10].

This type of app falls into the category of research tools used for ecological momentary assessment (EMA) [11-14]. Since the behaviors are daily and repetitive, we use the term "circadian EMA" (cEMA) and label all similar apps as a particular cEMA app. In general, all EMA apps address circadian problems: For example, how does a participant's mood change over multiple days [15] and how much exercise has a participant been getting and does that correlate with sleep [16]? These are both examples of measures that are changing (or have the potential to change) within and across days, and so finding the correlations between daily habits and some measure of long-term change is common to much of the EMA literature. Many EMA apps have been developed with different research foci than ours. Other intermittent behaviors, such as exercise and alcohol or drug use, call for a different app design.

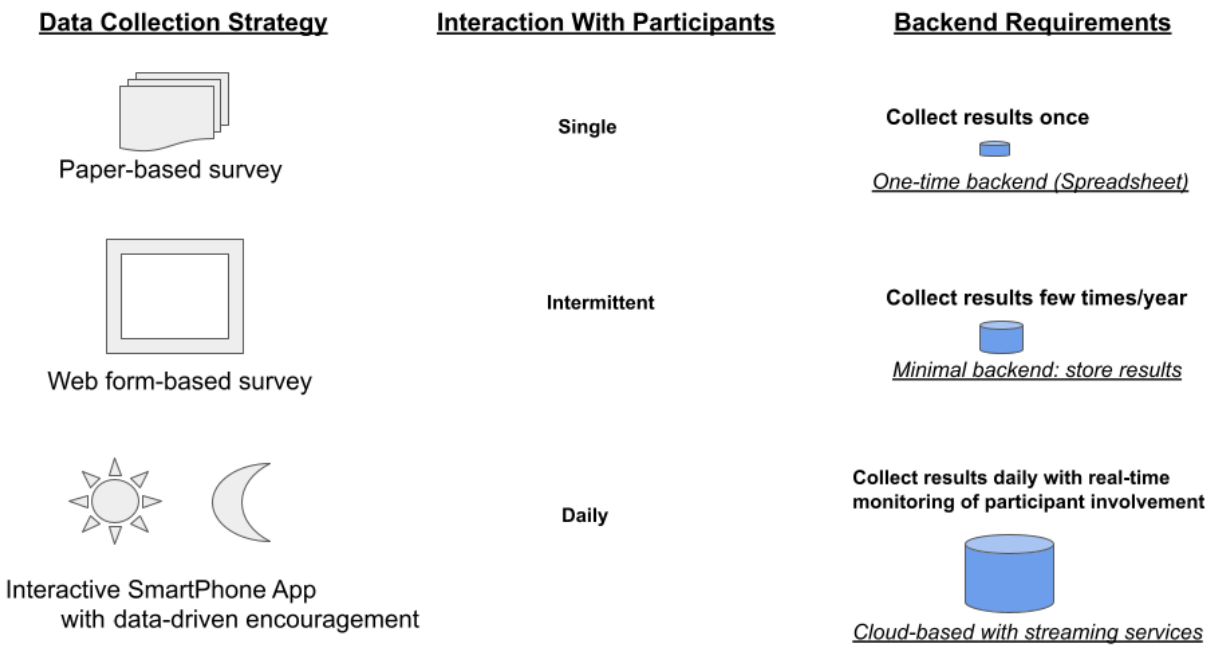
This paper sets out the requirements and design choices for mobile-based cEMAs that we faced during the creation of the Daily24 app. We note that others have addressed requirements for EMA, and we endeavor to add our experience without repeating previous observations [14,17-32]. The environment we describe consists of a user-facing smartphone-based app (Daily24), a back-end server to receive the data, and a research dashboard that enables management of the research process. We highlight the new challenges and opportunities provided through the ability to interact with study participants in real time for a period of months. We describe our design, testing, and key revisions to the app and the associated back end and present our design choices for automated messaging to participants and our real-time dashboards to monitor participant engagement. We then summarize the feedback collected through our user testing protocol and present a comparison of data collected through the app with recall data collected through a one-time, web-based survey. We end with additional considerations when deciding whether to use a mobile app in other research settings.

Methods

Parent Study Design

The overall study for which the mobile app was developed aimed to electronically recruit 1000 app users from the outpatient population at 3 major medical centers. Participants were expected to use the app periodically over the 6-month study period, specifically daily during the first 4 weeks (referred to as the "Power28"), then for 1 week in each of the remaining 5 months (the "PowerWeeks"). Participants were also asked to complete periodic online surveys and to grant permission to access their electronic medical record (EMR) data. A mobile app was considered the optimal data collection modality for this study given the long duration and emphasis on capturing daily variability (Figure 1). Inclusion criteria included being 18 years of age or older, English-speaking, and a patient of the sponsoring institutions and with access to a smartphone with data or Wi-Fi connection to transmit app data.

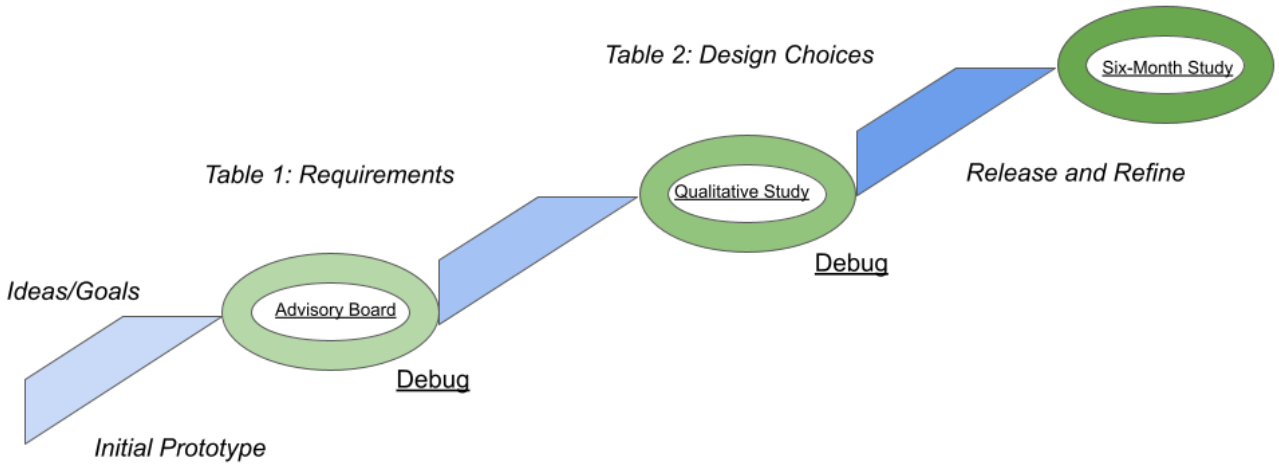
Figure 1. Comparing paper-based, web form–based, and smartphone app–based survey approaches. Note that paper-based surveys can be sent to more than one population or re-used, but often require manual data entry.



User Testing Study Design

The study team recognized the essential need to gather input from test users outside of the team to inform acceptability and usability of the app throughout the development process (Figure 2). During the initial development process, an advisory board of 8 individuals identified as patient advocates for the population we hoped to recruit from was assembled to provide feedback on design, usability, and ease of use. The advisory board was convened 3 times during the app development period. The first was during the design process to share the goals of the app and solicit feedback on the visual presentation. Board members then downloaded the first minimal version of the app and provided initial reactions at the next meeting, with additional feedback provided by phone after 2 weeks of use. At the final meeting, members were consulted about the recruitment and consent strategies for the cohort study, which was atypical in being conducted entirely online with no person-to-person interaction.

Figure 2. The agile development methodology used to stage the release and use of the app for the parent study.



After the initial app development was complete, we conducted a qualitative study to elicit feedback on the usability of the app from target potential users and also to test the back-end linkages between app data and the individual participant's EMR. Qualitative study participants were asked to complete a baseline online questionnaire, then download and use the test app for at least 4 days before meeting with a member of the study team for a 1-hour in-depth interview [33]. Inclusion criteria were the same as for the parent study, with the exception that participants had to be patients of the sponsoring institution.

Development of the Mobile App Front End

Based on participant characteristics from previous studies enrolling electronically from a similar population, we created

a persona of the demographic most likely to enroll for the purposes of designing the app: a woman in her mid-50s, with at least a high-school education, and with an interest in contributing research data for the greater good since there was no monetary compensation provided for participation. We did not expect all participants to be health-conscious or tech-savvy. We also imagined our participants as being concerned about their weight, but not self-managing multiple other chronic conditions or severe acute illness.

We wanted to enable a design that could be reused for other similar studies and that could scale up or down depending on the study size and population. We specifically conducted a multicenter study to establish the generalizability of both our app and our results. Additionally, to avoid selection bias implicit in limiting to a single operating system and to accommodate as many participants as possible, we developed for both iOS and Android using React Native [19], a JavaScript-based, cross-platform development environment. This platform choice brought with it some slower responses within the app and also meant that some user interface items that users on each platform take for granted were not readily available.

The most basic requirement for the mobile app was that the data could be collected on a daily basis, as part of the user's regular routine. For Daily24, the behaviors of interest were sleeping and eating, including wake time, sleep time, start and end time of eating, and an estimate of amount eaten. Our goal was to design the interface to be as simple as possible and to encourage minimal time investment for each participant in the daily logging of information. We had developed an earlier version (Metabolic Compass) of our final app that drew praise from about 50 users for its ability to present data back to participants; however, for this study, we wanted to limit the data shared back with users to keep from influencing their daily patterns.

An additional tradeoff and design decision was to forgo collecting detailed dietary data, choosing instead to collect estimated size of the eating occasion. There are many currently popular apps (for example, MyFitnessPal, MyPlate) that capture caloric information. However, the entry of detailed dietary data takes significant time and would add complexity to the simple interface we wanted and would overwhelm the user's altruism in providing data for research purposes. Additionally, the support required for the large lookup tables for calorie management was beyond both our budget and our developer team. We elected to include 6 broad categories of eating episodes: large, medium, and small meals; large and small snacks; and drinks (except water) without food.

Our budget did not permit the study coordination team to have frequent interactions with all participants and to encourage involvement with a high-touch modality. Therefore, we designed automated reminders and real-time dashboards to let our study coordination team identify those participants most in need of encouragement to stay actively involved. Users received reminders at sign-up and during their POWER28 and Power Weeks. Examples of the initial signup email, reminders, and update emails regarding data contributions are shown in Figures 3 and 4.

Figure 3. Daily24 registration screens.

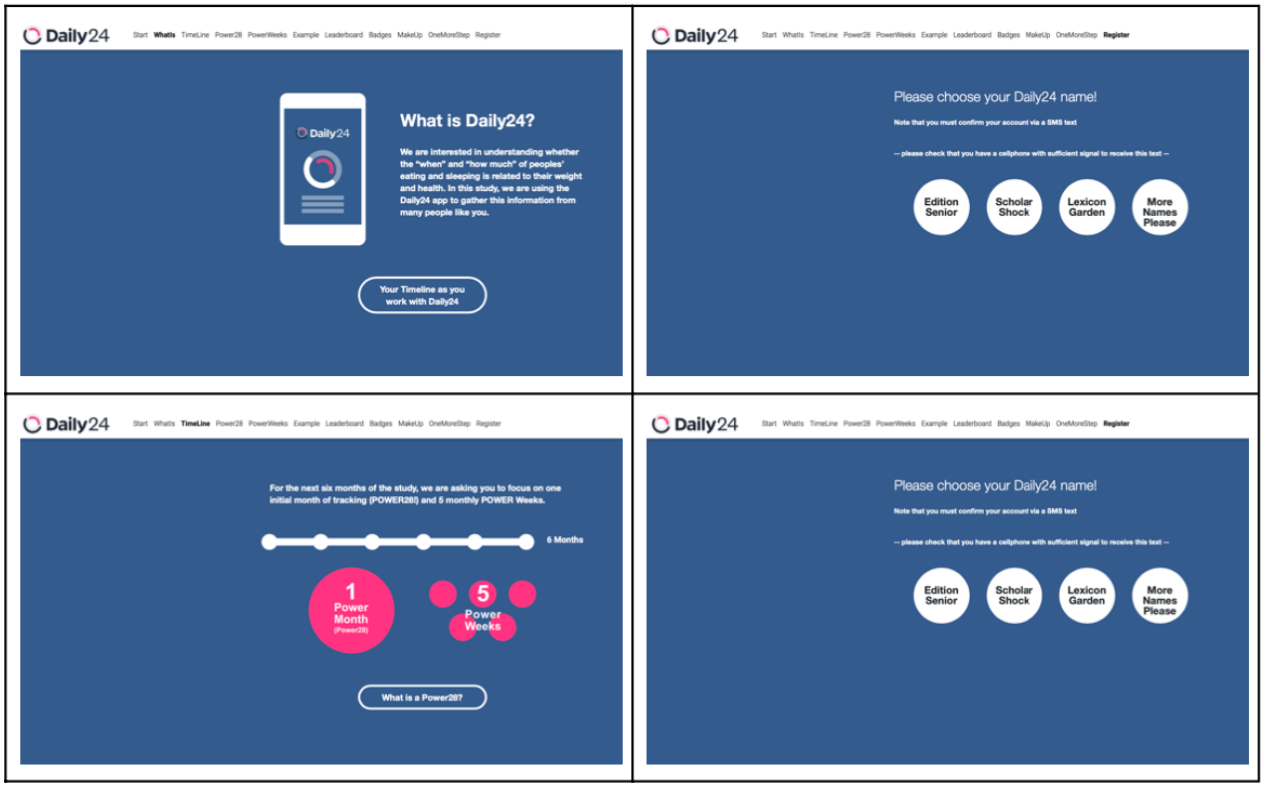
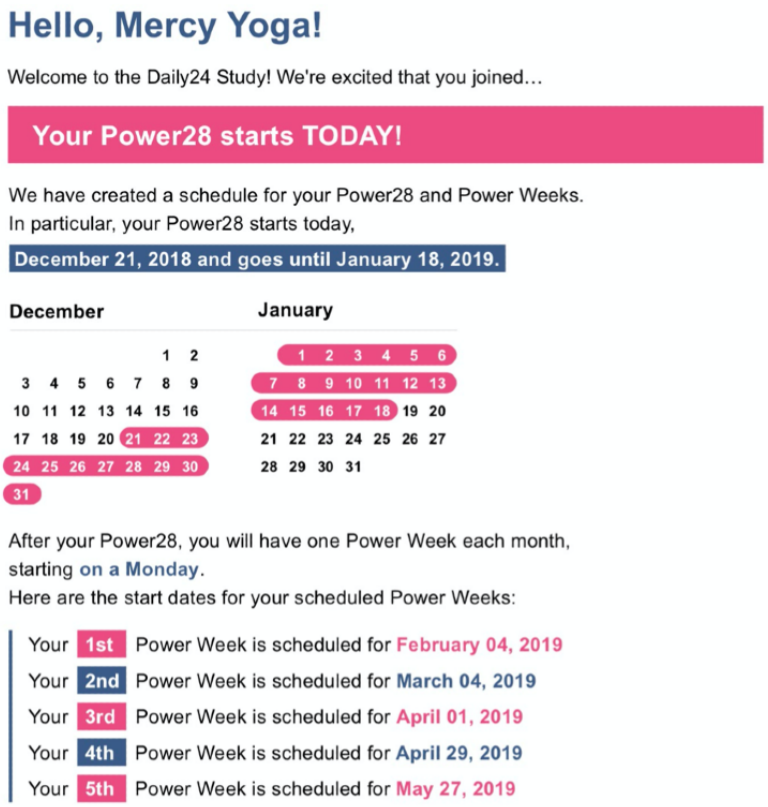


Figure 4. Examples of SMS and emails from a larger set of Amazon Web Services step function–controlled messages to participants.



Given the research context, we designed the app to protect participant privacy and to encourage competition between participants without any sharing of identifiable information. To create usernames, we tested, refined, and ultimately used 2 large tables of uplifting and nonobjectionable adjectives, nouns, and verbs to create names that users could select and identify with, without having to directly craft the names themselves. Example usernames like "YoungWinter" were fully separated from identifiable information. We used a universally unique identifier (for example "7beb5648a909a16fa39281e0ee1b564b") to link our data used for messaging with the data being collected on cEMA.

Development of the Back End for Messaging and Data Management

Continuous engagement was crucial. We had to design a real-time ability into our app and its back end to enable our study team to see how participants were responding to the app and to give us the opportunity to reach out to participants who might be in danger of leaving the study. We used Amazon Web Services (AWS) to support actions based on participants' responses or their relative time within the study. We chose to use AWS step functions and lambda functions to enable data to be placed within a DynamoDB structure and then processed by queries against a PostgreSQL database and with resulting values for display placed on S3. The step functions supported us in designing a logical series of actions based on a timer associated with when they signed up as a participant in the study.

Lastly, we gamified the participant's actions within the app, to encourage their continued involvement. Tactics included virtual trophies for different stages of completion and a real-time leaderboard that displayed where each anonymous individual stood relative to others contributing to the project. Our goal was to encourage a feeling among participants that they were contributing to biomedical research, that it was being logged, and that they could do still more, relative to their peers. The back end additionally was set up to send reminders via SMS, emails, and alerts to encourage a sense of belonging, along with value, and to support continued awareness of the need to enter data.

Comparisons Between Daily24 and Survey Data

Survey data collected as part of the parent study at baseline allowed a comparison to eating and sleeping windows reported through Daily24 to explore the accuracy and comprehensiveness of data entered through the app. Daily24 events are best viewed as an approximate daily entry to the weekly, monthly, and yearly habits of the participant. This approach to analysis may not reflect those with highly variable schedules (for example, Monday is always quite different than Wednesday). However, it provides a unified framework for approaching the very large number of individual data lines for each user.

Results

The full application development process, including user testing and revisions, along with development of the back end, took approximately 2 years. The final requirements and decisions are summarized in Table 1, while the costs associated with each stage and product are detailed in Table 2. Figure 5 displays the final Daily24 mobile app screens.

Table 1. Requirements, decisions, and considerations in the design of Daily24, a circadian ecological momentary assessment (cEMA) app.

Requirement	Daily24 design decisions	Additional considerations
Front end		
Collect recurring, circadian data, but limit collection to essential data	Focus on sleep and diet (and not activity)	Should be fast and easy to enter data; specific variables based on core (causal) model of the research hypothesis
Rely on recurring user data entry	Sleep times, times of eating occasions, meal and snack sizes eaten	There are no passive entry approaches at this point in time
Balance need for more research data against loss of engagement	Use categories of food size rather than specific foods and their calorie count	A simplified interface means that we gain from more daily interactions, but do lose some details
Minimize labeling bias in data entry and minimize feedback	App does not communicate judgment	Avoid feeding back data (eg, summary graphs); avoid guiding users towards a particular change in behavior
Maximize use over multiple days, minimize use within a day	Focus on data entry; simple interface	Target time frame was at least several weeks of daily input over 6 months
Maximize user engagement	Gamify to encourage fun interactions with the app and to reward those that track leaderboards, virtual trophies, “Power28,” “PowerWeek”	A specific challenge for a data collection app that does not offer any direct benefits (as research is not supposed to)
Maximize pool of potential research participants	Develop both for iOS and for Android; national + recruited	Used React Native to maximize developer time; trade off on national, beta-testing, commercial licensing, one-to-one distribution; national reviews might have decreased participation; loss of inter-app interoperability
Maintain privacy	Nonidentifiable usernames selected using random word-pairing generator	Avoids concern about users creating identifiable usernames
Manage expectations in comparison with commercial Apps (fitness trackers)	Address limited functionality up front during signup	None
Balance research-data feedback among research needs, user expectations, and research ethics	N/A[a]	Users of commercial apps expect feedback; research argues against feedback; ethics argues in favor of research
Involve target users in design	Stakeholder advisory board and user testing, iteration over options and discussions on what to take out and to leave in	None
Support multiple types of users	“Super users” that want to enter multiple times each day vs “once-a-day” interaction for a short window of time	None
Back end		
Minimize high-touch engagement costs	Real-time dashboards (updated hourly) and SMS and email messages	None
Minimize development cost	Re-used our initial backend for Metabolic Compass and added dashboards	As an academic use case, revenue generation is not expected, and therefore development costs are not recovered
Support the research process: Recruitment, Execution, Data Analysis	N/A	(Differs from commercial)
Protect participant privacy	Designed in strongly from the beginning: used a UUID[b] to link study data with messaging and created random usernames	HIPAA[c] and IRB[d] are major drivers of this desideratum
Support multi-institutional recruitment and data collection	Designed in strongly from the beginning	We collected REDCap survey data and recruited from multiple institutions
Continuous debugging and improvement of user experience	Used InstaBug to collect user feedback as well as technical issues	None

[a]N/A: not applicable.

[b]UUID: universally unique identifier.

[c]HIPAA: Health Insurance Portability and Accountability Act.

[d]IRB: institutional review board.

Table 2. Time to develop Daily24 as an example circadian ecological momentary assessment (cEMA) app.

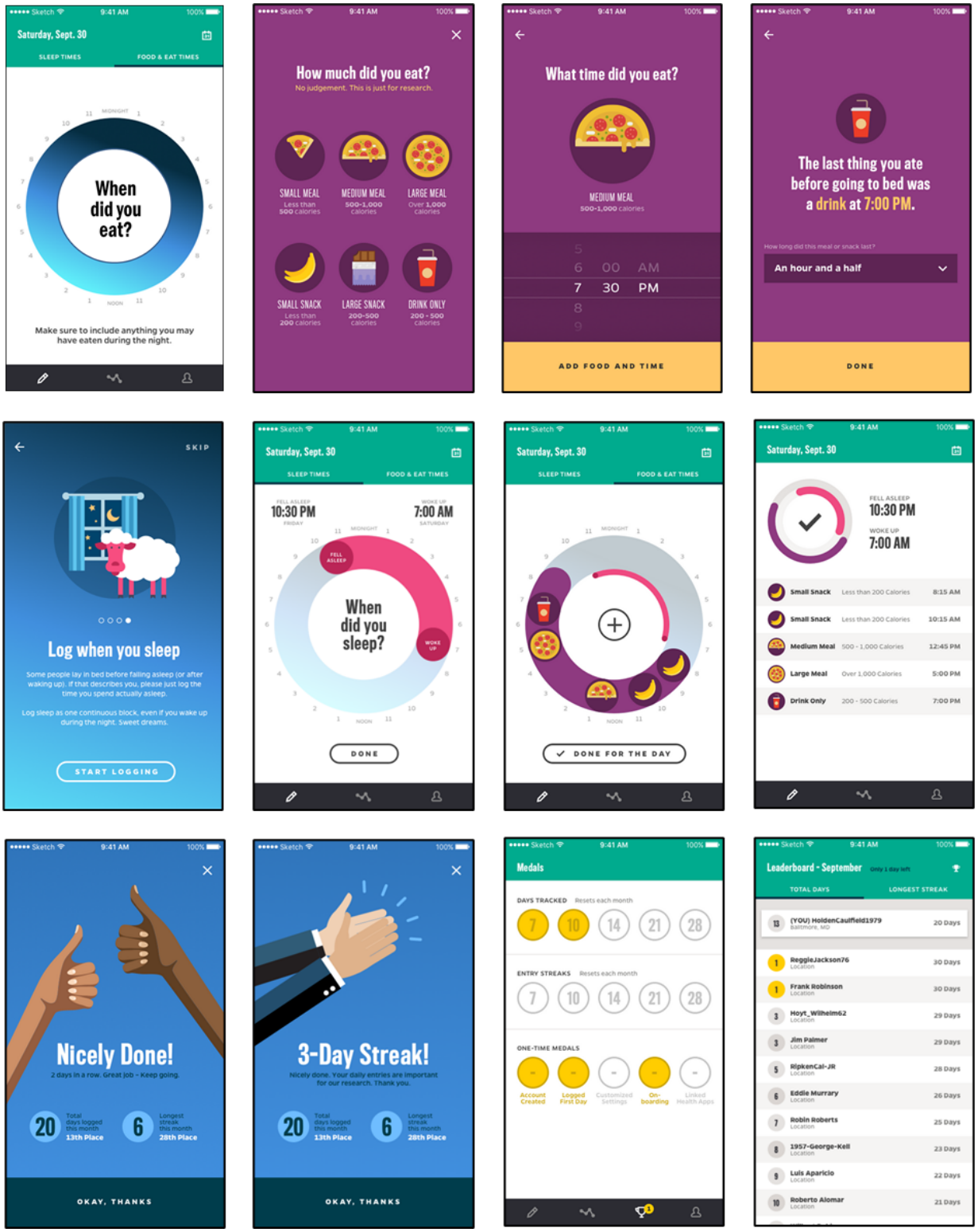
Programming or study need	Personnel involved	Time estimate
Front end		
Initial design workshop and planning	Study PI[a], study co-PI, project coordinator, designer, summer student	1-2 months
Design and stakeholder feedback	Designer, summer student, project coordinator, study PI, study co-PI	3-5 months
Initial MVP[b] rollout	Study coordinator, front end developer part-time, masters level part-time	6-9 months
Iteration for design changes and bug tracking	Front end developer, study coordinator	3-4 months
Near final with more bug reporting and testing	Front end developer, study coordinator	3-4 months
Released version with bug tracking and iterations	Study coordinator, front end developer part-time	12 months or more
AWS[c] or other cloud provider charges	May also include Github, Instabug, and other expenses	12 months or more
Back end: real-time dashboards and automated reminders to participants		
Lambda functions for analysis of incoming data	Back-end developer, masters-level part-time	1-2 months
SMS via AWS step functions	Back-end developer	1-2 months
Emails via AWS step functions	Back-end developer	1-2 months
Initial design of dashboard	Study coordinator, back-end developer	1-2 months
Iterative design to identify participants at risk of dropping out of study	Study coordinator, back-end developer	6 months or more
AWS or other cloud provider charges	Will vary with usage	12 months or more
Back end: datastores and analysis		
PostgreSQL tables	Back-end developer	3-5 months
DynamoDB table	Back-end developer	3-5 months
Trophy feedback	Back-end developer	1-2 months
Leaderboard feedback	Back-end developer	1-2 months
S3 backups and storage	Back-end developer	1-2 months
Maintaining back end for blacklist updates	Bachelors level part-time	12 months or more
SQL queries for analysis	Masters level part-time	12 months or more
AWS or other cloud provider charges	Partially fixed, but then increases with more data	12 months or more

[a]PI: principal investigator.

[b]MVP: minimum viable product (meaning that it is functional, but only minimally).

[c]AWS: Amazon Web Services.

Figure 5. Daily24 mobile app screens.



User Testing Recommendations

We enrolled 37 test users through the qualitative study (mean age, 46.1 years; 26/37, 70% female; 19/37, 51% White) in addition to the 8-member advisory board. Overall, the advisory board and qualitative study participants agreed that the app was fast and easy to use, that the 24-hour wheels were an appropriate way to display the data collected, and that they appreciated the broad meal and snack size categories over needing to enter specific foods consumed. However, several participants identified bugs in the sleep wheel and calendar features, which demonstrated that the app was operating differently on different operating systems and phone models despite using React Native. The extra users were instrumental in identifying these differences and addressing the problems.

The advisory board highlighted a major area of concern: the best way to visually represent the meal and snack size options. The initial icons depicted different foods at the various size

options. Advisory board members expressed a desire to select the icon that represented the type of food they had eaten rather than the size of the meal or snack. The icons were thus revised to show different portions of the same food (pizza pie) as a simple solution to address this concern (Figure 5). Advisory board members also shared ideas to make the calendar feature more visually engaging. Though they expressed a preference for entering interrupted sleep rather than a single sleep window, this feature was beyond the scope of this version of the app. They additionally identified bugs in the app and provided thoughts on the structure of prompts or reminders to enter data.

Qualitative study participants identified 2 main areas of concern in the design of the app. First, several users commented on their inability to record both a meal and a drink occurring at the same time, making it clear to the study team that the app did not clearly convey that the meal and snack icons encompassed drinks as well and that the drink only icon was to be used only in instances where a drink was consumed without food. The icon labels were reworded to more clearly convey this meaning, and the revised wording was tested with the remaining participants. A secondary concern regarding the inability to enter multiple sleep windows to capture interrupted night sleep or naps was also raised, as with the advisory board. The team used this feedback to clarify the app instructions to make it clear that only a single sleep window was to be entered.

App usage feedback highlighted the differences in usage patterns, with a split between participants who used the app throughout the day and those who used the app to enter all eating occasions one time per day. When asked to reflect on the times they did not use the app, participants were close to unanimous in requesting in-app reminders. They differed in their frequency preference, with some requesting multiple reminders per day to align with typical mealtimes and others requesting reminders only when a day passed without them entering data. This feedback was critical in the team's design of the app reminders to be useful without irritating users who wanted less frequent reminders.

In addition, we elicited, through the advisory board and our qualitative study, what would motivate a long-term, 6-month research engagement with the app and how to structure that time. We expected that 6 months of continuous entry would be too burdensome for many users, particularly across our hoped-for population of 500 or more participants. We considered as a study team the optimal schedule for collecting data that spanned a 6-month period, taking into consideration the need to not overburden participants but to also not go so long between uses that re-engagement would be difficult, and shared ideas with the qualitative study participants for feedback. The final decision to use the Power28 and 5 PowerWeeks resulted from these discussions.

Parent-Study Daily24 Usage Patterns

Our app met the goal of multiple, short sessions daily, with 70% of interactions with the app lasting less than 1 minute and with most users interacting with the app approximately 1 to 3 times during each day that they entered data. We found that roughly 25% of individuals used the app at least twice per day on days they entered data.

Comparisons Between Daily24 and Survey Data

Overall, the median values for sleep duration using the 2 modalities (Figure 6) are consistent, though there is more variability captured through the app data. The median length of the eating window reported through Daily24 is approximately 1 hour longer than that reported through a one-time survey recall, and the tail extends an additional hour. Similarly, the comparison between meal and snacks counts during the day (Figure 7) indicates that Daily24 captured more variability throughout the study period.

Figure 6. Comparison of (A) sleeping duration and (B) eating duration reported through the Daily24 mobile app and online survey.

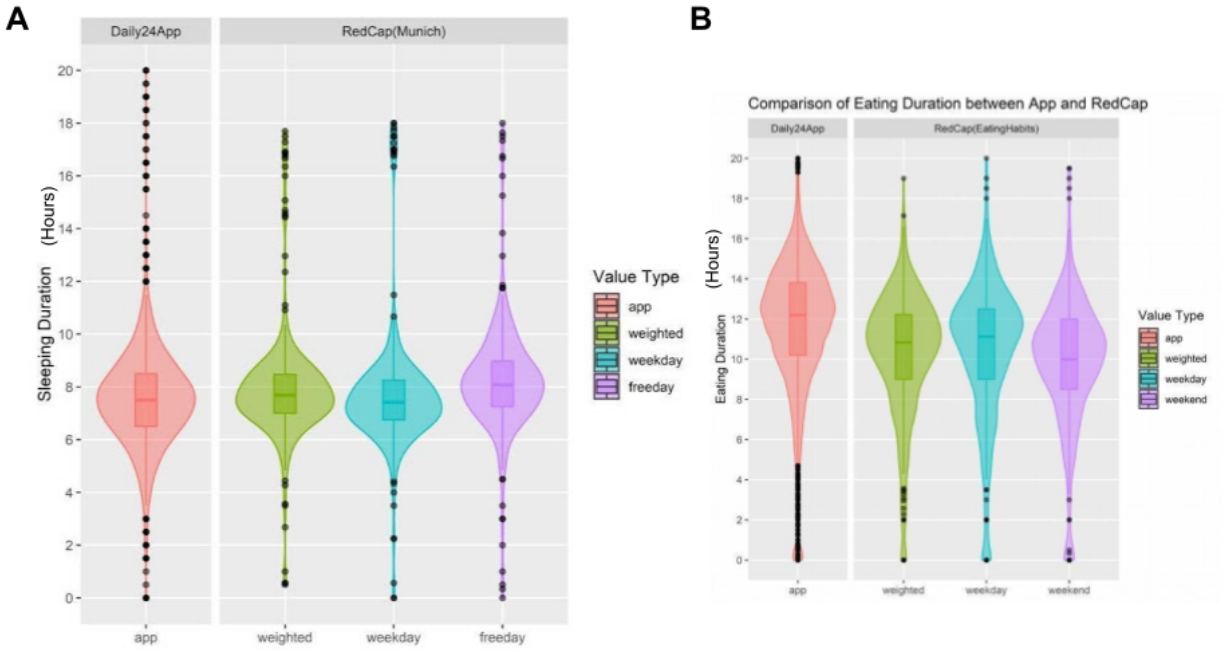
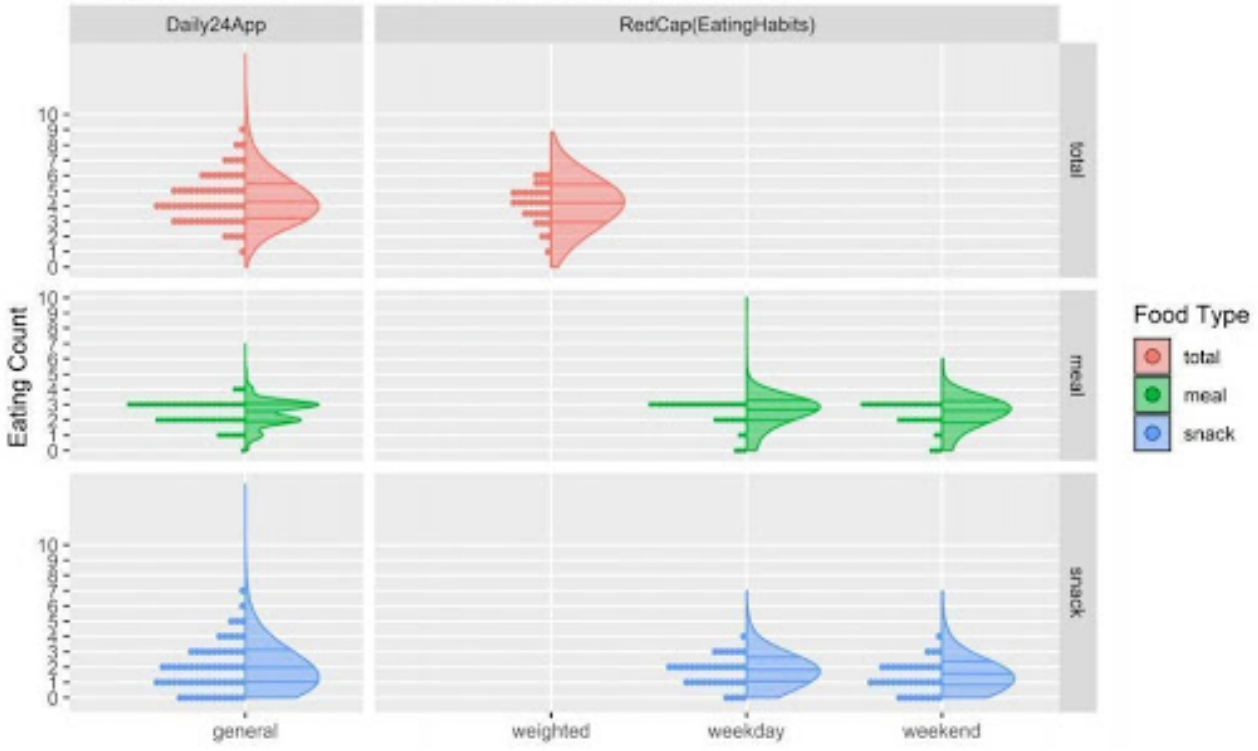


Figure 7. Comparison of eating counts reported through the Daily24 mobile app and the online survey.



Discussion

Overwhelmingly, we heard from users that entering data into the app was extremely efficient, presumably faster than other data collection platforms, and the app was obviously tailored for use on smartphones, which is often not the case for other data collection methods. Additionally, by the careful design of our reminders and by structuring our expectations for logging, we found that engaging and retaining participants without personal contact was possible. However, there were expectedly many bugs in the app that were difficult for our single programmer (during the support stage) to address, and users who encountered these bugs were frustrated that the app did not function as smoothly as commercial apps even after our attempts to mitigate their expectations.

The research context and goal of this type of app bring multiple challenges that are not present in the commercial realm. For example, there is no expectation for reclaiming any development costs when moving to production. At the outset, we recognized that users will be comparing the final product with commercial products from commercial development teams with much greater resources and larger engineering teams. Consequently, we designed our app with a tight range of objectives, a limited budget, and for a very special purpose. Others taking on this type of development should think carefully about the costs for design, development, testing, and continued production and analysis costs.

Though we attempted to communicate, through our recruitment materials and onboarding process, that this is a data collection app and not an app for losing weight, and further, that as a research app, this app would not have the features associated with commercially available apps, we found this message did not land with many participants. This most likely reflects the fact that most apps used daily are of extremely high quality and are supported by very large teams of programmers, data scientists, graphic artists, and advertising (or psychology-based) experts. Furthermore, as a health app associated with a renowned medical institution, users may have been predisposed to assume a health benefit of using the app. In retrospect, we needed to be clearer in our messaging to potential users of what they could — and could not — expect to gain personally from using the app and the difference between research and commercial apps to enable our participants to feel comfortable, rather than critical, at an early stage. Furthermore, we used our small incentives budget to purchase gift card prizes for weekly raffles, but in the future would try to find a larger incentives budget to compensate all participants who reach data entry milestones to provide additional incentive to use the app.

The value of the added accuracy and variability captured through the app depends on the goals of the individual project. Survey data reflect a perception of average daily behavior across many days or weeks and, as shown in the comparison of survey and app data, did not capture as much variability during the week or over a longer time span. For some studies, the extra effort and high cost to capture that additional variability may not be worth it, or perhaps other EMA approaches such as collecting data through instant messaging would capture sufficient variability at significantly lower cost. However, other projects might find that the story lies within that captured variability and may find the costs worthwhile.

The potential for the app to evolve for use in other studies may additionally factor into the cost-benefit analysis. The long-term benefits of app development become more apparent in projects that aim to build off initial results to study other populations or to develop behavior modification interventions. Several adjustments that the Daily24 architecture could accommodate are evident. For instance, the system of reminders and game rewards can be repurposed to support a shorter eating window. It would be easy for a participant to choose a time window for eating and then from that choice, both front end and back end could be working together to help reinforce that behavior. If a participant elected to start meals at a particular hour in the morning, a reminder could prompt them to enter whether they met that goal and to adjust their time entry for when they started their first meal. In a similar way, a prompt could readily be included to ask whether a participant has ended their meals for the day based on a time-based window for eating. The participant could then adjust the window to be smaller or larger based on their behavior. Game-like rewards for adhering to a time-based schedule would be easy to adjust from the current reward system for logging. This ability to adjust the app from a purely observational mode to a tool for behavior adjustment is a major benefit of the time and expense invested into the app.

Our experience is valuable for others considering cEMA apps and their associated back ends for clinical trials. We found that the development of an app and its associated back end was challenging, expensive, yet fully achievable in an academic setting. Like other research endeavors, we found that we could meet our major goals by carefully and iteratively identifying the data that we had to have and data or interactions we could live without. Our experience highlights the importance of a diverse and talented team, regardless of actual size, with an ability to be flexible and to listen to the participants. We believe that the future of this type of observational (and eventual interventional) study is with apps that encourage feedback from the participants, that enable the research team (often small and time-limited) to identify the participants most at risk of dropping out, and with an ability to collect, process, and display (subsets for the participants and all for the study team) real-time data. However, we suggest that anyone budgeting for this type of app be prepared for the long-term costs and the ups and downs associated with development and debugging and to expect that not all participants will “love the app.”

Acknowledgments

We acknowledge the following organizations: American Heart Association (AHA), Institute for Data Intensive Engineering and Science, AWS, Gnar.

Conflicts of Interest

TBW helped found DaiWare, which developed the software under a service contract with Johns Hopkins Univeristy and with funding from the AHA. There are no current plans to commercialize the app and this project was not initiated with any funds from DaiWare.

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Abbreviations

AWS: Amazon Web Services
cEMA: circadian EMA
EMA: ecological momentary assessment
EMR: electronic medical record

Edited by G Eysenbach; submitted 06.12.20; peer-reviewed by M Sobolev, R Krukowski, S Liu; comments to author 15.01.21; revised version received 12.03.21; accepted 04.04.21; published 23.07.21.

Please cite as:
Woolf TB, Goheer A, Holzhauer K, Martinez J, Coughlin JW, Martin L, Zhao D, Song S, Ahmad Y, Sokolinskyi K, Remayeva T, Clark JM, Bennett W, Lehmann H
Development of a Mobile App for Ecological Momentary Assessment of Circadian Data: Design Considerations and Usability Testing
JMIR Form Res 2021;5(7):e26297
URL: https://formative.jmir.org/2021/7/e26297
doi:10.2196/26297
PMID:34296999

Original Paper

Feasibility, Efficacy, and Efficiency of eHealth-Supported Pediatric Asthma Care: Six-Month Quasi-Experimental Single-Arm Pretest-Posttest Study

Mattienne van der Kamp[1,2], MSc; Pamela Reimering Hartgerink[1], MSN; Jean Driessen[1,3], MD, PhD; Bernard Thio[1], MD, PhD; Hermie Hermens[2,4], Prof Dr; Monique Tabak[2,4], PhD

[1]Department of Pediatrics, Medisch Spectrum Twente, Enschede, Netherlands

[2]Biomedical Signals and Systems, University of Twente, Enschede, Netherlands

[3]Department of Sports Medicine, Orthopedisch Centrum Oost Nederland, Hengelo, Netherlands

[4]Department of eHealth, Roessingh Research and Development, Enschede, Netherlands

Corresponding Author:
Mattienne van der Kamp, MSc
Department of Pediatrics
Medisch Spectrum Twente
Koningsplein 1
Enschede, 7512KZ
Netherlands
Phone: 31 534872310
Email: mattienne@gmail.com

Abstract

Background: Early detection of loss of asthma control can effectively reduce the burden of the disease. However, broad implementation in clinical practice has not been accomplished so far. We are in need of research investigating the operationalization of eHealth pediatric asthma care in practice, which can provide the most potential benefits in terms of adoption, efficiency, and effectiveness.

Objective: The aim of this study was to investigate the technical and clinical feasibility, including an exploration of the efficacy and cost-efficiency, of an eHealth program implemented in daily clinical pediatric asthma practice.

Methods: We designed an eHealth-supported pediatric asthma program facilitating early detection of loss of asthma control while increasing symptom awareness and self-management. In the 6-month program, asthma control was monitored by 4 health care professionals (HCPs) by using objective home measurements and the web-based Puffer app to allow timely medical anticipation and prevent treatment delay. Technical feasibility was assessed by technology use, system usability, and technology acceptance. Clinical feasibility was assessed by participation and patient-reported health and care outcomes and via a focus group with HCPs regarding their experiences of implementing eHealth in daily practice. The efficacy and cost-efficiency were explored by comparing pretest-posttest program differences in asthma outcomes (asthma control, lung function, and therapy adherence) and medical consumption.

Results: Of 41 children, 35 children with moderate-to-severe asthma volunteered for participation. With regard to technical feasibility, the Puffer app scored a good usability score of 78 on the System Usability Scale and a score of 70 for technology acceptance on a scale of 1 to 100. Approximately 75% (18/24) of the children indicated that eHealth helped them to control their asthma during the program. HCPs indicated that home measurements and real time communication enabled them to make safe and substantiated medical decisions during symptom manifestations. With an average time commitment of 15 minutes by patients, eHealth care led to a 80% gross reduction (from €71,784 to €14,018, US $1=€0.85) in health care utilization, 8.6% increase (from 18.6 to 20.2, *P*=.40) in asthma control, 25.0% increase (from 2.8 to 3.5, *P*=.04) in the self-management level, and 20.4% improved (from 71.2 to 76.8, *P*=.02) therapy adherence.

Conclusions: eHealth asthma care seems to be technically and clinically feasible, enables safe remote care, and seems to be beneficial for pediatric asthma care in terms of health outcomes and health care utilization. Follow-up research should focus on targeted effectiveness studies with the lessons learned, while also enabling individualization of eHealth for personalized health care.

(JMIR Form Res 2021;5(7):e24634) doi:10.2196/24634

KEYWORDS

telemedicine; feasibility studies; child; self-management; asthma; patient acceptance of health care; ambulatory care; remote sensing technology; cost-benefit analysis; health care costs

Introduction

Asthma is one of the most common chronic diseases in childhood with an estimated prevalence of 7%-10% [1]. Pediatric asthma is an episodic obstructive airway disease leading to attacks, which can hamper physical and emotional well-being [2-4]. The organization of long-term pediatric asthma care currently consists of scheduled periodical hospital visits during which children are clinically evaluated, while being usually symptom-free [5]. Parents and children are also educated during these visits to recognize loss of asthma control and instructed how to manage their symptoms when they occur at home. This, however, relies on an accurate symptom perception of parents and children, which is inaccurate one-third of the times [6,7]. Sears et al [8] showed that inadequate assessment of severity and failure of the family to call for help when required are the major risk factors for serious exacerbations and deaths due to pediatric asthma. Asthma attacks are still one of the main causes of emergency department visits and hospitalizations, thereby imposing a great burden on the pediatric health care system [9-11].

Previous studies have shown that the implementation of strategies aimed at the early detection of asthma, thereby providing access to proper and timely treatment, effectively reduced the burden of the disease [5,9,12]. However, these strategies have not been implemented on a large scale in clinical practice [13]. Health care professionals (HCPs), children, and parents may lack reliable and affordable tools, which can unobtrusively assist disease monitoring and improve health outcomes. eHealth pediatric asthma care supported by home-monitoring technology such as hand-held spirometers or smart inhalers could be such a strategy as it can provide (1) quantitative insight into the dynamics of chronic disease progression; (2) insight into the severity, dynamics, and perception of asthma symptoms, as it exploits repeated measurements of asthma status during symptomatic periods, thereby enabling self-assessment and self-management [14,15] and building symptom perception [16]; and (3) early detection of loss of control and identification of cues and causes of asthma control deterioration [17], which could facilitate timely and targeted medical anticipation and rapid regain of the control of asthma, preventing asthma attacks. Combining these aspects, eHealth strategies may optimize and increase compliance to treatment regimens and may be beneficial in improving health outcomes [18].

Existing evidence on the impact of eHealth in the management of asthma has high heterogeneity in the study endpoints and designs [19]. To date, the largest proportion of eHealth research zeros in on either improving therapy adherence [20-22] or boosting self-management [23-25] and is often not specifically tailored to the pediatric population. The research gap, therefore, lies in the development and evaluation of an eHealth strategy for children with asthma that is based on real-time communication with HCPs and a multi-parameter monitoring approach that facilitates timely anticipation in case of worsening of disease progression. Reaching optimal effects of eHealth care is conditional upon the (1) readiness, acceptance, and engagement of the technology, (2) reliability of the clinical content, and (3) adoption and implementation in clinical practice [26-29]. Only if these 3 conditions are met, optimal efficacy can be expected and options for permanent embedding in practice can be properly evaluated. Currently, the evaluations of eHealth interventions are often executed within either a short pilot or a larger controlled research setting, both lacking to fulfil condition 3 (adoption and implementation in clinical practice) and therefore, not resembling daily care practice. Many of these studies indicate that more research is needed to evaluate the barriers and facilitators for the implementation of an eHealth program in daily practice outside a study setting [30]. Therefore, in this study, we used an exploratory study design adopted in daily clinical care to investigate the operationalization of an eHealth pediatric asthma care program, supported by home-monitoring technology. This study investigates the technical feasibility, that is, technology use, usability, and acceptance, and clinical feasibility, that is, where we can expect the greatest effects and under what conditions we can expect these. The clinical feasibility includes an exploration of the efficacy (in terms of self-reported asthma outcomes, therapy adherence, and inhalation technique combined with lung function) and cost-efficiency (ie, health care utilization). The lessons learned from this study can lay the foundation for targeted effectiveness studies [30].

Methods

Study Design

This exploratory study had a quasi-experiment single arm pretest-posttest design to assess the feasibility of an eHealth program implemented in pediatric asthma care. To explore the efficacy and efficiency of the eHealth program compared to those of regular care, historical data were used for comparison.

Subjects

In total, 41 children (age 4-18 years) with moderate-to-severe pediatrician-diagnosed asthma were asked to participate. They were recruited from the pediatric department of Medisch Spectrum Twente, Enschede, The Netherlands between July 2018 and May 2019 by using consecutive sampling. Children with comorbid chronic diseases or children/parents unable to understand or speak Dutch were not eligible to participate. Offline written informed consent from parents and children >12 years was obtained prior to enrolment. During the exploratory eHealth program, both the HCPs and children and parents could restore regular outpatient follow-up if desired or medically justified.

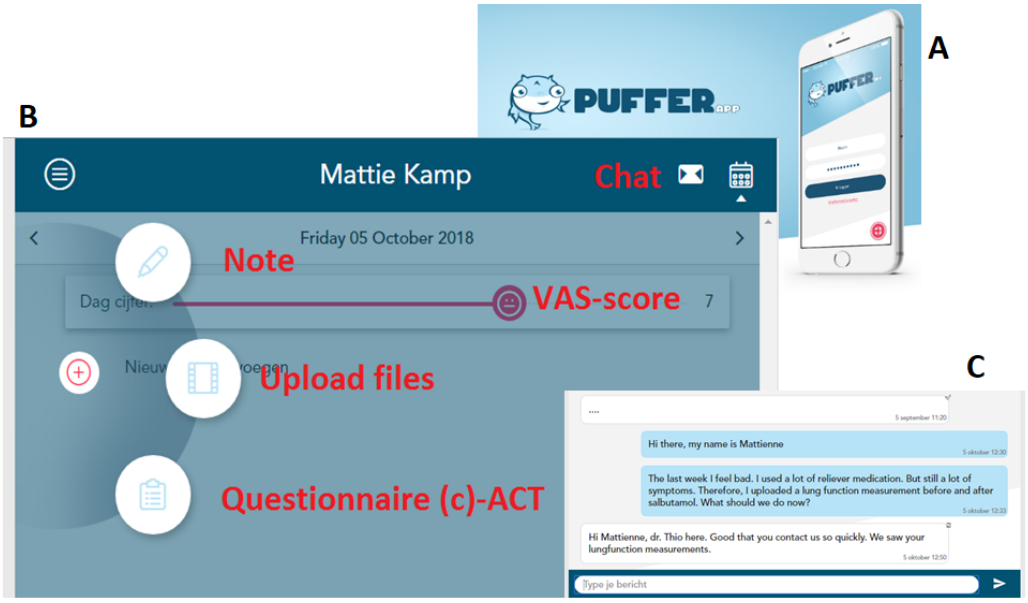
The eHealth Program

The eHealth program (Multimedia Appendix 1) was designed to detect the loss of asthma control in daily life timely and accurately [17], to increase awareness of the severity of asthma symptoms, and to improve the safety of care for both physicians and patients by using objective measurements as the basis for joint decision making. The development and content of the eHealth program was frozen during this study and consisted of the Puffer app and a set of 2 monitoring devices:

1. Monitoring of lung function was performed using the hand-held Spirobank advanced II (MIR Inc). Spirometer flow-volume loops were classified by the HCPs based on self-reported events (regular, pre-exercise, postexercise, symptom, after reliever use). Incorrectly performed spirometer measurements were excluded, according to the American Thoracic Society and European Thoracic Society criteria for standardization of lung function testing [31]. Single spirometry outcome measures (such as forced expiratory volume in 1 second [FEV_1], FEV_1/forced vital capacity [FVC], FEF_{25-75} [mean forced expiratory flow between 25% and 75% of the FVC], and peak expiratory flow) and combined measures (pre-post exercise FEV_1 differences, pre-post reliever use FEV_1 differences and FEV_1 variation) were monitored. Children were asked to perform a spirometry measurement once a week and during symptom occurrence.
2. Medication adherence and inhalation techniques were electronically tracked with the Amiko Respiro smart inhalers (Amiko Inc). This information is essential as many studies have shown that adherence and inhaler technique in children with asthma is poor [32,33]. Moreover, Chrystyn et al [34] recently indicated that smart inhaler studies need to be carried out to demonstrate their potential to improve disease control, prevent exacerbations, and justify their costs. Controller adherence was calculated by dividing the amount of controller medication taken by the amount of medication prescribed (%). Inhalation technique data consisted of the inhalation flow, inhalation duration, and device orientation and were visualized with respect to the regulative values per inhalation device.

The web-based Puffer app (Figure 1) consists of the following functionalities:

Figure 1. An overview of the Puffer app. A: image of the logo and design of log-in screen with username and password; B: overview of the functionalities (the red words indicate the functionalities); C: chat screen. ACT: asthma control test; VAS: visual analog scale.



1. Share photos, videos, and sound recordings: Sharing symptom recordings (ie, allergic reactions, wheeze, cough, and dyspnea) allowed the assessment of asthma severity, especially in younger children [35]. These children have little capacity to compensate for hypoxia and a compliant chest wall; therefore, videos may reveal multiple observational signs (eg, tachypnea, retractions, nasal flaring, speaking in words) [36]. The video option could also be used, as needed, to assess the adequate use of the inhaler and spirometer [37].
2. Chat function: The chats were stamped with a date and time label and the messages receive a checkmark when read by the HCPs and vice versa.
3. Emergency button: It provides the emergency action plan.
4. Share monitoring data: Children could indicate their daily dyspnea symptoms using the visual analog scale (VAS) [38] indicated by emojis, 1 (worst dyspnea ever: sad crying emoji) and 10 (no dyspnea at all: happy face emoji). Asthma control was monitored via the childhood asthma control test (C-ACT) questionnaire [39].

The program was offered for 6 months. Before start, children and parents received the monitoring devices and app, instruction materials, and were instructed on site by the HCPs. A self-made animation (Multimedia Appendix 2) was shared with the participants to illustrate the purpose of the program. Participants were in contact from home with their HCPs (nurse practitioners, technical physician, and pediatric pulmonologist) via a web-based app (Puffer app). Within the 6-month program period, children and parents were free to use the Puffer app

whenever they felt to but were encouraged to update the HCPs at least weekly. Moreover, children and parents were instructed to contact the HCPs as soon as possible when symptoms occur but were also explicitly instructed to not wait for web-based communication in case of emergency asthma exacerbations by pursuing the regular paths within the health care system. HCPs checked the Puffer app daily for new content and data and provided personalized advice via the chat based on the communication and monitored data. All data were visible to both the participants and HCPs. Moreover, once a week, the HCPs came together for a multidisciplinary consultation, in which the data trends and the communications of all patients were discussed.

Outcome Measures

Demographic characteristics (ie, age, gender, inhaled corticosteroid use, long-acting beta-agonist use, and inhalation allergy) were retrieved from the electronic patient record. The health care utilization of the patient was categorized (light ambulatory, middle ambulatory, and clinical) according to the Dutch healthcare registration system of the Dutch Health Care Authority.

Technical Feasibility

Technical feasibility was assessed by technology use, system usability, and technology acceptance. Technology use was determined continuously by the number of chat messages, time spent using the Puffer app (minutes/week), and the adherence (%) of the spirometry data uploads (assuming 1 lung function measurement per week). System usability and technology acceptance were assessed using the System Usability Scale and Technology Acceptance Model [40,41] at the end of the eHealth program (T_{end}), and in addition, by means of a nondirective interview (with an average duration of 5 min) in which the children and parents were asked to provide their experiences of using the technology as part of the eHealth program. From the interview, an overview of the issues was made by grouping similar issues and those were converted into categorical codes (0=negative, 1=positive) to allow for statistical analyses. Moreover, the issues were categorized as minor, serious, or critical based on the frequency and consequences as described by Duh et al [42] and verified by the involved HCPs.

Clinical Feasibility

Clinical feasibility was assessed by participation rate, patient-reported health and care outcomes, and implementation experiences of the HCPs by exploring efficacy and efficiency. The participation rate was the proportion of children who volunteered to participate after being approached for participation. The patient-reported outcomes were quality of care (client satisfaction questionnaire-8 items [CSQ-8]), self-management level (patient activation measure-13 items questionnaire), and quality of life (EuroQol-5D) [43-45]. In addition, participants were also asked whether the proposed eHealth care could support them to control their asthma and whether it could help to prevent emergency department visits and admissions to the hospital (with the answer options: yes absolutely, I don't know, and no). All patient-reported outcomes were assessed on paper prior to the start of the eHealth program (T_{start}) and at the end of the eHealth program (T_{end}). To assess the experiences of HCPs with the eHealth program, 4 HCPs that were part of the eHealth care team were asked to verbalize their thoughts and practical experiences of the eHealth care in a focus group of approximately 60 minutes. The primary aim of the focus group was to identify the barriers and facilitators of pediatric eHealth care, to investigate to what extent the eHealth care program is implementable in their pediatric asthma care center, and to yield pragmatic recommendations. The outcomes were structured under the themes: technical innovations, eHealth asthma care, and implementation considerations [46].

The efficacy of the eHealth care was assessed by lung function tests at home, therapy adherence, inhalation technique, and self-reported asthma outcomes (C-ACT scores and VAS scores of dyspnea) [38,39]. Efficacy was explored by investigating the change in asthma outcomes between the start (first 3 measurements within the first month) and end of the eHealth care (last 3 measurements within the last month of the eHealth care). Health care utilization data consisted of all asthma-related medical procedures (diagnostics, therapy, admissions, emergency department visits, consultations) and were retrieved from the hospital registration system. The unit cost prices of these procedures were determined according to the cost price model guideline of the Dutch Health Care Authority [47]. The costs of the eHealth care program were evaluated by combining the depreciation costs of the equipment and the additional workhours of all HCPs. Research-related costs were excluded. The efficiency of the care was then explored by a within-subjects paired comparison between (1) the historical health care utilization data from a half year prior to the inclusion till the moment of inclusion and (2) the health care utilization data during the eHealth program.

Statistical Analysis

This explorative study used a per-protocol analysis as the dropout rate was low, causing the analysis to better reflect the effects of eHealth when used adherently and without complications in the majority of the asthmatic children. Missing data of children who finished the eHealth program were handled by pairwise deletion. Descriptive statistics were used to examine all the continuous outcome measures and were expressed in mean (SD) for normally distributed variables and in median (IQR) for not normally distributed variables. Univariate analyses were performed on the pretest-posttest differences of the patient-reported outcomes, asthma outcomes, and care utilization with SPSS statistics (IBM Corp). The Shapiro-Wilk test was used to determine whether the variables were normally distributed. The variables that did not have a normal distribution were tested for paired differences with the Wilcoxon signed-rank test. Normally distributed variables were tested with a paired two-tailed *t* test. *P* values less than or equal to .05 were considered as significant.

Results

Demographic Characteristics

Of the 35 children who participated, 30 children (mean age 11.1 [SD 4.1] years, 22 boys) finished the half-year eHealth care period. Table 1 shows an overview of the characteristics of the children. The majority (25/30) of these children had a high health care utilization.

Table 1. Patient characteristics (n=30).

Patient characteristics	Value
Age (years), mean (SD)	11.1 (4.1)
Gender (male), n (%)	22 (73)
BMI z-score, mean (SD)	0.52 (0.87)
Inhaled corticosteroid use, n (%)	30 (100)
Long-acting beta-agonist use, n (%)	24 (80)
Inhalation allergy, n (%)	27 (90)
Childhood asthma control test score, mean (SD)	18.6 (5.0)
Asthma care registration (in half year prior to inclusion), n (%)	
Light ambulatory[a]	5 (17)
Middle ambulatory[b]	15 (50)
Clinical[c]	10 (33)

[a]Light ambulatory is defined as having 1 or 2 outpatient visits for pediatric asthma without additional care utility.

[b]Middle ambulatory is defined as having 3 or more outpatient visits or day treatment or diagnostic testing or any combination of these.

[c]Clinical is defined as having a hospital admission for pediatric asthma.

Technical Feasibility

With regard to technology use, on average, 103 (SD 71) chat messages were sent and received per patient within the half year eHealth care, which is approximately 2 messages per patient per week. The median time spent on using the Puffer app by the participants was 15 minutes per week (IQR 10-26.25 minutes per week). The spirometry adherence was on average 55.7% (SD 9.5%), with week 4 as their median first week for skipping the data upload and week 10 as their median time to have skipped 3 weeks of spirometry data. The system usability score was 78 (SD 17), which indicated good usability. The technology acceptance score was 70 (SD 18) on a scale from 0 to 100. The specific components that made up the technology acceptance showed the highest scores on intention to use (81 [SD 17%]) and ease of use (77 [SD 24%]) and lowest on control over the system (64 [SD 25%]). No critical issues were identified from the nondirective interview with children and parents. Six participants indicated the serious issue that “it would be useful if you were notified if there was a new message from the doctor,” 3 participants preferred a native app instead of a web-based app, and 2 participants indicated that they would like a graphical overview for inspection of their own data.

Clinical Feasibility

Participation rate was high, as 85% (35/41) of the eligible children were willing to participate in the eHealth program. Of these 35 children, 2 dropped out as they indicated to prefer regular care because the eHealth care required “too much effort” from their side. The other 3 excluded participants were prematurely excluded on indication of the HCPs as they felt that the responsibility of care came at stake owing to insufficient good quality home-monitoring data, repeated technology issues that could not be solved remotely, or late responses of the participants to symptoms. Table 2 shows the patient-reported health and care outcomes at the start and at the end of the eHealth program. It reveals that the self-management score and the associated self-management level (patient activation measure-13 item questionnaire) significantly increased through participation in the eHealth care program (P=.02). The quality of care (CSQ-8) was significantly lower at the end of the program (P=.03). The quality of life showed no significant paired differences. Prior to the start of the project, 77% (10/13) of the participants indicated that eHealth could help to control the disease compared to 75% (18/24) afterwards. Prior to the start of the project, 69% (9/13) of the participants indicated that eHealth could help to prevent admissions and emergency department visits compared to 92% (22/24) afterwards.

The focus group was attended by 4 HCPs (a pediatric pulmonologist, a technical physician, a nurse practitioner, and an asthma nurse), who were all part of the eHealth asthma team. Table 3 shows an overview of the barriers, facilitators, and recommendations mentioned, categorized into 3 main domains: technical innovations, eHealth asthma care, and implementation considerations. An elaborate written collection of the experiences of the HCPs can be found in Multimedia Appendix 3.

Table 2. Patient-reported outcomes.

Outcome	Patients (n)	Start of eHealth care intervention, mean (SD)	End of eHealth care intervention, mean (SD)	Relative difference (%)	*P* value
Quality of care (client satisfaction questionnaire-8 items) (0%-100%)	9	94.4 (4.9)	84.7 (10.6)	–10	.03
Self-management score					
Patient activation measure-13 items (13-52)	10	40.8 (4.3)	44.2 (5.0)	+8	.02
Patient activation measure level[a] (1-4)	10	2.8 (0.9)	3.5 (0.7)	+25	.04
Quality of life (EuroQol-5D, 0-100)[b]	10	94.8 (8.4)	93.0 (10.8)	–2	.50

[a]Level 1: start taking on a role, level 2: building knowledge and trust, level 3: take action, level 4: sustain behavior.

[b]EuroQol-5D: European Quality of Life-5 dimension scale.

Table 3. An overview of the barriers, facilitators, and recommendations of the health care professionals.

Theme, subtheme	Barriers	Facilitators	Recommendations
Technical innovations			
General	• Technical difficulties for children/parents learning to operate new diagnostic devices	• Objective assessment • Visualization of trend data	• Create help desk • Expand instruction with run-through on own devices
Smart inhaler	• Nuisance of device updates • Limited compatibility to iPhone operating system • Limited number of inhalers compatible	• Ability to track therapy compliance real-time • Gain insight into medication use behavior • Assessing inhalation technique to select appropriate inhaler type for child	• Expand range of compatible (pediatric) inhalers • Automatic synchronization
Puffer app	• No integration with electronic health record • Absence of real-time reminding system	• Video assessment of symptoms • Assessment of symptom perception by combining subjective and objective measures	• Include pop-up reminders • Connect data trend log to electronic health record
eHealth asthma care			
General	• Risk of missing symptoms in case of noncompliance to eHealth • Lack of physical examination	• Individualized care plan • Safe “substantiated by data” medical decision making • Ability to step-wise learn for children/parents to self-manage asthma • Shared care responsibility between health care professionals and children/parents	• Children with uncontrolled moderate-to-severe asthma are primarily suited for eHealth • Discuss the overlapping disease management goals at start of eHealth period • The extent of eHealth care should be adaptable and confined to the individual needs.
Implementation considerations			
Time investment	• Difficult to schedule time for eHealth care due to its varying character • Increased time expenditure per patient	• Parents/children admire the additional time effort	• Regional cooperation to enable scheduled shifts • No fixed eHealth period; option to quickly de-escalate eHealth care and option to easily restart.
Health care professionals	• Requires reorganization of personnel	• Efficient task reallocation • Multidisciplinary approach	• Weekly multidisciplinary consultation • Include a technical oriented care professional to the eHealth team.
Compliance	• Less compliance to eHealth in times when symptoms are not perceived	• Ability to automatically track compliance to care tasks	• Create a weekly routine of measurements • Transparent noncompliance flowchart to protocolize reminders and eventual exclusion

Efficacy Outcomes

This eHealth program led to an improvement in asthma outcomes, as shown in Table 4. It is noticeable that lung function (+10%), self-interpreted dyspnea (VAS) (+8%), and therapy compliance (+20%) increased significantly. Moreover, an average increase of 1.7 points in the C-ACT score was noticeable after eHealth care, shifting the average from uncontrolled asthma (≤19) to controlled asthma (>20); however, this difference was not statistically significant.

Table 4. Asthma outcomes.

Outcome measure	Patients (n)	Start of eHealth care, mean (SD)	End of eHealth care, mean (SD)	Relative difference (%)	*P* value
Lung function (forced expiratory volume in 1 second % predicted)	24	82.2% (18.1)	90.1 (18.1)	+10	<.001
Dyspnea score (visual analog scale 1-10)[a]	17	7.8 (1.5)	8.4 (1.0)	+8	.01
Childhood asthma control test	9	18.6 (5.0)	20.2 (4.0)	+9	.40
Therapy adherence (% of prescribed)	16	59.9 (33.3)	72.1 (20.3)	+20	.02
Inhalation technique (% correct intake)	16	71.2 (27.4)	76.8 (18.9)	+8	.09

[a]Score1: most severe imaginable dyspnea symptoms; score 10: no symptoms of dyspnea at all.

Efficiency Outcomes

The asthma care registration before and after eHealth care changed as follows: clinical T_{start}, n=10, T_{end}, n=2; middle ambulatory T_{start}, n=15, T_{end}, n=2; and light ambulatory T_{start}, n=5, T_{end}, n=26. Moreover, Table 5 shows that eHealth care resulted in a reduction of care utilization in all aspects, with 85% (from 13 to 2 admissions, 11/13) fewer hospital admissions, 81% (from 21 to 4 emergency visits, 17/21) fewer emergency department visits, and 83% (from 116 to 20 outpatient visits, 96/116) fewer outpatient visits. The reduction in care utilization ensured an average cost reduction per patient of €1925.52 (US $1=€0.85) per half year (80%). Of this, 38.2% (735.55/1925.52) is covered by outpatient savings and therefore 61.8% (1189.97/1925.52) by savings on clinical care. The average program cost was €1291.50 consisting of €420 for the monitoring devices and €871.50 for the additional hours of the HCPs. Therefore, the net cost reduction was 26.3% (634.02/1925.52).

Table 5. Health care utilization.

Care utilization	Six months prior to inclusion	Six months in eHealth care	Difference (relative difference in %)
Hospital admissions (n)	13	2	–11 (–85)
Emergency visits (n)	21	4	–17 (–81)
Outpatient visits (n)	116	20	–96 (–83)
Diagnostic tests (n)	20	1	–19 (–95)
Telephonic consultation (n)	21	9	–12 (–57)
Total health care costs (euro)[a]	€71,784	€14,018	–€57,766 (–80)
Program costs (euro)	N/A[b]	€38,745	+€38,745
Net cost reduction	€71,784	€52,763	–€19,021 (–26)

[a]US $1=€0.85.

[b]N/A: not applicable.

Discussion

Principal Findings

This exploratory study revealed a high feasibility for the use of eHealth-supported pediatric asthma care to monitor and manage children with moderate-to-severe asthma. The exploratory findings showed an increase in self-management, lung function, and therapy adherence and a gross reduction in health care utilization of 80% compared to the historical medical utilization in the same patients. With regard to the technical feasibility, the eHealth system showed good usability and good technology acceptance. No critical issues were identified, but improvements were suggested by patients and HCPs to increase compatibility, enable reminders, and work toward a higher technology readiness level. The technology use of participants was sufficient but became less adherent over time and were mainly adherent to the instructed monitoring frequency in periods with increasing asthma symptoms, consistent with the “law of attraction” as previously described by Eysenbach [48] and comparable to other asthma telehealth tools [49]. Participants indicated that the lack of time and lack of pop-up reminders made them forget to share data/communications. Moreover, participants may grow into “e-attainers,” thereby receiving what was needed (eg, experienced symptom reduction) from this program, even if not from the HCPs, and they would become less adherent [13,50].

This study showed that eHealth-supported asthma care can be beneficial for patients, HCPs, and care organizations. With a participation rate of 85.4%, our eHealth program compared well to other pediatric eHealth initiatives, especially considering the half year time span of the study [51-53]. The high willingness to participate in eHealth care could be due to strengthened position of the children and parents by engaging in their own health care [54]. This provided an opportunity for them to express themselves, measure their symptoms, discuss their insecurities, and enabled them to participate in decision making [55]. Moreover, 75% of the participating children/parents were convinced that this type of eHealth care could help control the disease. In line with this, our study revealed a significant increase in self-management, which is in line with the meta-analytic review of Cushing and Steele [56] who stated, "eHealth interventions that incorporate behavioral methods (eg, self-monitoring, goal setting, immediate feedback, contingency management) produce larger effect sizes for health behaviors and their associated outcomes than interventions that rely solely on education." Moreover, de Jongh et al [57] reported that mobile phone messaging may facilitate self-management of long-term illnesses, emphasizing the importance of direct communication between HCPs and patients. In particular, communication substantiated by self-monitoring data can build up the confidence of children and parents and enhance understanding and self-management of disease. The C-ACT score did not show a significant improvement. However, the average increase from 18.6 (which reflects uncontrolled asthma) to 20.2 (which is clinically interpreted as controlled asthma) indicates a fair margin of improvement in the moderate-to-severe asthma in the population included in this study [5].

This study showed a 80% gross reduction in health care utilization, which was also reflected by the beliefs of the participants themselves; 77% (23/30) of the parents at the start of the program and 92% (24/26) after participating in the program claimed that eHealth in children with asthma could help prevent admissions and emergency department visits. The eHealth care provided a platform for transparent knowledge transfer about the course of individual asthma symptoms and how to manage these. This may have undermined a common belief in patients that asthma is an acute rather than a chronic condition [58], leading to improved therapy compliance and better asthma outcomes in a majority of the children and parents.

Implications For Future Research and Daily Care Practice

Although most eHealth interventions report improved patient outcomes, there still is skepticism about the use of eHealth [59-61]. What is the balance between obtrusiveness of home measurements versus the relevance for disease monitoring? How does eHealth adapt to the individual needs of a patient? Does continuous data collection at home compete with privacy rights and how are data securely managed, processed, and stored? These aforementioned barriers combined with the contextual obstacles (such as workplace reorganization and changes in employment and work priorities) contribute to the conservative attitude of HCPs toward eHealth [59,60]. In contrast, this proof-of-concept study and the study of Simpson et al [62] show legitimate support of mHealth to assist with asthma self-management by both individuals with asthma and HCPs. The HCPs who participated in this study's focus group were confident and enthusiastic about the potential of eHealth care and indicated that current barriers in the organizational and technological aspects are solvable. Specific future focus should be on the safety aspects of eHealth care so that noncompliance to eHealth cannot lead to missing crucial disease information. HCPs also expressed that the ever-expanding data-driven community combined with the increasing amount and quality of available eHealth technologies will slowly occupy a permanent place within the pediatric asthma care. Nonetheless, there is still a lot to gain in bringing these interventions to practice. Next to technological and contextual improvements, HCPs indicated that follow-up research should focus on investigating the adoption of eHealth within the medical guidelines, individualization of eHealth interventions, and protocolization of eHealth use for specific subissues (ie, poor adherence, at risk for exacerbations, and low self-management level). Although cost-effectiveness is particularly important in health care, only few eHealth systems have demonstrated economic advantage, which makes investments in technology by commissioners of services unlikely and implementation even harder [61]. This exploratory study investigated the economic effect and revealed a marked reduction in health care costs by secondary and tertiary prevention with the use of objective monitoring and direct communication. Taking into account the task reallocation of the HCPs and the additional costs of eHealth care resulted in an estimated net cost reduction of 26%, enabling further steps for financial coverage.

Strengths and Limitations

The eHealth program incorporated combined sensing technologies, which could be used to monitor and estimate the disease course, enabling HCPs to anticipate early by medical interventions. This has not been explored in the field of pediatric eHealth care effect studies before and builds upon existing evidence of improved asthma outcomes in eHealth studies using questionnaire-based asthma monitoring or digital self-management support [63-66]. Moreover, our program focused on the development of self-management by using quick, substantiated (by data), and personalized communication by the HCPs in periods of symptoms. Another strength of this program was that children with moderate-to-severe asthma were included and that the baseline characteristics reflect this population well. This population is eminently the group at risk for exacerbations and hospitalizations, and therefore, the first target group for eHealth interventions to enable more effective and efficient pediatric asthma care [67].

This study was limited by the amount of missing questionnaire data. Questionnaires that were not filled completely or incorrectly (multiple answers given in multiple choice) were excluded from the analysis to retain the validity of the questionnaire scores. Moreover, some participants returned the questionnaires by post, which additionally contributed to missing data. Web-based survey systems may help to overcome these issues [68]. The EuroQol-5D quality of life questionnaire showed to be prone to ceiling effects in the pediatric asthma population, as the questions do not really correspond to the burden of asthma on children. Therefore, specific quality-of-life

questionnaires for pediatric asthma such as the pediatric asthma quality of life questionnaire are recommended [69,70].

Although this program strongly suggests that eHealth asthma care might enhance asthma outcomes with a reduction in hospital care utilization, this study was not designed as a randomized controlled trial. At the start of the program, the development of the Puffer app was frozen, but the knowledge, skills, and expertise of HCPs for applying eHealth technology in the pediatric asthma care was expected to progress, which made it better suited for a quality improvement methodology [13]. This study, therefore, demands replication and validation with a control group.

Conclusions

This study revealed a high feasibility for the use of ambulatory pediatric asthma care supported by combined sensing technology that monitors moderate-to-severe asthma and provides timely and substantiated medical anticipation. Future research should focus on investigating adoption of eHealth within the medical pediatric asthma guidelines and individualization of eHealth interventions to reach maximal adoption. These studies can contribute to the development and implementation of feasible ambulatory pediatric asthma interventions, which may help reducing the health burden by increasing long-term respiratory health outcomes.

Acknowledgments

This study was financially supported by the innovation fund “Samenwerken aan Waarde” 2018 of Medisch Spectrum Twente hospital and Menzis health care provider. We thank the innovation fund “Samenwerken aan Waarde” of Medisch Spectrum Twente and Menzis for the unrestricted grant to be able to perform this explorative eHealth program. We also thank J Pierik for her advice and help to set up this program in her hospital. Moreover, we would like to acknowledge the eHealth asthma team of the Medisch Spectrum Twente hospital in Enschede for their continuous effort to provide the best quality remote asthma care.

Authors' Contributions

MvdK designed and performed the study, processed the study data, performed the analysis, and wrote the draft of the manuscript. PRH performed the study and codirected the project in the hospital. BT conceived the presented idea, directed the project in the hospital, and contributed substantially to the final manuscript. JD contributed substantially to the final manuscript. HH supervised the project. MT contributed substantially to the final manuscript and supervised the project. All authors discussed the results, commented on the manuscript, and approved the final manuscript.

Conflicts of Interest

MvdK, JD, and BT contributed to the conceptualization, development, and implementation of the web-based Puffer app. None of the authors declare any other conflict of interest.

Multimedia Appendix 1
Flowchart showing the overview of the eHealth program.
[PNG File , 102 KB - formative_v5i7e24634_app1.png]

Multimedia Appendix 2
eHealth program animation.
[MP4 File (MP4 Video), 59620 KB - formative_v5i7e24634_app2.mp4]

Multimedia Appendix 3
Summary document of the focus group: the experiences of the health care professionals.
[DOCX File , 17 KB - formative_v5i7e24634_app3.docx]

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Abbreviations

C-ACT: childhood asthma control test
CSQ-8: client satisfaction questionnaire-8 items
FEF: forced expiratory flow
FEV_1: forced expiratory volume in 1 second
FVC: forced vital capacity
HCP: health care professional
VAS: visual analog scale

Edited by G Eysenbach; submitted 05.10.20; peer-reviewed by R Krukowski, H Mehdizadeh; comments to author 11.11.20; revised version received 28.12.20; accepted 16.05.21; published 26.07.21.

Please cite as:
van der Kamp M, Reimering Hartgerink P, Driessen J, Thio B, Hermens H, Tabak M
Feasibility, Efficacy, and Efficiency of eHealth-Supported Pediatric Asthma Care: Six-Month Quasi-Experimental Single-Arm Pretest-Posttest Study
JMIR Form Res 2021;5(7):e24634
URL: https://formative.jmir.org/2021/7/e24634
doi:10.2196/24634
PMID:34309568

Review

Use of Telemedicine in Depression Care by Physicians: Scoping Review

Jean-François Echelard[1], MD

Faculty of Medicine, Université de Montréal, Montreal, QC, Canada

Corresponding Author:
Jean-François Echelard, MD
Faculty of Medicine
Université de Montréal
2900 Edouard Montpetit Blvd
Montreal, QC, H3T 1J4
Canada
Phone: 1 (514) 343 6111
Email: jfechelard@hotmail.com

Abstract

Background: Depression is a common disorder, and it creates burdens on people's mental and physical health as well as societal costs. Although traditional in-person consultations are the usual mode of caring for patients with depression, telemedicine may be well suited to psychiatric assessment and management. Telepsychiatry can be defined as the use of information and communication technologies such as videoconferencing and telephone calls for the care of psychopathologies.

Objective: This review aims to evaluate the extent and nature of the existing literature on the use of telemedicine for the care of depression by physicians. This review also aims to examine the effects and perceptions regarding this virtual care and determine how it compares to traditional in-person care.

Methods: The Arksey and O'Malley framework and the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews) guidelines were followed. Relevant articles were identified through a search of three databases (MEDLINE, Cochrane Database of Systematic Reviews, and PsycArticles) on October 11, 2020. The search terms were "(*virtual* OR *telemedicine* OR *teleconsultation** OR *telehealth* OR *phone** OR *webcam** OR *telepsychiatry*) AND (*depress**)". Eligibility criteria were applied to select studies about the use of telemedicine for the care of patients with depression specifically by physicians. An Excel file (Microsoft Corporation) was used to chart data from all included articles.

Results: The search resulted in the identification of 28 articles, and all 13 nonreview studies were analyzed in detail. Most nonreview studies were conducted in the United States during the last decade. Most telemedicine programs were led by psychiatrists, and the average study population size was 135. In all applicable studies, telepsychiatry tended to perform at least as well as in-person care regarding improvement in depression severity, patient satisfaction, quality of life, functioning, cost-effectiveness, and most other perceptions and variables. Cultural sensitivity and collaborative care were part of the design of some telemedicine programs.

Conclusions: Additional randomized, high-quality studies are recommended to evaluate various outcomes of the use of telemedicine for depression care, including depression variables, perceptions, health care outcomes and other outcomes. Studies should be conducted in various clinical contexts, including primary care. Telepsychiatry is a promising modality of care for patients suffering from depression.

(JMIR Form Res 2021;5(7):e29159) doi:10.2196/29159

KEYWORDS

telemedicine; telepsychiatry; depression; mental health; videoconferencing

Introduction

The Burdens of Depression

Depression is a very common disorder and thus represents a heavy mental health burden. Although estimates vary widely, the lifetime and 12-month prevalence of depression may be close to 10% and 5%, respectively, and these values are higher in high-income countries [1]. Suicidal risk and ideations have a high incidence among patients with depression. Although estimates vary widely, the incidence of suicide among patients with depression may be as high as 15%, while up to 70% of patients with acute depression may experience suicidal ideas [2]. Unfortunately, depression is associated with an elevated risk of early death. This is partly due to suicidal risk but also to the heavy physical health burden of this psychopathology. Indeed, depression is a predictor of many physical diseases, including coronary artery disease, myocardial infarction, stroke, diabetes, and various cancers. Certain physical disorders also tend to be more severe among patients with depression. There is a reciprocal relationship between depression and physical pathologies. Biologically plausible mechanisms include behaviors such as smoking, drinking alcohol, obesity, low compliance with treatment regimens, and a variety of hormonal and immune dysregulations. Unsurprisingly, depression is also associated with lower perceived overall health [1]. Caring for mentally and often physically sick patients is expensive and requires resources. Thus, the health care burden of depression is heavy. The costs of this disease have been increasing in recent decades and amount to hundreds of billions of dollars in the United States [3]. Depression is highly socially burdensome in several other ways. It is associated with termination of education, lower probability of marrying, marital dissatisfaction, negative parenting behaviors, adolescent childbearing, unemployment, work disability, absenteeism, low work performance, lower personal earnings, and lower household income [1]. Approximately half of all costs associated with depression are workplace costs [3].

Approaches to Depression Care

Although traditional in-person consultations are the usual modality of caring for patients with depression, telemedicine may be well suited to psychiatric assessment and management. This modality of care may also offer many advantages, such as improving access to care in rural areas [4]. In fact, medicine as a whole is becoming increasingly digitalized as competencies required to provide health care are evolving [5]. Other components of depression care include collaborative care and culturally sensitive approaches. Collaborative care is an integrated model in which many health care professionals work together with the patient to better manage the patient's disease in a synergic manner [6]. Cultural aspects must also be considered, as beliefs regarding depression and mood influence how patients perceive their psychological health [7].

Defining Telepsychiatry

For the scope of this review, telepsychiatry is defined as the use of information and communication technologies such as videoconferencing and telephoning for the diagnosis and management of psychopathologies. Telepsychiatry is thus a synonym of telemedicine for mental health. Psychiatrists, general practitioners, and other physicians can practice telepsychiatry. Other health care professionals, including psychologists, social workers, and nurses, can use telemedicine for mental health as well. Broader or narrower definitions of telepsychiatry could be used by other authors. Various technologies could also be included in other definitions, including artificial intelligence, augmented or virtual reality, mobile apps, and the Internet of Things. Other terms such as telemental health, e-mental health, and connected mental health could also be used to describe related concepts [8].

Goal of This Study

Telepsychiatry is a broad concept, and it has many applications. This results in heterogeneity in the literature. One key aspect of telepsychiatry is its use by physicians for various aspects of depression care, including assessment, evaluation, diagnosis, management, and follow-up. This review therefore aims to evaluate the extent and nature of the existing literature on telemedicine for the care of depression by physicians. This review also aims to examine the effects and perceptions of virtual care and how it compares to traditional in-person care.

Methods

Theoretical Framework

This scoping review was conducted by following the Arksey and O'Malley framework as well as the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews) guidelines. The five methodological stages were the identification of the research question, the identification of relevant articles, the study selection, the data extraction, and the collating, summarizing, and reporting of the results [9].

Identification of the Research Question

As described above, this review's main objectives are to map the literature on telemedicine in the diagnosis and management of depression by physicians and to examine the effects of telemedicine and how it is perceived. In other words, this review examines the virtual care of patients with depression by physicians. The identification of this research question is closely related to the burdens of depression and the potential of innovative psychiatric care.

Identification of Relevant Articles

A systematic literature search was performed in MEDLINE, Cochrane Database of Systematic Reviews and PsycARTICLES. These databases were chosen based on their relevance and specificity for peer-reviewed articles on medical and psychiatric topics. No search for gray literature was performed because the scope of this review did not extend to articles that had not been peer-reviewed. The list of keywords used was developed through a preliminary search on PubMed, and the keywords were selected based on their sensitivity and specificity for relevant articles. The search terms used for the database searches in this review are listed in Textbox 1. The literature search was performed on October 11, 2020, and it yielded 4782 articles.

Textbox 1. Search string with the keywords used for the database searches.

(*virtual* OR *telemedicine* OR *teleconsultation** OR *telehealth* OR *phone** OR *webcam** OR *telepsychiatry*) AND (*depress**)

Study Selection

Following removal of all 532 duplicates, the remaining 4250 articles were screened based on the eligibility criteria detailed in Textbox 2. Articles were initially screened based on their title and abstract, and full text articles were obtained when more information was needed for screening. The final count of studies included in this review is 28.

Textbox 2. Eligibility criteria for study selection.

Inclusion criteria

- Directly related to telemedicine
- Directly related to the evaluation or treatment of depression
- Care provided by physicians (eg, general practitioners, psychiatrists)

Exclusion criteria

- Mobile health apps as the primary focus
- Texting and emails as the primary focus
- Psychotherapy as the main intervention (eg, articles about web-based cognitive behavioral therapy)
- Psychotherapy or care provided by health care professionals other than physicians
- Depressive symptomatology from bipolar disorder, anxiety disorder, or schizoaffective disorder
- Depressive symptomatology as an outcome of telemedicine for diseases other than depression (eg, multiple sclerosis, heart failure, cognitive impairment)
- Data from patients with depression mixed with data of patients without depression (eg, telepsychiatry in general, anxiety and depression)
- Not peer-reviewed
- Published research protocols that had not yet been completed
- Conference proceedings
- Supported neither by empirical data nor by a formal literature review (eg, editorials)
- Published in a language other than English or French
- Full article could not be obtained

Data Extraction

An Excel file (Microsoft Corporation) was used to chart the data from all included articles. Throughout the charting process, the extraction grid was iteratively revised to refine its components.

Collating, Summarizing, and Reporting the Results

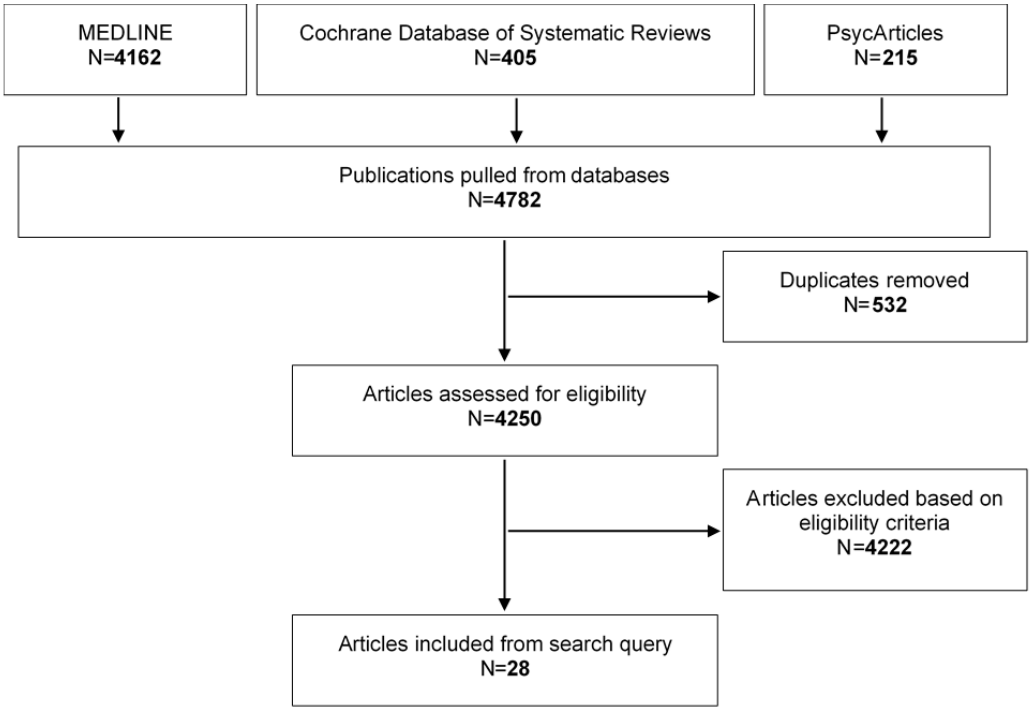
Results regarding the study characteristics for both the included review and nonreview articles are reported below. However, analysis of the outcomes and results of the included articles was limited to nonreview articles because the included reviews had high heterogeneity and their aims tended to differ significantly from the scope of this scoping review. In-depth analysis of outcomes and results was also limited to the scope of this review. Tables were used to report relevant data comprehensively. Figures were produced using Excel.

Results

Selection Process

A total of 28 articles were included in this review. The study selection process is detailed in Figure 1 [10-37].

Figure 1. Study selection flow diagram.

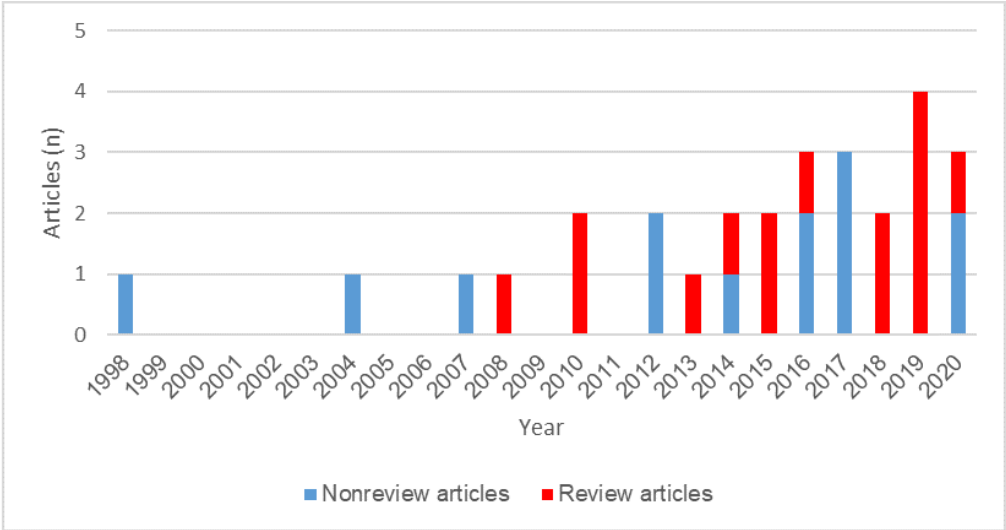


Characteristics of the Included Articles

Although all the articles were published in peer-reviewed journals, an absence of conflicts of interest was clearly and explicitly declared in only a small majority (17/28).

All included papers were published between 1998 and 2020. The great majority had been published since 2010 (24/28), and more than half had been published since 2015 (17/28). The publication years of the papers are illustrated in Figure 2.

Figure 2. Histogram of the numbers of review and nonreview articles published per year.



A total of 13 studies were conducted using a nonreview methodology, while 15 articles were reviews. Most nonreview studies (9/13) compared a virtual intervention group and a nonvirtual group, and almost all of these comparative studies (8/9) included a randomization process.

Most nonreview studies were conducted in the United States. Locations represented in nonreview articles are displayed in Table 1. Another notable characteristic of the populations of these studies was their size, which ranged from 1 to 309 patients. The average study population size was 135 patients. The intervention in almost all these studies included a psychiatrist (12/13) instead of a primary care provider or as well as one. Collaborative care was part of most interventions (7/13). A nonvirtual comparison group was included in nine studies. Characteristics of the populations, virtual interventions, and nonvirtual comparisons of the nonreview studies are detailed further in Table 2 [10-22].

Table 1. Study locations with the associated numbers of nonreview articles (n=13).

Location	Nonreview articles, n (%)
United States	10 (76.9)
Europe	1 (7.7)
Brazil	1 (7.7)
Columbia	1 (7.7)

Table 2. Population, virtual intervention, nonvirtual comparison, outcomes and results relevant to the scope of this review for the included nonreview articles.

Authors (year)	Population	Intervention (virtual)	Comparison (nonvirtual)	Outcomes and results
Amirsadri et al (2017) [15]	1 patient; United States; comorbid schizophrenia	Videoconferencing with a telepsychiatrist; home visits by a social worker and a nurse	None	• Diagnosis: Detecting undiagnosed depression. • Treatment: Development of a treatment plan. • Function: Improved. • Quality of life: Improved. • Longitudinal history: Discovery of trauma history. • Patient satisfaction: Very happy with the service. Wanted it to be available for others. • Caregiver satisfaction: Very convenient. Good care.
Barrera-Valencia et al (2017) [12]	106 patients; Colombia; inmates	2 interventions: asynchronous care by the telepsychiatrist, who receives clinical information from the general practitioner's evaluation; synchronous care by the telepsychiatrist through videoconferencing	None	• Depression severity: Significant improvement in the Hamilton Depression Rating Scale scores for both telepsychiatry modalities. Higher effectiveness for the asynchronous modality. • Consultation time: No difference between the two telepsychiatry modalities. • Consultation costs: Higher for the synchronous modality. • Cost-effectiveness: Higher for the asynchronous modality. • Patient satisfaction: A dependent variable for the prediction of the cost of care.
Choi Yoo et al (2014) [11]	309 patients; United States; patients with cancer	INCPAD[a] trial; centralized telecare management; automated home-based symptom monitoring; collaborative care by an oncologist, a nurse depression-pain care manager, and a supervising psychiatrist	Treatment as usual; screening results provided to their oncologist	• DFDs[b]: 227.38 for the intervention group during the 12-month follow-up compared with 167.08 for the usual care group. This is an increase of 60.30 DFDs (P<.01) compared to the usual-care group. • QALYs[c]: With 0.2 to 0.4 QALYs per additional DFD, there was a gain of between 0.033 and 0.066 QALYs. By other metrics, the intervention resulted in a gain of between 0.013 and 0.088 QALYs. • Physician time cost[d]: $43,226 total and $281 per patient. • Nurse care manager costs: $61,906 total and $402 per patient. • Automated monitoring system cost: $506 per patient. • Sum of the physician, nurse care manager and monitoring cost: $1189 per patient. • Post–start-up automated monitoring maintenance cost over the 3 years of the trial: $20,000 total and $813 per patient. • Cost per DFD: Between $19.72 and $26.95. • Cost per QALY: $10,826 to $73,286. • Post–start-up incremental cost per DFD gained: $13.48. • Post–start-up incremental cost per QALY gained: Between $7564 and $51,199.

Authors (year)	Population	Intervention (virtual)	Comparison (nonvirtual)	Outcomes and results
Chong and Moreno (2012) [13]	167 patients; United States; Hispanic participants; low-income, uninsured, and underinsured	Videoconferencing with a telepsychiatrist	Treatment as usual; primary care setting	• Appointment keeping: Same for both groups. • Visit satisfaction: Higher for the intervention group • Patient rating of the working alliance with their provider: Higher for the intervention group • Use of antidepressant medication: Higher for the intervention group. • Depression severity: Both groups showed a decrease in symptoms. • Depression severity improvement rate: Higher for the intervention group. • Number of days in which their symptoms rendered them less productive or worse, unable to carry out their normal responsibilities: Decrease for both groups. • Whether the project helped or made them better: 84% of both groups indicated that it did help them or make them better. • Satisfaction with provided support: 50% of both groups indicated that the project and staff provided much-appreciated support. • Satisfaction with session length: 12% of the intervention group patients wanted longer sessions. • Satisfaction with session quantity: 12% of the comparison group wanted more sessions. • Satisfaction with the webcam sessions: 22% of the intervention group patients mentioned that they liked the webcam sessions. • Need for time to adapt: 14% of the intervention group patients reported that they needed some time to adapt. • Willingness to pay for mental health services: High for both groups. • Depression care satisfaction rating: High for both groups. • Satisfaction with the randomized assignment they received: High for both groups.
Christensen et al (2020) [22]	199 patients; 11 European countries; mild to moderate depression.	MasterMind program; videoconferencing facilitating collaborative care interventions; telepsychiatrists, general practitioners, and other health care professionals	None	• Patient satisfaction: High. Scores varied significantly between regions, but there was no correlation with age and gender.
Emery-Tiburcio et al (2017) [16]	131 patients; United States; aged ≥60 years	BRIGHTEN[e] program; telepsychiatrists and other health care professionals	None	• Depression severity: Significant improvements in Geriatric Depression Scale rating and 12-Item Short Form Survey Mental Health Composite at 6-month follow-up. Equal benefit from the program for individuals with different ethnic, educational, and income characteristics. • 12-Item Short Form Survey Physical Health Composite: No differences observed at 6-month follow-up.
Hilty et al (2007) [10]	121 patients; United States; rural	Intensive disease management module; videoconferencing with a telepsychiatrist; training for the primary care physician	Usual care; disease management module	

Authors (year)	Population	Intervention (virtual)	Comparison (nonvirtual)	Outcomes and results
				• Depression severity: Significant reduction at 3, 6, and 12 months for both groups, with no significant difference between the groups. According to a post-hoc analysis, the score for one depression subscale score was nearly significantly higher in the intervention group when those in the comparison group with an initial telepsychiatric consultation were removed from the analysis. There was a relationship between depression and health functioning scores. No relationship was found between depression scores and satisfaction. • Health functioning: No significant change or significant difference between groups. There was a relationship between depression and health functioning scores. No relationship was found between satisfaction and health functioning. • Patient satisfaction: Significantly higher in the intervention group at 6 and 12 months. No relationship between depression scores and satisfaction; no relationship between satisfaction and health functioning. • Study retention: Significantly higher in the intervention group; higher in older patients. • Comorbid somatization, phobia, and anxiety: Significantly higher improvement in the intervention group
Hungerbuehler et al (2016) [14]	107 patients; Brazil; 3 hours of mean traveling time to psychiatric hospital	Videoconferencing with a telepsychiatrist; significantly higher baseline depression severity	Treatment as usual; in-person consultations with a psychiatrist	• Depression severity: Significant decrease in severity for both groups. No significant difference in severity between groups at 6 and 12 months. Significant interaction between treatment and time regarding severity. • Medication: Most of the participants continued taking antidepressants at 6 and 12 months within the recommended dosages, often combined with sedatives. No significant difference between groups for the type and dosage of medication at 6 and 12 months. Low adherence in both groups. No significant difference in adherence between groups. • Treatment adherence validated by the number of missed appointments and dropouts: Significantly more dropouts in the nonvirtual group at 6 months, but no significant difference at 12 months. More missed appointments in the nonvirtual group. • Patient satisfaction: No significant difference between groups at 6 and 12 months. A significant increase was observed during the first 6 months and then remained stable until the end of the study. No significant changes over the entire study period. No significant interaction between group assignment and time. • Working alliance: Significant increase over 12 months for both groups. No significant difference between groups
Moreno et al (2012) [20]	167 patients; United States; Hispanic	Videoconferencing with a telepsychiatrist	Treatment as usual; community health center	• Depression symptoms: Significant reduction in both groups. Significantly higher reduction in the virtual group. Significant effect of time. • Depression response (50% or greater decrease in severity ratings): More than half of the study population. No significant difference between groups, but tendency for higher rate in the virtual group. • Depression remission (75% or greater decrease in severity ratings): Less than half of the study population. No significant difference between groups, but tendency for a higher rate in the virtual group. • Quality of life: Significant increase for both groups. Significantly higher increase in the virtual group. Significant effect of time. • Health-related functional ability: Significant increase for both groups. Significantly higher increase in the virtual group. Significant effect of time.

Authors (year)	Population	Intervention (virtual)	Comparison (nonvirtual)	Outcomes and results
Norden et al (2020) [21]	114 visits; United States; Stanford's Accountable Care Organization's patient population (younger, healthier, more tech-savvy)	Stanford ClickWell Care, a novel virtual primary care clinic; videoconferencing or telephone visits with a primary care provider	In-person visits at the Stanford ClickWell Care clinic with a primary care provider	• Number of visits: Significantly higher in the virtual setting than in-person. • Number of labs ordered: No significant difference between groups. • Number of images ordered: No significant difference between groups.
Ruskin et al (1998) [17]	30 patients; United States; psychiatric inpatients	1 in-person consultation with a psychiatrist; 1 videoconferencing consultation with a telepsychiatrist	2 in-person consultations with a psychiatrist	• Interrater reliability for results from the Structured Clinical Interview for DSM-III-R[f]: High for both groups. No significant difference between groups. • Patient satisfaction: High for both groups. No significant difference between groups. • For the intervention group, "Overall, which did you prefer?": Most preferred the in-person consultation. • For the intervention group, "Would you rather have a video examination with a psychiatrist or an in-person examination by a general practitioner who might know a little less about psychiatry?": Most preferred the virtual consultation. • For the intervention group, "If you lived two hours away from the hospital, would you rather travel to the hospital to see the psychiatrist in person or go to a place close to your home and see the psychiatrist by video?": Most preferred the virtual consultation.
Ruskin et al (2004) [19]	119 patients; United States; veterans	Videoconferencing with a telepsychiatrist	In-person consultations with a psychiatrist	• Depression severity: Significant reduction in both groups. No significant difference between groups. • Depression response (50% improvement from the first to the last visit): Similar rate in both groups. • Depression remission (17-item Hamilton Depression Rating Scale score ≤7): Similar rate in both groups. • Treatment adherence in terms of dropout rates, time course of dropouts, number of session appointments kept, and pill counts: No significant difference between groups. • Patient satisfaction: High for both groups. No significant difference between groups. • Psychiatrist satisfaction: High for both modalities of care. Significantly higher for nonvirtual care. • Resource consumption or "cost effects" through per-session cost with or without factoring psychiatrist travel time and total Veterans Affairs health care resource consumption: $86.16 for a telepsychiatry session and $63.25 for an in-person session. Equal cost if the psychiatrist had to travel 22 miles to the clinic. Modality of care was not associated with significantly different consumption of health care.
Yeung et al (2016) [18]	190 patients; United States; monolingual Chinese American immigrants	T-CSCT[g]; T-CSCT involving culturally sensitive psychiatric assessment, and collaborative care; videoconferencing with a bilingual telepsychiatrist; primary care provider, bilingual telepsychiatrist, and bilingual care manager	Treatment as usual; in-person consultations with a primary care provider; a single videoconferencing evaluation with a telepsychiatrist; treatment recommendations from the telepsychiatrist	• Depression severity: Significantly higher reduction for the intervention group. • Depression response rate (Hamilton Depression Rating Scale score improvement of ≥50%): Significantly higher for the intervention group. • Depression remission rate (Hamilton Depression Rating Scale score ≤7): Significantly higher for the intervention group. • Quality of life: No significant difference between groups.

[a]INCPAD: Indiana Cancer Pain and Depression.

[b]DFD: depression-free day.

[c]QALY: quality-adjusted life year.

[d]All monetary values are reported in US dollars.

[e]BRIGHTEN: Bridging Resources of an Interdisciplinary Geriatric Health Team via Electronic Networking.

[f]DSM-III-R: Diagnostic and Statistical Manual of Mental Disorders (Third Edition, Revised).

[g]T-CSCT: Telepsychiatry-based culturally sensitive collaborative treatment.

Main Results for Nonreview Articles

Of the 13 nonreview papers, 11 included results regarding depression variables, 8 included results with regard to perceptions, and 11 included results regarding other variables. Outcomes and results relevant to the scope of this review for the included nonreview articles are detailed in Table 2 [10-22].

Regarding depression outcomes and variables, all 11 studies resulted in improvement in depression with the use of virtual care, and studies that compared the virtual intervention group with a nonvirtual comparison group either obtained equivalent improvement or better results with virtual care. Studied depression outcomes and variables include depression severity, severity improvement rate, depression-free days (DFDs), response rate, remission rate, treatment aspects such as adherence, and depression interrater reliability for diagnosis.

Perceptions regarding virtual care were favorable to virtual care or equivalent to in-person care according to almost every metric studied. Examined perceptions include patient satisfaction, caregiver satisfaction, psychiatrist satisfaction, working alliance, need for time to adapt, willingness to pay for mental health services, and care preferences.

Other variables were significantly improved with virtual care. Studied variables included quality of life, quality-adjusted life years (QALYs), functioning, appointment keeping, number of visits, number of complementary tests ordered, physical health, and comorbid somatization, phobia, and anxiety.

It was also proven that telepsychiatry can be more cost-effective than in-person psychiatry. Examined costs and related variables include consultation time, consultation cost, cost-effectiveness, per-session costs, physician time cost, nurse care manager cost, system cost, system maintenance costs, cost per DFD or QALY, and post–start-up incremental cost per DFD or QALY gained.

Discussion

Overview of the Literature

This review aimed to map the literature on use of telepsychiatry to treat depression by physicians as well as to examine the effects and perceptions regarding telepsychiatry and how it compares to traditional in-person care. A total of 28 articles were included [10-37], and all 13 nonreview articles were analyzed further [10-22]. The generalizability of the findings may be modulated by the fact that most studies were recent, but it may be limited for primary care populations and countries other than the United States. Although quality appraisal of the studies was not part of the methodology of this study, bias risk may be modulated by the high proportion of randomized studies, the low proportion of clear and explicit declared absence of conflicts of interest, and the average study size, which may arguably be considered sufficiently small or large. The analyzed articles contained measured outcomes related to depression variables, perceptions, and other variables. All applicable studies resulted in improvement in depression with the use of telepsychiatry, which was always measured to be equivalent or better for virtual care compared with in-person psychiatry. Patient satisfaction and other perceptions were examined, and telepsychiatry again performed at least as well as in-person care according to almost every metric studied. Quality of life, functioning, and similar variables were significantly improved with virtual care. Telepsychiatry also tended to perform better than in-person care. Cultural sensitivity and collaborative care were also part of some studied telemedicine programs.

Gaps in the Literature

Additional research should be conducted on themes already covered in the articles included in this review. These themes include depression outcomes, perceptions such as patient satisfaction, cost-efficiency, and other outcomes. However, stakeholders would benefit from larger study populations, more studies conducted outside the United States, and more studies about general practitioners, as well as fewer potential conflicts of interest and more transparency.

Research should also be conducted on aspects of telepsychiatric care of patients with depression that are not covered as extensively in the included articles. These aspects include effects on suicide risk, suicidal ideation incidence, evolution of comorbid diseases, health behaviors, societal productivity, work productivity and absenteeism, personal and household income, marital outcomes, and parenthood outcomes, as well as the well-being of caregivers and relatives. Many perceptions could be studied, including those of patients, physicians, health care professionals, caregivers, and relatives. Studies should also be conducted regarding medical student training in telepsychiatry [5].

Research themes could be explored through various methodologies, including systematic reviews and randomized clinical trials.

Limitations

The results of this review are subject to limitations. As definitions of telepsychiatry may differ, the scope of this review might also be considered too narrow in various ways, such as its focus on physicians, its exclusion of psychotherapy as the main intervention, its exclusion of patients with anxiety disorders, and other eligibility criteria that may be considered limited or firm. The chosen search terms may have further influenced the identification of relevant articles in this direction or may have hindered the identification of relevant articles such as studies about telephone medicine, asynchronous telemedicine, pediatricians, or special patient populations. The selected databases may have also influenced the results of this review; however, this decision was supported by the characteristics of the selected databases as well as the preliminary search. Arguably, other databases could have been considered.

Similarly, not searching the gray literature may have influenced the results; however, it was decided that this review would be limited to peer-reviewed articles. Backward and forward reference searching has not been conducted. Including other professions may have better covered some research themes, such as quality of work life, quality of personal life, health behaviors, and other aspects. Some may also disapprove of the use of the PRISMA-ScR guidelines or the Arksey and O'Malley framework [9]. The choice to include a case study may be criticized, as the study population consists of only 1 patient [15]. Finally, the generalizability of the findings may be limited for certain locations, medical specialties, patient subsets, and other clinical environment characteristics not represented among the included articles.

Conclusions

This review examines the literature on telemedicine in the care of depression by physicians, as well as its related effects and perceptions. More research is recommended to fully understand the current and potential roles of telepsychiatry when used by physicians caring for patients with depression. This research should examine various outcomes, including depression variables such as symptom severity and suicidal risk, perceptions such as stakeholder satisfaction and working alliance, health care outcomes such as cost-effectiveness, and other outcomes such as quality of life and work productivity. Studies should be conducted in various clinical contexts, such as urban or rural primary care, and in developing countries.

This review suggests that telemedicine tends to be at least as effective for depression care compared with in-person care, and it may be more cost-effective. Patient satisfaction tends to be high and perceptions tend to be favorable.

As depression is a highly prevalent and burdensome disease, its toll on patients' mental and physical health as well as its health care burden can probably be reduced by improving and implementing virtual psychiatric care of depression by physicians.

Acknowledgments

The author personally conducted and funded the whole review. The author acknowledges having had many enriching discussions about virtual psychiatric care of patients with depression with the resident and attending physicians from the Groupe de médecine de famille universitaire (GMF-U) du Marigot clinic. He also acknowledges discussing the identification of the research question with the scientific affairs team at the GMF-U du Marigot clinic.

Conflicts of Interest

None declared.

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Abbreviations

DFD: depression-free day
GMF-U: groupe de médecine de famille universitaire (university family medicine group)
PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews
QALY: quality-adjusted life year

Edited by G Eysenbach; submitted 29.03.21; peer-reviewed by A Naser, D Hilty; comments to author 03.05.21; revised version received 15.05.21; accepted 31.05.21; published 26.07.21.

Please cite as:
Echelard JF
Use of Telemedicine in Depression Care by Physicians: Scoping Review
JMIR Form Res 2021;5(7):e29159
URL: https://formative.jmir.org/2021/7/e29159
doi:10.2196/29159
PMID:34309571

Original Paper

Conceptualizing Usability for the eHealth Context: Content Analysis of Usability Problems of eHealth Applications

Marijke Broekhuis[1,2], MSc; Lex van Velsen[1,2], PhD; Linda Peute[3], PhD; Meilani Halim[4], BSc; Hermie Hermens[1,2], Prof Dr, IR

[1]Roessingh Research and Development, Enschede, Netherlands

[2]Biomedical Signals and Systems, Faculty of Electrical Engineering, Mathematics and Computer Science (EEMCS), University of Twente, Enschede, Netherlands

[3]Center for Human Factor Engineering of Health Information technology, Department of Medical Informatics, Amsterdam UMC, University of Amsterdam, Amsterdam, Netherlands

[4]Communication Sciences, Faculty of Behavioural, Management and Social Sciences (BMS), University of Twente, Enschede, Netherlands

Corresponding Author:
Marijke Broekhuis, MSc
Roessingh Research and Development
Roessinghsbleekweg 33b
Enschede, 7522 AH
Netherlands
Phone: 31 0880875728
Email: m.broekhuis@rrd.nl

Abstract

Background: Usability tests can be either formative (where the aim is to detect usability problems) or summative (where the aim is to benchmark usability). There are ample formative methods that consider user characteristics and contexts (ie, cognitive walkthroughs, interviews, and verbal protocols). This is especially valuable for eHealth applications, as health conditions can influence user-system interactions. However, most summative usability tests do not consider eHealth-specific factors that could potentially affect the usability of a system. One of the reasons for this is the lack of fine-grained frameworks or models of usability factors that are unique to the eHealth domain.

Objective: In this study, we aim to develop an ontology of usability problems, specifically for eHealth applications, with patients as primary end users.

Methods: We analyzed 8 data sets containing the results of 8 formative usability tests for eHealth applications. These data sets contained 400 usability problems that could be used for analysis. Both inductive and deductive coding were used to create an ontology from 6 data sets, and 2 data sets were used to validate the framework by assessing the intercoder agreement.

Results: We identified 8 main categories of usability factors, including basic system performance, task-technology fit, accessibility, interface design, navigation and structure, information and terminology, guidance and support, and satisfaction. These 8 categories contained a total of 21 factors: 14 general usability factors and 7 eHealth-specific factors. Cohen κ was calculated for 2 data sets on both the category and factor levels, and all Cohen κ values were between 0.62 and 0.67, which is acceptable. Descriptive analysis revealed that approximately 69.5% (278/400) of the usability problems can be considered as general usability factors and 30.5% (122/400) as eHealth-specific usability factors.

Conclusions: Our ontology provides a detailed overview of the usability factors for eHealth applications. Current usability benchmarking instruments include only a subset of the factors that emerged from our study and are therefore not fully suited for summative evaluations of eHealth applications. Our findings support the development of new usability benchmarking tools for the eHealth domain.

(JMIR Form Res 2021;5(7):e18198) doi:10.2196/18198

KEYWORDS

usability benchmarking; eHealth systems; content analysis; usability framework; summative evaluation; mobile phone

Introduction

Background

Usability tests of eHealth applications can be either formative (where the aim is to detect usability problems) or summative (where the aim is to benchmark usability). Formative usability tests use qualitative methods, *think aloud* protocols [1,2], interviews [3], cognitive walkthrough [4], heuristic evaluation [5], or quantitative methods, such as user task performance [6]. Formative tests are mainly used to track usability problems, which are crucial for optimizing a system. However, they do not provide an absolute score of a system's usability. Instead, this can be achieved via usability benchmarking methods during summative evaluations. A usability benchmark is a clear indicator of when the usability of an eHealth application is considered sufficient or insufficient. Furthermore, benchmarking makes it easy to compare the usability of an eHealth application with that of competitors, or to compare scores of new and old versions of the same system to determine whether usability has dropped, improved, or stayed the same. Benchmarking the usability of an eHealth application is most frequently done using questionnaires [7], such as the Poststudy System Usability Questionnaire (PSSUQ) [8], the questionnaire for user interface satisfaction [9], and the system usability scale (SUS) [10]. In addition, there are dedicated eHealth-specific usability benchmarking instruments, such as the Health Information Technology Usability Evaluation Scale (Health-ITUES) [11] and the Mental Health App Usability Questionnaire (MAUQ) [12]. The SUS is currently the most popular usability benchmarking tool for eHealth applications [13]. However, a recent examination of the suitability of the SUS to the eHealth context found that this instrument was not sufficient [14]. All of these questionnaires provide a verdict on usability based on the outcomes of the average scores of user-rated items. Each of these items is related to overarching factors that make up the construct of usability. Traditionally, usability is broken down into three factors: effectiveness, efficiency, and satisfaction [15]. However, each questionnaire proposes a different set of factors and thus, provides a different interpretation of usability. For example, the PSSUQ assesses usefulness, information quality, and interface quality, whereas the Health-ITUES measures the quality of work life, perceived usefulness, ease of use, and user control. Finally, the SUS has no constructs, only items that result in a single score for overall usability without defining what this score means. Thus, the proper benchmarking of usability should start by defining which factors make up the usability of a particular type of system [16].

It has been argued that usability should be considered from the perspective of the system domain [17]. eHealth applications are designed to inform about, prevent, diagnose, treat, or monitor health conditions. This requires users to, for example, understand the health information the system offers, need to be able to keep track of their progress, or need to be able to correctly perform exercises or fill out questionnaires based on the information that is available in the system. These activities can be complicated if patients have low health literacy [18] or if there are health impairments that are common for the intended patient group, which could hinder user-system interaction [19,20]. Furthermore, eHealth applications that are designed for a large audience, such as preventative healthy aging systems, need to consider an extremely diverse user group in terms of motivation and educational level [21].

The problems with current usability benchmarking tools for the eHealth context stem from a general lack of understanding of usability within the eHealth context [12]—eHealth usability. Many studies that attempt to classify usability factors for eHealth do so via a theoretical reclassification of earlier, traditional models [22-27]. This means that we merely rephrase or recategorize the same factors for eHealth instead of eliciting domain-specific usability factors. In order to gain insights into the factors that make up eHealth usability, we need to go back to the drawing board: analyzing problems end users experience when interacting with eHealth applications. The proper usability of eHealth applications is not just about smooth navigation, clear understanding of used language, or prevention of system errors but also involves the patient's perspective and focuses on understanding how a system supports them in prevention, diagnosis, treatment, or monitoring of their health condition [28-30]. However, chronic illnesses can increase patients' feelings of stress and anxiety [31], which can affect the manner in which they interact with an eHealth application and thus the perceived usability. In contrast, for health professionals, for example, nurses, proper usability could mean an entirely different thing. For them, it is important that the system fits within their daily work routine. The study by Ash [32] describes how digital patient care information systems, while implemented with good intentions to make work easier for health professionals, can have unforeseen negative consequences (eg, additional workload or information overload of overfragmentation of data), making it unusable for the intended user group. A thorough understanding of eHealth usability supports formative evaluation methods that aim to elicit lists of usability problems, as well as supporting benchmarking tools.

Objectives

By analyzing multiple data sets of usability problems found in contemporary eHealth applications, we propose a conceptualization of usability for the eHealth domain from the patient's perspective. An overview of eHealth-specific usability factors helps usability practitioners to link usability problems to an overarching classification that is tailored to the specific medical context in which these applications are embedded.

Methods

Data sets of usability tests were collected to conduct a content analysis of usability problems found in eHealth usability tests.

Data Source Collection

We analyzed 8 data sets from different usability tests conducted at institutions affiliated with the researchers. The data sets were strategically chosen to reflect a wide range of eHealth applications with different end-user groups, devices, and health goals. A data set was included if the eHealth application was recently developed; usability problems were elicited via at least one qualitative data collection method (eg, thinking aloud,

interviews, and observations); and the participants of the usability tests consisted of patients.

The following eHealth applications were included in this study: (1) Stranded, a web-based gamification application in which users can progress in the game by regularly performing physiotherapeutic exercises that are scheduled by a physiotherapist [14]; (2) a web-based screening module provided by a tablet and a care robot (NAO, a humanoid robot from SoftBanks Robotics), in which older adults completed a frailty test and performed physical exercises [33]; (3) cVitals, a home-monitoring module for patients with chronic obstructive pulmonary disease to monitor their health, which consists of a web application that is connected to a blood pressure monitor and weight scale monitor; (4) Council of Coaches, a web-based multi-agent virtual coaching platform for older adults to support a healthy lifestyle via dialogues, web-based coaching, and exercises from multiple virtual coaches that represent various health dimensions (eg, social and physical and mental health); (5) Pandit, a web application for patients with diabetes that provides insulin dosing advice using a clinical decision support system [34]; (6) Pregnancy and Work application (in Dutch: Zwangerschap en Werk) a mobile app for pregnant women to inform them about the rules and regulations on the work floor with regard to pregnancy; (7) FatSecret, a mobile food diary app for diabetes patients; and (8) Hospitality app, a mobile app that provides valet navigation service for out-clinic patients to heighten hospitality toward patients and facilitate hospital attendance [35].

Usability Problems and Severity

The data sets had a total of 486 usability problems. We excluded usability problems that had unclear formulation, were duplicated, or were unrelated to usability (eg, user experience and motivation). For example, the problem *User presses the home button of the iPad for too long, after which Siri comes up instead of home screen* (from data set 3) is a problem with the device (tablet) and not with the eHealth application. Another problem, *Not willing to watch the video and starts practicing* (from data set 2), is a problem with user motivation and not with the eHealth application. In addition, the problem, *It took users a long time to find the correct functions* (from data set 7) does not specify what functions are difficult to find. Finally, the problem *Does not like the music* (from data set 1) is not a usability problem but a user experience problem.

A total of 86 usability problems were eliminated from the data set, resulting in 400 usability issues that were suitable for the analyses. Each usability problem was assigned to a severity category. Most data sets included severity ratings based on the severity index of Duh et al [36]. This categorization differentiates among minor, serious, and critical usability problems. A minor usability problem occurs infrequently among the participants or the problem only increases the task completion time slightly. A serious usability problem frequently occurs among the participants or the problem severely increases the task completion time. A critical usability problem occurs when all participants have the same problem or the problem prevents participants from completing tasks. In case a data set consisted of different severity index, this index was transposed to the index of Duh et al [36].

Table 1 presents a complete overview of the characteristics of the eHealth applications, the end-user group, and the evaluation method per system.

Table 1. Overview of data sets (N=8).

Data set	eHealth application	Description of app	Main health goal	Device platform	Target end-user group	Participants, n	Evaluation method	Length of session (minutes)	Usability problems, n
1	Stranded	Web-based gamified app	Offers fall prevention training via video instructions in a gamified environment	Computer	Prefrail[a] and frail older adults (aged ≥65 years)	19	Concurrent think aloud and screen capture recordings	60	66
2	N/A[b]	Web-based screening module	Identifies frailty levels among older adults and supports physical exercising	Tablet and social robot	Prefrail and frail older adults (aged ≥70 years)	20	Video observation	50	64
3	cVitals	Home-monitoring tool	Allows self-management of health by providing and supporting health measurements at home	Smartphone	Patients with heart failure or COPD[c] (aged ≥65 years)	10	Concurrent think aloud and observations	60	39
4	Council of Coaches	Web-based coaching platform with virtual coaches	Supports a healthy lifestyle for older adults	Computer	Older adults (aged ≥55 years)	18	Think aloud and observations	60	60
5	Pandit	Web-based application	Allows self-management of health by providing insulin dosing advice	Computer	Patients with type 2 diabetes (aged 40-64 years)	5	Concurrent think aloud and observations	15	28
6	Pregnancy and Work	Informational application	Provides information on health risks and regulations during pregnancy	Smartphone	Pregnant women (aged 25-40 years)	12	Concurrent think aloud and observations	45	84
7	FatSecret	Calorie counter application	Provides nutritional information	Smartphone	Older adults with type 2 diabetes (aged ≥55 years)	10	Concurrent think aloud and observations	15	41
8	Hospitality app	Patient hospitality app	Provides information on how to prepare for a visit to medical facilities	Smartphone	Prefrail and frail older adults (aged ≥65 years)	8	Concurrent think aloud and observations	30	18

[a]Prefrail refers to the initial state of a health condition called *frailty*. This condition entails a gradual decline in physical and cognitive functions, mostly occurring among older adults, that can lead to recurrent falls, hospitalization, and even death [37].

[b]N/A: not applicable.

[c]COPD: chronic obstructive pulmonary disease.

Data Analysis

A content analysis was conducted according to the methods of Bengtsson [38], which consists of four stages: decontextualization, recontextualization, categorization, and compilation. Below, we describe the process for each phase. The content analysis was performed by 3 people, all with a background in behavioral sciences, but with different degrees of expertise in coding qualitative data, namely novice (MH), experienced (MB), and expert (LVV).

First, in the decontextualization phase, 2 researchers (MB and MH) familiarized themselves with the data sets. Then, they independently started an inductive coding process. Each usability problem was assigned a code that represents the usability factor. On the basis of data sets 1, 2, and 3, each researcher developed their own codebook. These two codebooks

were discussed and merged in one mutually agreed upon codebook, consisting of 9 main categories and 32 factors. Second, in the recontextualization phase, 2 researchers (MB and MH) independently recoded data sets 1-3 using the new codebook. If they found a usability problem that they could not classify using the codebook, a new code was added to the codebook. The resulting codebooks were then compared and discussed, leading to an updated codebook. These steps were performed several times until no new codes emerged. Third, in the categorization phase, definitions for each factor in the updated codebook were formulated, which now consisted of 10 categories and 28 factors. Then, a third independent researcher (LVV) familiarized himself with the data, codebook, and definitions. On the basis of triangular findings, alterations were made to the codebook, resulting in 9 categories and 24 factors. Finally, in the compilation phase, data sets 4, 5, and 6 were independently recoded by two researchers (MB and LVV) using the codebook (deductive coding). Discussions revealed that, although no new categories or factors emerged, there was some overlap in the definitions of some categories and factors that caused confusion about which factor to assign to the usability problem. Therefore, the codebook and definitions were adjusted. The final codebook consisted of 8 categories and 22 factors. The intercoder agreement between researchers MB and LVV was determined by coding data sets 7 and 8 and calculating Cohen κ values for both the category and variable levels.

Cohen κ is the most widely used means for measuring the intercoder agreement. However, it has its limitations, especially for nondichotomous variables, a measure of relative rather than absolute agreement [39]. One of the main problems with Cohen κ is that the higher the number of categories, the less likely there is chance for strong intercoder agreement when using the Cohen κ [40]. Therefore, we supplemented Cohen κ with a percentage agreement. As a final part of the analysis, we compared the number of minor, serious, and critical usability problems between the usability factors and categories to analyze whether some factors or categories had a significantly higher number of severe usability problems than others.

Results

Intercoder Agreement

Validation of the analysis was performed by calculating Cohen κ values for both category and factor levels (Table 2). The resulting Cohen κ values were ≥0.62, both on usability category and factor levels; all percentages were ≥66%. These scores can be interpreted as sufficient agreement between the researchers [41].

Table 2. Intercoder agreement expressed as Cohen κ and percent agreement for usability categories and factors.

Data set	Agreement level	
	Usability category	Usability factor
Data set 8		
Usability problems, n	18	18
Percent agreement (%)	72	67
Cohen κ	0.62	0.63
Data set 7		
Usability problems, n	41	41
Percent agreement (%)	76	66
Cohen κ	0.67	0.62

Usability Factors for eHealth Applications

Overview

The ontology for usability problems for eHealth applications, which resulted from the coding process, consists of 8 overarching usability categories and 21 factors (Table 3). We differentiated between general usability factors (ie, design clarity, interface organization, and navigation) and eHealth-specific usability factors (ie, fit between system and health goals, accommodation to physical limitations, and procedural health-related information). The difference between these 2 types of usability factors (general and eHealth-specific) is that general factors are factors found in eHealth applications that we considered not unique to the eHealth domain (eg, system errors could occur regardless of the type of system), whereas eHealth-specific usability factors are factors related to the medical context in which eHealth applications are embedded (eg, health information, medical terminology, and health goals).

Table 3. Ontology for usability problems in eHealth applications.

Category of usability problem and usability factor	Type of usability factor
Basic system performance	
Technical performance	General
General system interaction	General
Task-technology fit	
Fit between system and context of use	General
Fit between system and user	General
Fit between system and health goals	eHealth-specific
Accessibility	
Accommodation to perceptual impairments or limitations	eHealth-specific
Accommodation to physical impairments or limitations	eHealth-specific
Accommodation to cognitive impairments or limitations	eHealth-specific
Interface design	
Design clarity	General
Symbols, icons, and buttons	General
Interface organization	General
Readability of texts	General
Navigation and structure	
Navigation	General
Structure	General
Information and terminology	
System information	General
Health-related information	eHealth-specific
Guidance and support	
Error management	General
Procedural system information	General
Procedural health-related information	eHealth-specific
Satisfaction	
Satisfaction with system	General
Satisfaction with system's ability to support health goals	eHealth-specific

Category 1: Basic System Performance

This category includes usability problems related to the system's technical stability and the user-system interaction. The factor *technical performance* describes usability problems related to the technical performance of the system, such as system errors, response times, and compatibility with external devices. An example of such a usability problem is the connection with a blood pressure monitor (Omron and Withings) does not work (data set 3, usability problem number 32). The factor *general system interaction* includes usability problems related to general system interaction elements (eg, use of buttons, scroll bars, swipes, and clicks) and concepts (eg, *the types of data entry are inconsistent through the app: String and integer entry, choices, scrolling through dates* [data set 7, usability problem number 1]).

Technical problems, such as nonresponsive buttons, can negatively affect efficient system interaction and perceived ease of use. These system errors can seriously hinder task completion and influence users' opinions of other usability aspects. For example, if page load time takes too long (data set 1, usability problem number 19), a user can also give low ratings to the system's ease of use, navigation, or satisfaction. Good technical performance of the system is essential to facilitate smooth and easy user-system interaction.

Category 2: Task-Technology Fit

Usability problems found in this category address the match between the system on the one hand, and the user, their context, and health goals, on the other hand. As such, this category is related to the model of Goodhue and Thompson [42], which defines task-technology fit as "the degree to which a technology assists an individual in performing his or her portfolio of tasks."

The three factors describe usability problems that occur because the eHealth application is not considered suitable because of (1) the daily (clinical) context of use in which the app is to be implemented (eg, participant indicates that she could not print something from the phone easily [data set 6, usability problem number 86]), (2) the needs of the intended end-user group (eg, *the default given for date of birth might not be optimal from the perspective of the average diabetic* [data set 7, usability problem number 3]), and (3) the intended health goals the app is designed to support (eg, *the user did not take the system seriously, it was perceived more as a game than as a tool for living more healthily* [data set 4, usability problem number 12]). When users perceive a good match between the system and the context, health goals, and themselves, it will lead to not only a more positive impression of the usability of an eHealth application but also a better understanding of its added value.

Category 3: Accessibility

The category *accessibility* addresses usability problems that stem from the system's inability to adequately consider or compensate for physical (eg, *not able to do the exercise completely due to physical impairments* [data set 2, usability problem number 15]), cognitive (eg, *the explanation in the support video in the mailbox goes too fast for the user* [data set 1, usability problem number 37]), or perceptual (eg, *not able to hear NAO due to hearing impairment* [data set 2, usability problem number 38]) limitations or impairments that are common to the identified patient groups. These impairments could affect how the user interacts with the system. Problems with moving one's wrist, or having tremors, could make it more difficult to move a mouse and click on objects or buttons. The system could make the buttons larger to make it easier for patients to click on it. Cognitive problems, such as concentration or memory problems, could make a person more forgetful of the things he or she has read. The system can accommodate this by repeating information. To address perceptual problems, for example, bad vision, the system could make the font size larger, so that texts are easier to read.

We were aware that the category *accessibility*, as the name indicates, is strongly linked to the concept of accessibility [43,44] or related concepts such as universal design [45] and user-sensitive inclusive design [46]. Although it is generally argued that these three concepts are not part of the system usability, previous studies [43-46] have acknowledged that there is a strong link. Our decision to include the category of *accessibility* hinges on three arguments. First, accessibility, as part of universal access, can promote usability [45]. Second, although accessibility is considered a functional and objective prerequisite for systems, user evaluation of these functionalities remains subjective and from a user perspective, cannot be perceived as separate from the general usability of a system. Third, eHealth applications are often designed for specific patient groups who can have physical, cognitive, or perceptual impairments or limitations. The user-friendly design of such systems therefore inherently provides access to people with such disabilities.

Category 4: Interface Design

The fourth category, *interface design*, focuses on the visibility of general user interface (GUI) elements. It has four variables. The first variable, *design clarity*, includes usability problems related to the size and clarity of a single GUI element (eg, buttons, icons, and graphics). One of the problems we found was that *calendar (buttons) was too small, and the user accidentally tapped the field behind the calendar* (data set 6, usability problem number 13). The variable *symbols, buttons, or icons* covers usability problems about the purpose of the GUI elements in the system. Does the user understand what these are for? For example, *it is unclear what it means when the light of the Withings blood pressure monitor blinks* (data set 3, usability problem number 1). The third variable, *interface organization*, concerns the placement and organization of GUI elements on a single screen, for example, *the user had problems with the layout of the answering options with a 7 pt Likert scale* (data set 4, usability problem number 3). The last variable, *readability of texts*, describes usability problems related to ease (eg, format, organization, and information density) with which a user can read a text, as well as typographic aspects (eg, font size and line height). For example, *information overload in frequently asked question takes a long time to find answers* (data set 8, usability problem number 19).

Category 5: Navigation and Structure

This category describes usability problems related to the simplicity and intuitiveness with which a user can move between different system components and a general understanding of the different system components. The factor *navigation* relates to the flow between multiple pages and is able to make correct predictions of what can be found in the system. An example of a navigational problem is *that navigation with the game is unclear, and the user uses nongaming elements to navigate between the different screens* (data set 1, usability problem number 30). Good navigation allows for efficient user-system interaction, that is, it takes less time to complete tasks, and it is easily understood how to perform the tasks [47]. Although system structure is often mentioned as a basic concept that users should be able to understand while using a system [48,49], there is little clarity with regard to the meaning of this concept. In our analysis, the usability factor *structure* emerged as one that relates to the user's understanding of the system components and the relationships between these different system components. An example of a structural issue is *the connection between the beachcomber cabin (for storing stranded items) and the drift bottles (for receiving stranded items) is unclear* (data set 1, usability problem number 59). A system structure in which users easily understand how different components relate to each other will positively affect the efficiency and effectiveness with which users can complete system and health-related tasks.

Category 6: Information and Terminology

This category consists of explanatory, nonaction-related system information and terminology in the app. Usability problems can include issues with understanding labels or terminology, the level of language, or the use of a foreign language. In this category, we made a distinction between system and

health-related information. The first type includes information about the understandability of explanatory, nonaction-related information and terminology about the system, such as the use of nonnative language (eg, *chronic obstructive pulmonary disease questionnaire appears to be in English instead of Dutch* [data set 3, usability problem number 35]), whereas the latter includes information related to the understandability of explanatory, nonaction-related information about health, medical terminology, or achieving health goals (eg, *patient is not familiar with the word hypoglycemia [does not understand if this means a high or low blood sugar level], but he does understand hypo* [data set 5, usability problem number 18]). It is important for eHealth applications that are designed for patients to have medical terminology that is aligned with the patients' vocabulary.

Category 7: Guidance and Support

The *guidance and support* category describes usability problems that occur when the system does not provide sufficient support and feedback for tasks that the user has to perform and (potential) errors the user makes. The variable *error management* refers to the (lack of) feedback mechanisms that are incorporated within the system to prevent user errors. For example, "It was not clear that an incorrect blood sugar level was entered, the error pop-up only explained that there was insufficient information related to the field fasting blood sugar levels" [data set 5, usability problem number 12]. The other two variables in this category covered procedural information. Ummelen [50] describes procedural information as information that is related to conditions for actions, the manner in which actions are to be performed, and results and feedback from these actions. Next, a distinction is made between procedural *system* information and procedural *health-related* information. The first describes problems related to system actions (eg, "The system does not explain that the age of the user should be entered numerically, not alphabetically" [data set 4, usability problem number 6]). The second type of procedural information describes problems related to health-related tasks, such as performing physical exercises, filling in food diaries, and completing health questionnaires to measure physiological parameters. For example, i*t is unclear that the first time is to watch how NAO [a social robot] does the exercise* (data set 2, usability problem number 44). These factors, such as error prevention and feedback, are embedded in general usability design principles and heuristics [51]. However, for eHealth applications, these factors are also important to support users in the self-management of their health. For example, being unable to correctly perform physical exercises or not knowing if an exercise has been finished can be detrimental to perceived usability. Users do not know how to successfully complete health tasks and thus, do not know whether and how these tasks contribute to their health.

Category 8: Satisfaction

This final category concerns the user's satisfaction with the system and addresses the subjective opinion of the user on, or likeability of, an eHealth application. System satisfaction is one of the standard usability variables according to the ISO (International Organization for Standardization) definition [15] and includes usability problems related to the user's satisfaction with the system in general. In addition to this factor, we have identified a second type of satisfaction, namely *satisfaction with the system's ability to support health goals*. This second variable was added because although the user could believe that the system is nice or fun to use, this does not mean that the system also satisfactorily supports them in their intended health goals. The difference between these two variables is illustrated as follows: the users did not like it when different virtual coaches contradict one another (data set 4, usability problem number 20). This is a system-satisfaction problem. Some users also mentioned that they did not like the background stories of the virtual coaches (data set 4, usability problem number 15). This is a satisfaction problem related to the potential of the system to support health goals.

Descriptive Analysis

The eHealth usability ontology includes a total of 21 usability factors, of which 7 are eHealth-specific and 14 are context-independent. Table 4 displays the distribution of 400 usability problems that were included in the analyzed data sets over the different factors. It shows that about 69.5% (278/400) of the identified issues were of a basic nature and 30.5% (122/400) were health specific. This distribution is also present when we focus on minor, serious, and critical usability problems.

Next, we determined the number of minor, serious, and critical usability problems across the 8 categories (Table 5). The guidance and support category contained the highest number of usability problems, followed by the interface design, basic system performance, and navigation and structure categories. Accessibility and satisfaction had the lowest number of usability problems. Interestingly, although the interface design category has a high number of usability problems, which is 24% (96/400) of the total number of usability problems, only 7 usability problems were marked as critical.

Table 4. Number of basic and health usability problems according to severity category.

Factor type	Usability problems (n=400), n (%)	Severity category, n (%)		
		Minor (n=186)	Serious (n=147)	Critical (n=67)
Basic	278 (69.5)	130 (69.9)	101 (68.7)	47 (70.1)
Health	122 (30.5)	56 (30.1)	46 (31.3)	20 (29.9)

Table 5. Number of usability problems of usability categories according to severity level.

Usability category	Severity category			Total (n=400), n (%)
	Minor usability problems (n=186), n (%)	Serious usability problems (n=147), n (%)	Critical usability problems (n=67), n (%)	
Basic system performance	32 (17.2)	10 (6.8)	14 (20.9)	56 (14)
Task-technology fit	16 (8.6)	7 (4.8)	5 (7.5)	28 (7)
Accessibility	2 (1.1)	5 (3.4)	1 (1.5)	8 (2)
Interface design	51 (27.4)	38 (25.9)	7 (10.4)	96 (24)
Navigation and structure	12 (6.4)	18 (12.2)	12 (17.9)	42 (10.5)
Information and terminology	13 (6.9)	13 (8.8)	1 (1.5)	27 (6.7)
Guidance and support	56 (30.1)	55 (37.4)	25 (37.3)	136 (34)
Satisfaction	4 (2.1)	1 (0.7)	2 (3)	7 (1.7)

Discussion

Principal Findings

On the basis of the results of this study, we can reconceptualize the traditional concept of usability in the eHealth context. Our analysis of usability problems in eHealth applications identified 8 main categories for eHealth usability: (1) basic system performance, (2) task-technology fit, (3) accessibility, (4) interface design, (5) navigation and structure, (6) information and terminology, (7) guidance and support, and (8) satisfaction. In each usability category, we made distinctions between factors that were related to general usability (basic usability factors) and those related to the health goals of the system, the medical context, or the characteristics of the intended patient group (health usability factors). We identified 14 general factors and 7 eHealth-specific factors from the analysis. Further examination of the number of usability problems between general and eHealth-specific usability factors revealed that 69.5% (238/400) of all usability problems were related to general factors and 30.5% (122/400) to eHealth-specific factors. When looking at the severity categories (minor, serious, and critical), we observed the same distribution (70:30) between these two types of factors. This implies that when one applies a general usability benchmarking instrument for evaluating eHealth applications, such as the SUS [10] or the PSSUQ [8], the final score cannot fully cover all usability problems (ie, eHealth-related ones), as eHealth-specific attributes of usability are not taken into account in these instruments. In other words, these general instruments can only explain a maximum of 70% of the app's usability. To fully assess the usability of eHealth applications, it is necessary to consider these additional eHealth-specific factors.

Comparison With Prior Work

The finding that the context, be it eGovernment, eCommerce, or eHealth affects usability is, of course, not surprising. Context has been a prominent factor in the definition of usability since the emergence of this construct [52]. However, no studies have yet identified the factors that comprise the usability construct in the eHealth context. In contrast, much research has been conducted to create generic instruments to obtain a rapid and very general assessment of the status of usability of systems, regardless of the system domain or context. Our results showed that the factors related to the medical context influence approximately 30.5% (122/400) of the usability problems that users encounter in eHealth applications, which is a substantial part. Interestingly, several usability evaluation studies of eHealth applications implicitly mentioned how the medical or health context affects the usability of these systems [53-55]. However, these health-related problems are often inadequately categorized under broad concepts, such as usefulness, ease of use, and layout. Our study ties together these findings by providing a fine-grained ontology to which all these health usability problems can be linked. This allows for a better understanding of the usability of eHealth applications. We have provided several examples found in recent literature of why this is necessary.

First, Voncken-Brewster et al [53] found that users, that is, people with a chronic illness, believed that the feedback of the system was not suitable for them because of the progressive physical limitations they experienced. In this study, they classified their usability problems into three main categories: layout, navigation, and content. Although their article did not describe the category under which this problem fell, it feels that none of these three would be a good match. Our ontology provides an alternative option, as this problem can be categorized under accessibility or guidance and support, depending on the specific formulation of the usability problem. Second, Mirkovic et al [54] evaluated the usability of an eHealth application that has two health goals: (1) patient-centered care and (2) self-management of a chronic illness. Their study found that users' evaluation of the usefulness of system modules is based on the need for these modules within their phase of illness. Self-management modules were mostly useful for users who were recently diagnosed. For users who are in a more advanced phase of the illness, patient-doctor communication modules were more important. Although Mirkovic et al [54] categorized this problem as a useful problem, our ontology would suggest the category task-technology fit, as it illustrates how the health goals of a user depend on their phase of illness, which influences the users' opinions on the usability of the evaluated system. Third, Stinson et al [55] found that users had difficulty understanding the labels of the classification of medication types. Although they classified this as a presentation error, our analysis revealed similar problems related to the understanding

of medical information and terminology. In addition to problems related to the health context, Hattink et al [56] showed that experiencing technical problems is also a major reason for not using systems. Although it seems logical that system errors can affect user friendliness, many benchmarking instruments or heuristics [57,58] do not mention this aspect. In contrast, it was a frequent problem that was identified in our content analysis of usability problems.

With regard to the similarities between, on the one hand, our conceptualization of usability for eHealth and, on the other hand, usability questionnaires, such as the PSSUQ [8], SUS [10], Health-ITUES [11], and MAUQ [12], we observed that each questionnaire measures some of the usability factors we identified in our ontology. For example, the PSSUQ contains items on general system interaction, error management, interface organization, and procedural system information. The SUS contains items on general system interaction, interface organization, and structure. Both of these general usability questionnaires do not consider other general usability factors, such as technical performance, task-technology fit, design clarity, navigation, and health usability factors. eHealth usability benchmarking instruments, such as Health-ITUES and MAUQ, are more suited to measure how an eHealth application can support users in self-managing their health or be applied in a medical context. The Health-ITUES focuses on how the system fits to the daily clinical setting but neglects factors such as navigation, understandability of medical terminology, or interface organization. The MAUQ includes items on how a mobile health app supports users in managing their health and receiving health care or services, in addition to some general usability items such as navigation and interface organization. Each of these four questionnaires covered a handful of the usability factors identified in this study. Our ontology provides a more detailed and thorough overview of the most common usability factors that could hinder the usability of eHealth applications. Therefore, the currently available questionnaires are limited in their predictive value for determining the actual usability of an eHealth application.

Limitations

This study had two main limitations. First, we intended to include data sets from a wide variety of eHealth application designed for different end-user groups. This was deemed necessary, as we wanted to develop a framework for eHealth applications in general. However, the eHealth applications that we included were, although quite diverse in nature, largely intended for middle-aged or older adults (aged ≥40 years). eHealth applications for other age groups, such as adolescents, could have specific usability problems that are underrepresented in this framework. Future research should determine if these other target groups have other common usability problems that need to be included in the eHealth usability ontology. Second, the Cohen κ values of the intercoder agreement were, although sufficient, not strong. One reason for the low Cohen κ scores is that usability problems were often ambiguously formulated. Although we excluded many of these problems beforehand, during coding it became notable that the researchers had different opinions about the origins of some problems. This is not completely avoidable in qualitative research but does highlight the common problem in usability evaluation studies: the evaluator effect [59]. The usability researcher has a large influence on the output of usability evaluation studies (and thus the formulation of usability problems). A means to establish a more uniform approach for formulating usability problems was provided by Khajouei et al [60]. It describes a framework for high-quality reporting of usability problems that mentions the underlying causes, severity, and impact on task performance. Furthermore, the use of a standardized framework for coding usability problems can provide support against the evaluator effect, as it helps create a common ground between researchers.

Conclusions

The current set of usability benchmarking instruments only provides a limited overview of the usability of eHealth applications, as they do not consider eHealth-specific factors. Our reconceptualization of usability in the eHealth context will help practitioners and researchers better understand the usability problems they encounter in their evaluations and develop suitable benchmarking tools.

Conflicts of Interest

None declared.

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Abbreviations

GUI: general user interface
Health-ITUES: Health Information Technology Usability Evaluation Scale
ISO: International Organization for Standardization
MAUQ: Mental Health App Usability Questionnaire
PSSUQ: Poststudy System Usability Questionnaire
SUS: system usability scale

Edited by G Eysenbach; submitted 11.02.20; peer-reviewed by J Kimmerle, CH Chang, A Coe, H Witteman; comments to author 29.06.20; revised version received 02.09.20; accepted 31.05.21; published 27.07.21.

Please cite as:
Broekhuis M, van Velsen L, Peute L, Halim M, Hermens H
Conceptualizing Usability for the eHealth Context: Content Analysis of Usability Problems of eHealth Applications
JMIR Form Res 2021;5(7):e18198
URL: https://formative.jmir.org/2021/7/e18198
doi:10.2196/18198
PMID:34313594

Original Paper

Development of a Video-Observed Therapy System to Improve Monitoring of Tuberculosis Treatment in Thailand: Mixed-Methods Study

Ponlagrit Kumwichar[1], MD; Virasakdi Chongsuvivatwong[1], MD, PhD; Tagoon Prappre[1], BSc

Epidemiology Unit, Faculty of Medicine, Prince of Songkla University, Songkhla, Thailand

Corresponding Author:
Virasakdi Chongsuvivatwong, MD, PhD
Epidemiology Unit
Faculty of Medicine
Prince of Songkla University
Kanjanavanich Rd, Kho Hong, Hat Yai District
Songkhla, 90110
Thailand
Phone: 66 74451165
Email: cvirasak@medicine.psu.ac.th

Abstract

Background: Directly observed therapy programs for monitoring tuberculosis (TB) treatment in Thailand are unsustainable, especially during the COVID-19 pandemic. The current video-observed therapy (VOT) system, the Thai VOT (TH VOT), was developed to replace the directly observed therapy program.

Objective: This study aimed to describe the VOT system design and identify the potential for system improvements.

Methods: This pilot study was conducted in Na Yong district, a small district in Trang province, south of Thailand. The TH VOT system consists of a smartphone app for patients, a secured web-based platform for staff, items used, and standard operating procedures. There were three groups of users: observers who were TB staff, healthy volunteers as simulated patients, and patients with active TB. All participants were trained to follow the standard operating procedures. After 2-week usage, VOT session records were analyzed to measure the compliance of the patients and observers. The User Experience Questionnaire was used to lead the participant users to focus on 6 standard dimensions of usability, and was supplemented with an in-depth interview to identify potential system improvements from users' experience.

Results: Only 2 of 16 patients with currently active TB had a usable smartphone. Sixty of 70 drug-taking sessions among 2 patients and 3 simulated patients in 2 weeks were recorded and uploaded. Only 37 sessions were inspected by the observers within 24 hours. All participants needed a proper notification system. An audit system was also requested.

Conclusions: Before upscaling, the cost of smartphone lending, audit management, and notification systems should be elucidated.

(JMIR Form Res 2021;5(7):e29463) doi:10.2196/29463

KEYWORDS

app; mixed-methods analysis; remote monitoring; therapy; tuberculosis; user experience; video directly observed therapy; video-enhanced therapy; video-observed therapy

Introduction

Thailand is currently one of 30 countries worldwide with the highest tuberculosis (TB) rate [1]. Directly observed treatment (DOT) has been implemented since 1996 [2]. Despite 2 previous studies showing the poor sustainability of DOT, the country has not made any change owing to a lack of alternative strategies [3,4]. As such, the National Tuberculosis Control Program Guideline has recommended health personnel as the first-choice observer [5]. However, family-based DOT is administered to 60%-75% of TB cases owing to the complacency of the health care system [6,7]. Family-based DOT is also complacent because of the nature of family relationships [8-10]. Ultimately, nobody has been formally accountable for DOT with regard to the patient. Consequently, the cumulative number of drug-resistant TB cases detected has increased from approximately 500 in 2014 to 1200 cases in 2019, which indicates the poor quality of DOT in the health care system [1].

Additionally, the health care situation has been worsened by the ongoing COVID-19 pandemic [11,12]. Therefore, newer studies are needed to develop a new observed therapy method to mitigate the existing issues and accelerate the End TB Strategy of the World Health Organization [1].

Recently, with advancements in smartphone technology, internet penetration has increased the access of the whole population to mobile phones and other electronic devices. Consequently, a new technology called video-observed therapy (VOT) has been introduced to replace DOT [13]. VOT is a platform that allows health personnel to observe medical ingestion through a television system. There are two types of VOT: synchronous VOT (S-VOT) and asynchronous VOT (A-VOT). S-VOT is the live form of VOT in which the patient and health care personnel interact in real time. However, A-VOT is a platform on which the patient records and uploads a video to the health service, and the health care personnel review the video later [14]. Two randomized controlled trials in the United Kingdom and the United States reported that both S-VOT and A-VOT could lower health service costs compared to traditional DOT [15,16].

In Thailand, the "TH VOT" has been developed by our group. This is an A-VOT system with a smartphone app available on the Google Play Store. A-VOT has been selected because the internet bandwidth in rural areas where patients with TB live is still too deficient to allow for S-VOT on a real-time interface. In the background, a secured website platform was developed, which allowed only the approved HCP to review the video. With standard operating procedures (SOPs), the TH VOT platform was tested in Na Yong district, Trang province, southern Thailand. The objectives of this study were to describe how the VOT system was designed and to identify potential system improvements.

Methods

Overview of the Study and the TH VOT System

In Thailand, a patient with active TB would be transferred to be monitored by the DOT program of a primary care unit (PCU) close to the patient's home. Normally, 1 of the health care personnel at the PCU is assigned to be an observer to monitor medication adherence of the patient; this person is called the "TB staff." The TB staff could also assign his/her observation to a local village health volunteer or a family member owing to the inadequate labor force. The TH VOT system was specifically designed to replace the DOT program in the setting. In the VOT system, an observer must be a PCU staff member. This study consisted of two parts: the system design and identification of potential system improvements.

System Design

The TH VOT system included a smartphone app for patients, a secure web-based platform for staff, items used, and SOPs.

Smartphone App for Patients

The TH VOT app was programmed using Dart language and had the following features:

1. Login interface: the first page that requires a username and password to sync with our online Structured Query Language database.
2. Main interface: only 1 main interface of this app with an obvious button to turn on the camera.
3. Video recorder: using a smartphone-based camera feature to record a video.
4. Uploading feature: a back-end function to compress the size of the recorded video to accelerate the uploading process, considering the low internet speed in Thailand.
5. Notification system: push notification that pops up on a screen at any time set by the user.

Secure Website Platform for VOT Observers

The website interface was coded using Cascading Style Sheets and its features were programmed in JavaScript:

1. Login interface: the first page that requires a username and password to sync with the same Structured Query Language database as that of the TH VOT app.
2. Main interface: an interface of the platform to choose 1 of 3 menus—a review dashboard, a registration page, and a user settings page.
3. Review dashboard: a daily automatically updated spreadsheet with records of registered patients in rows and information including note-taking, the video file with a button for pop-up video verification, patient identification number, time when the video arrived, and approval status in columns (Figure 1).
4. Registration: a webpage to register a patient under the direct responsibility of the observer (Figure 2A).
5. Video verification: a window pop-up after pressing a play button on the dashboard. The video file can be inspected at various speeds to be approved (Figure 2B).
6. User settings: a page to edit user information and choose an option of notification.
7. Notification system: LINE application programming interface that pushes the notification to the observer when the video has already arrived. LINE token access from the observer must be activated to use this feature.

In this pilot study, the notification system was omitted owing to budget-related issues.

Figure 1. The review dashboard.

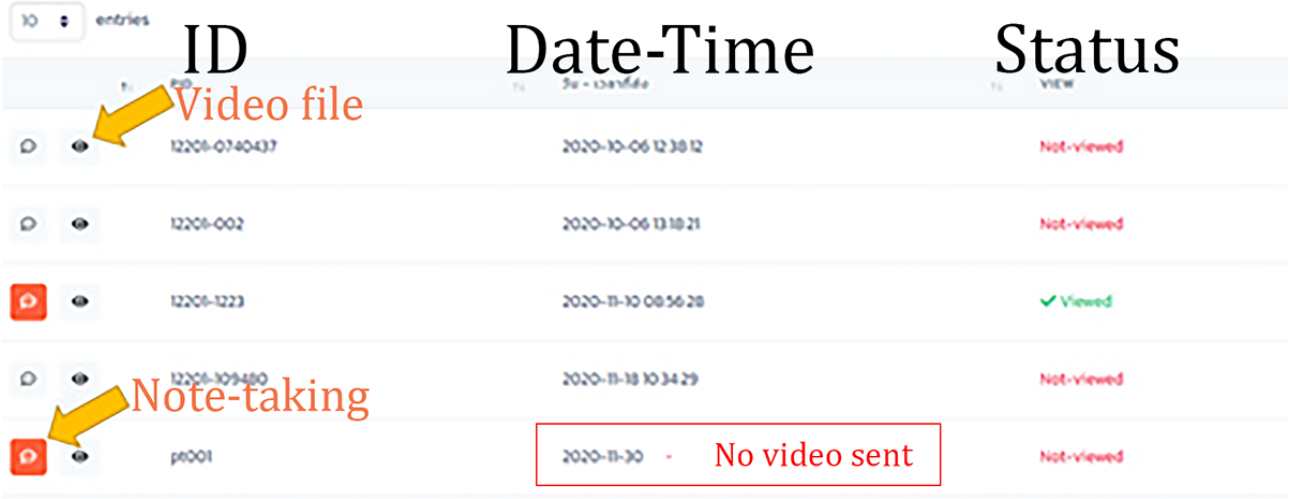
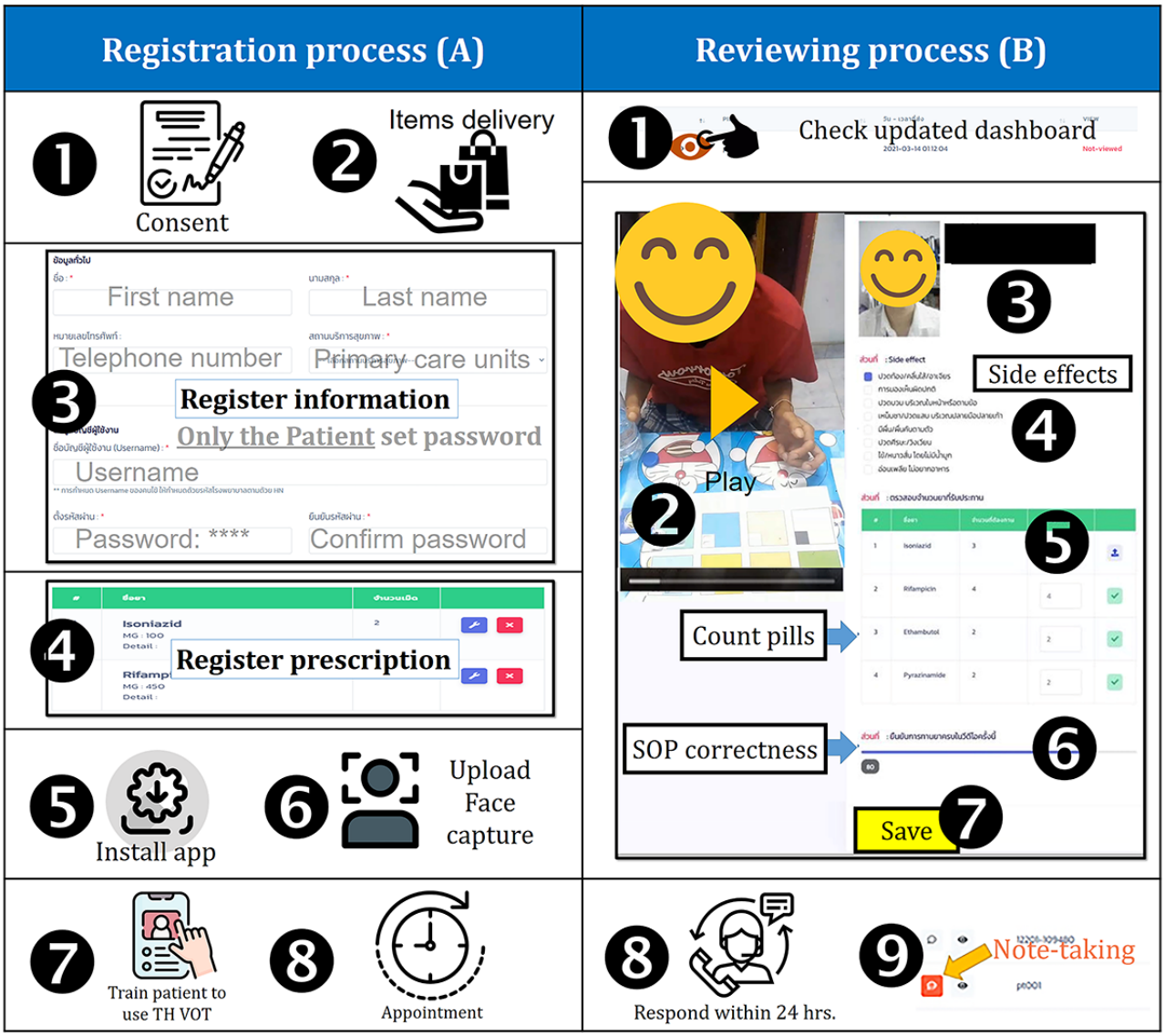


Figure 2. Standard operation procedures of the video-observed therapy at the patients' end. SOP: standard operating procedure, TH VOT: Thai video-observed therapy.



Items Used

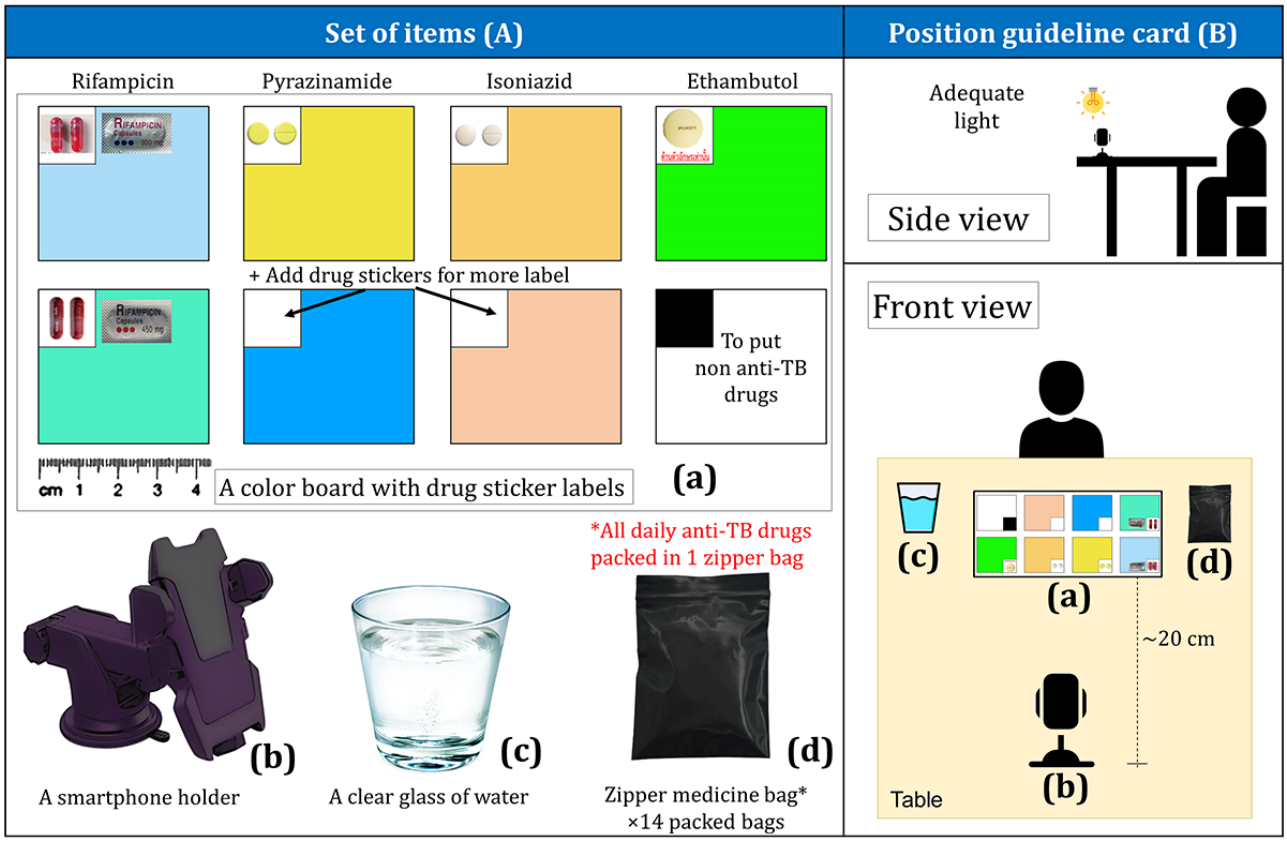
Essential items that must be provided to patients are listed in Textbox 1 and illustrated in Figure 3.

Textbox 1. A list of items delivered to the patients.

Items:

- A color board with drug labels (20×10 cm) (Figure 3A)
- A smartphone holder (Figure 3A).
- A clear glass (200 mL) (Figure 3A)
- 14 zipper medicine bags with a daily anti-TB dose packed inside (2 vitamin tablets per bag for a simulated patient) (Figure 3A).
- A position guideline for the patient (Figure 3B)

Figure 3. A set of items provided to a patient (A) and a position guideline for a patient (B). TB: tuberculosis.



SOPs

SOPs were divided into two series: patient SOP and observer SOP.

SOPs of the VOT at the Patients' End (Patient SOP)

Instructions for the preparation process for patients with TB (Figure 4A) were as follows:

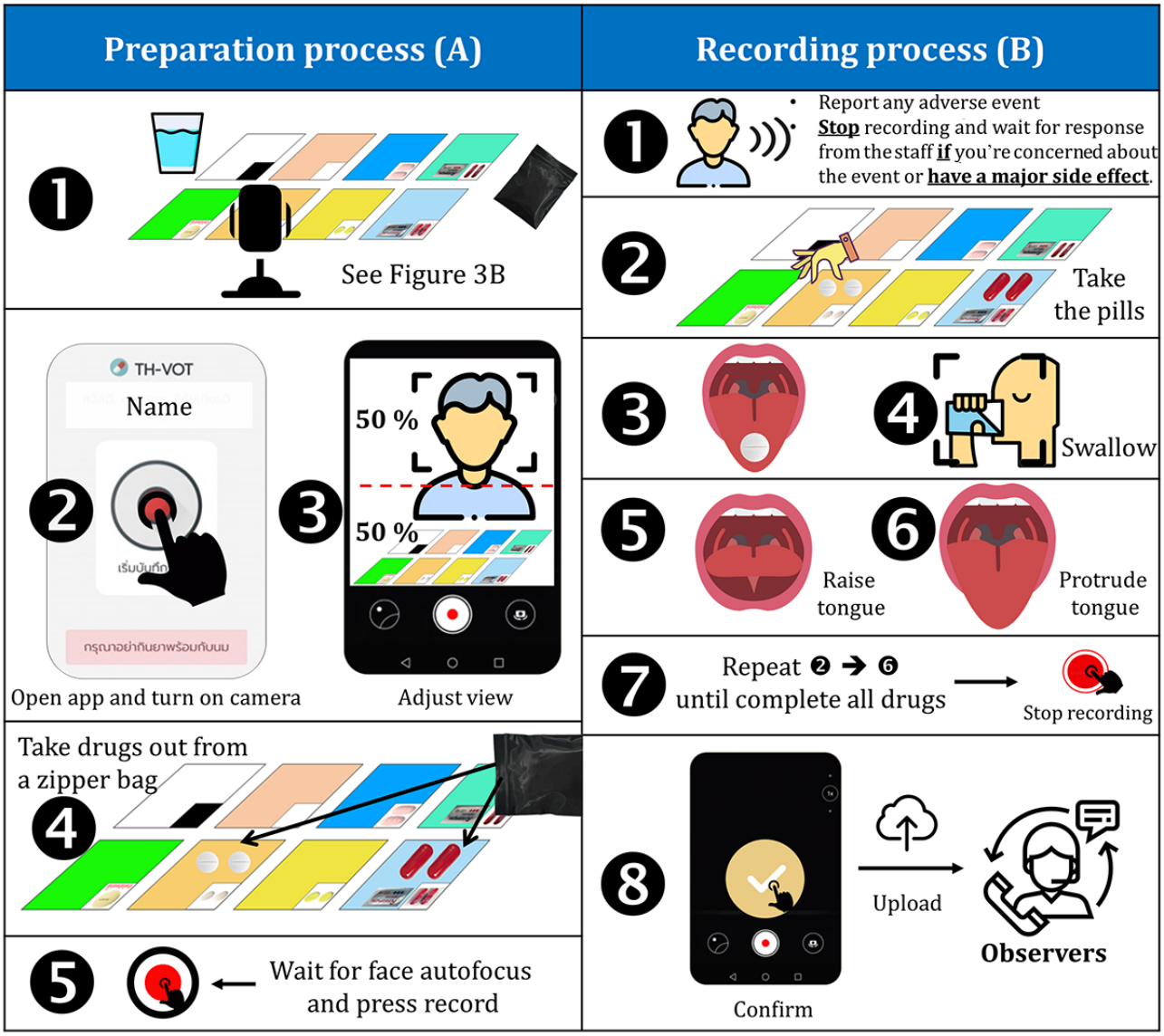
1. Place the given items on a table as shown in the position guideline (Figure 3B).
2. Open the TH VOT app and turn on the front camera.
3. Adjust the frame as appropriate. The upper half of the frame should contain a full-face image.
4. Remove all the anti-TB drugs from the daily zipper bag and place them on their color labels.
5. Wait for autofocus at the face and press the recording button.

Instructions for the recording process for patients with TB (Figure 4B) were as follows:

1. Depending on the condition:
   - If you are feeling unwell owing to the drugs, please report your adverse event through the app, call the TB staff, and temporarily stop taking the pills.
   - If you have any major side effects (vision changes, jaundice, confusion, vomiting, and skin rash), stop the medication and call the TB staff.
   - If you experience anaphylaxis, call the emergency department of Na Yong Hospital (Tel. +66-075-299-099)
   - Otherwise, continue to step 2.
2. Remove the pill from its label and place it on your tongue.
3. Protrude your tongue to show the tablet or capsule.

4. Swallow it. Note that multiple tablets or capsules can be placed on your tongue as convenient before swallowing in order to reduce water intake.
5. Raise your tongue to show your sublingual area.
6. Protrude your tongue to expose your palate area.
7. Repeat steps 2-6 until completion of the daily dose and stop recording.
8. Confirm your video and upload it to the TH VOT database.

Figure 4. Standard operation procedures of the video-observed therapy at the observers' end.



SOPs of the VOT at the Observers' End (Observer SOP)

Instructions for the registration process for the observers (Figure 2A) were as follows:

1. Request informed consent from the patient.
2. Provide the items listed in Textbox 1 to the patient.
3. Register the patient on the secure web-based platform and let the patient set his/her password privately.
4. Register the prescription for the patient.
5. Install the TH VOT app on the patient's smartphone.
6. Let the patient attempt to log into his/her account and use the smartphone to capture a photograph of his/her face and upload it to the system as proof for future facial identification.
7. Train the patient to use the TH VOT app in accordance with the patient SOP.
8. Appoint the time range for the patient's drug-taking and explain the reminding process.

Instructions for the reviewing process for the observers (Figure 2B) were as follows:

1. In the appointed time range, open the review dashboard of the secure web-based platform, check the rows of video sessions uploaded and consider the following:
   - If no video is sent, call the patient to provide him/her a reminder, and then continue to step 8.
   - Otherwise, click the eye button in the row with an unapproved status to pop up a window of video verification, and then continue to step 2.
2. Click "Play" to start the video.
3. Confirm the identity of the patient in the video.

4. Listen to any adverse event complaints and check the boxes of common side effects or type in other adverse events found in the video.
5. Identify the tablets or capsules of the anti-TB drugs taken by the patient by using the color board, and enumerate the consumed pills.
6. Use the checklist provided in Figure 4B. Assign 1 score to each correctly performed procedure (ranging 2-7). If there is any mistake, call the patient and provide advice to carry out the correct procedure in future.
7. Click "Save" to close the pop-up window.
8. Contact and respond to the patient if any adverse event or any other issue that occurs within 24 hours.
9. Take notes of any response in the record row of the dashboard.

Identification of Potential System Improvements

This study was approved by the Human Research Ethics Committee, Faculty of Medicine, Prince of Songkla University (approval# 64-03618-9). The implementation was approved by the research team and the chief medical officer of Na Yong Hospital.

Study Design

A mixed-methods pilot study was conducted through users' experiences of 2-week usage. The potential for system improvement was identified on the basis of two aspects: user compliance and user suggestion.

Participants

In Na Yong district, 6 PCUs served a total of 16 patients with active TB. Only 3 patients from 3 different PCUs had a smartphone and were thus recruited in our study. One TB staff as an observer and 1 healthy volunteer as a simulated patient were then recruited to attempt using the TH VOT system in each of these 3 PCUs. All participants were trained to use the TH VOT system in accordance with the aforementioned SOPs.

Data Collection

After the 2-week usage, the system's data records were automatically collected in the database of the TH VOT system since the beginning of the observation period. The video session records in the TH VOT system were retrieved to assess the compliance levels of all participants.

The participants were assigned to score the validated Thai user experience questionnaire (UEQ) [17]. The UEQ contained six dimensional scales: attractiveness (6 items), perspicuity (4 items), efficiency (4 items), dependability (4 items), stimulation (4 items), and novelty (4 items). The items were developed on the basis of the shape of a semantic differential scale with 7-point scales. Two words with opposite meanings represented each item. The order of the itemized terms was randomized with half of the scale's items beginning with a positive term (+3) and the other half of the items beginning with a negative term (–3). The neutral point was always 0. Cronbach α coefficient values from the original paper were as follows: attractiveness=.86, perspicuity=.71, efficiency=.79, dependability=.69, stimulation=.88, and novelty=.84 [18].

When participants completed scoring, the scores were processed in the researcher's computer and individually revealed to the score raters, and each dimensional score was compared with the upper limit of the general thresholds [19]. Then, each participant was privately asked to explain why those scores were assigned. The reflections on the users' experiences and suggestions for further development were collected using unstructured in-depth interviews to clarify users' reasons and their compliance. Participant interviews lasted 30-45 minutes each.

Results

Results Overview

Of the 9 participants initially recruited, 8 completed the study and 1 patient with TB retreated after 1 day of use owing to crashing of the app. Data from the 8 remaining participants were used to identify the potential for system improvement.

User Compliance

Overall, 70 video sessions were expected (2 from real patients and 3 from simulated patients over 14 days). A total of 60 sessions were recorded and submitted. Of these, 37 sessions were inspected by the staff within 24 hours.

User Suggestion

UEQ scores were revealed to each participant before starting their in-depth interviews. As shown in Table 1, all patients and simulated patients assigned higher scores in all dimensions than the upper limit of the general thresholds. The observers assigned high scores on attractiveness and novelty but poor scores on other dimensions.

According to the in-depth interviews, the patients and simulated patients forgot to take medication on some days, and the observers did not make a phone call to remind them. The push notification of the app was sometimes not seen as well. The observers requested to have the automatic notification system and suggested the need for auditing by their supervisors.

Table 1. The users' experience scores.

Participant group and #	User Experience Questionnaire score					
	Attractiveness	Perspicuity	Efficiency	Dependability	Stimulation	Novelty
Good benchmark[a]	1.41	1.84	1.43	1.53	1.10	0.87
Observer						
O1	2.17	1.25	0.75	1.50	–0.25	1.00
O2	1.67	0.25	0.50	1.25	–0.75	1.00
O3	1.67	0.75	0.75	1.25	–1.00	1.00
Simulated patient						
S1	2.67	2.25	1.75	1.75	1.00	1.00
S2	1.50	2.00	1.75	2.00	1.50	1.25
S3	2.17	2.50	1.50	2.00	1.50	1.25
Real patient						
P1	1.67	2.5	1.75	1.75	1.50	1.25
P2	2.17	2.00	1.50	2.00	1.50	1.00
P3	N/A[b]	N/A	N/A	N/A	N/A	N/A

[a]Upper limit of the general thresholds [19].

[b]N/A: not available; this patient withdrew from the trial because the app crashed.

Discussion

Principal Findings

According to the participant recruitment requirements, possession of a smartphone was the main problem of the A-VOT system, as only 2 patients owned a usable smartphone in this study. However, this problem could be resolved by providing smartphones with public cellular internet to patients who did not have a smartphone or their caretakers. An Android smartphone compatible with the TH VOT system could be purchased for approximately 900-1200 Baht (US $27.44-36.59), which was less than the total cost of drugs for standard TB treatment per patient: 1300-1800 Baht (US $39.63-54.88) [20]. After the patient was cured, the smartphone would be returned to the health service for use by the next patient with TB.

For user compliance, the level of use was not high on the patients' end and low on the observers' end compared to those in the United States and the United Kingdom [15,16]. Two more system elements would be needed: the audit and notification systems. The chief of the TB staff should be assigned to audit the quality of the VOT used by the patients and observers. A notification should be set up to provide feedback and notify the evaluation to the patients and observers.

Potential system improvements indicated by all users included the notification system, which was inactivated owing to budget-related problems. A largely well-known notification system, such as SMS or LINE, may be more effective to stimulate users than the current push notification. To overcome this problem, the option of an application programming interface of LINE notifications must be activated in further studies.

Limitations

This pilot study was limited by its small budget. Our findings indicate the need for adequate financial preparation to cover smartphone lending, audit management, and notification systems. The UEQ scores of this study could not be interpreted to conclusively determine usability levels owing to the small sample size of our study. Two weeks of observation may not be long enough to assess the burnout effect on users. Furthermore, simulated patients who did not take TB medication could not appropriately represent the side effect detection process.

Conclusions

To improve the TH VOT system, smartphones should be lent to patients with TB who do not own a smartphone. An audit system and web-based notification system to remind the observers and patients must be set up.

Acknowledgments

This study and the system development were funded by the Prince of Songkla University, Thailand. The researchers would like to sincerely thank all the TB staff in Na Yong district for their engagement in the implementation of the TH VOT system. Research reported in this publication was supported by the Fogarty International Center and the National Institute of Allergy and Infectious Diseases, of the National Institutes of Health under Award Number D43 TW009522. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Conflicts of Interest

None declared.

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Abbreviations

A-VOT: asynchronous video-observed therapy
DOT: directly observed therapy
PCU: primary care unit
SOP: standard operating procedure
S-VOT: synchronous video-observed therapy
TB: tuberculosis
TH VOT: Thai video-observed therapy
UEQ: user experience questionnaire
VOT: video-observed therapy

Edited by G Eysenbach; submitted 09.04.21; peer-reviewed by R Garfein, H Takiff; comments to author 30.04.21; revised version received 15.05.21; accepted 05.07.21; published 27.07.21.

Please cite as:
Kumwichar P, Chongsuvivatwong V, Prappre T
Development of a Video-Observed Therapy System to Improve Monitoring of Tuberculosis Treatment in Thailand: Mixed-Methods Study
JMIR Form Res 2021;5(7):e29463
URL: https://formative.jmir.org/2021/7/e29463
doi:10.2196/29463
PMID:34313602

Original Paper

A Biofeedback App for Migraine: Development and Usability Study

Sigrid Hegna Ingvaldsen[1], MSc; Erling Tronvik[1,2], MD, PhD; Eiliv Brenner[1,2], MD, PhD; Ingunn Winnberg[2], MD; Alexander Olsen[3,4], PhD; Gøril Bruvik Gravdahl[1,2], MSc; Anker Stubberud[1,2], MD, PhD

[1]Department of Neuromedicine and Movement Science, Norwegian University of Science and Technology, Trondheim, Norway

[2]National Advisory Unit on Headaches, Department of Neurology and Clinical Neurophysiology, St. Olavs Hospital, Trondheim, Norway

[3]Department of Psychology, Norwegian University of Science and Technology, Trondheim, Norway

[4]Department of Physical Medicine and Rehabilitation, St. Olavs Hospital, Trondheim, Norway

Corresponding Author:
Sigrid Hegna Ingvaldsen, MSc
Department of Neuromedicine and Movement Science
Norwegian University of Science and Technology
Edvard Griegs Gate 8
Trondheim
Norway
Phone: 47 73 59 20 20
Email: sigrid.h.ingvaldsen@ntnu.no

Abstract

Background: Biofeedback is effective in treating migraines. It is believed to have a beneficial effect on autonomous nervous system activity and render individuals resilient to stressors that may trigger a migraine. However, widespread use of biofeedback is hampered by the need for a trained therapist and specialized equipment. Emerging digital health technology, including smartphones and wearables (mHealth), enables new ways of administering biofeedback. Currently, mHealth interventions for migraine appear feasible, but development processes and usability testing remain insufficient.

Objective: The objective of this study was to evaluate and improve the feasibility and usability of an mHealth biofeedback treatment app for adults with migraine.

Methods: In a prospective development and usability study, 18 adults with migraine completed a 4-week testing period of self-administered therapist-independent biofeedback treatment consisting of a smartphone app connected to wearable sensors (Cerebri, Nordic Brain Tech AS). The app included biofeedback training, instructions for self-delivery, and a headache diary. Two wearable sensors were used to measure surface electromyographic voltage at the trapezius muscle and peripheral skin temperature and heart rate at the right second fingertip. Participants were instructed to complete a daily headache diary entry and biofeedback session of 10 minutes duration. The testing period was preceded by a preusability expectation interview and succeeded by a postusability experience interview. In addition, an evaluation questionnaire was completed at weeks 2 and 4. Adherence was calculated as the proportion of 10-minute sessions completed within the first 28 days of treatment. Usability and feasibility were analyzed and summarized quantitatively and qualitatively.

Results: A total of 391 biofeedback sessions were completed with a median of 25 (IQR 17-28) per participant. The mean adherence rate was 0.76 (SD 0.26). The evaluation questionnaire revealed that functionality and design had the highest scores, whereas engagement and biofeedback were lower. Qualitative preexpectation analysis revealed that participants expected to become better familiar with physical signals and gain more understanding of their migraine attacks and noted that the app should be simple and understandable. Postusability analysis indicated that participants had an overall positive user experience with some suggestions for improvement regarding the design of the wearables and app content. The intervention was safe and tolerable. One case of prespecified adverse events was recorded in which a patient developed a skin rash from the sticky surface electromyography electrodes.

Conclusions: The app underwent a rigorous development process that indicated an overall positive user experience, good usability, and high adherence rate. This study highlights the value of usability testing in the development of mHealth apps.

(JMIR Form Res 2021;5(7):e23229) doi:10.2196/23229

KEYWORDS

mHealth; headache; wearables; smartphone

Introduction

Migraine is a very common disorder [1] and the leading cause for disability in people aged 15 to 55 years [2]. Frequent migraine attacks warrant preventive treatment, and nonpharmacological prophylaxes are a valid option, with few adverse events and a potential adjunctive effect to medication [3-5]. Several nonpharmacological interventions are proven to be effective, and among these, behavioral interventions are the most widely used [6]. Specifically, biofeedback is one of the most prominent behavioral approaches, and meta-analytical evidence suggests that it is effective in treating migraines [7].

During biofeedback, individuals learn to voluntarily modify their bodily reactions through feedback from their own physiological processes. The most frequently used modalities are peripheral skin temperature, blood volume pulse, and surface electromyography (SEMG) [8]. The exact mechanisms of the biofeedback training effect in migraine treatment are not known. It is believed to have a beneficial effect on autonomous nervous system activity, render individuals resilient to stressors, and possibly mediate a beneficial afferent vagus nerve stimulation [9]. Through regular training, individuals may learn a long-lasting reduction in muscle tension, rise in peripheral skin temperature, and lower heart rate. These measures are believed to be beneficial in reducing the migraine burden and are associated with increased parasympathetic tone [10,11]. Biofeedback treatment typically requires a trained therapist and specialized equipment measuring the chosen physiological parameter [8]. Today, biofeedback is primarily available in clinic-based formats, and to some extent in electronically delivered formats, and there is no clear evidence if the latter is inferior [12]. However, the need for a trained therapist and suitable equipment is costly and time-consuming, hampering the widespread use of biofeedback as a migraine prophylaxis.

Nevertheless, new digital technologies, including wearable sensors and smartphones for medical purposes (mHealth), provide new possibilities [13-15]. Recent research suggests that behavioral mHealth interventions for headaches are feasible, but development processes and usability testing remain insufficient [16]. Specifically, there is a lack of collaboration with health care professionals in the development process of pain apps [17-19]. Also, few existing mHealth pain apps use physiological and behavioral components that are often important factors for self-management interventions [20]. In addition to the limited development processes, efficacy measures are uncertain [12]. This study aimed to investigate the feasibility, usability, safety, and tolerability of a biofeedback treatment app and wearable sensors among adults with migraine.

Methods

Study Design and Participants

The study was designed as a prospective development and usability study at St. Olavs University Hospital in Trondheim, Norway, from December 2019 to March 2020. Adults with migraine were recruited from the outpatient headache clinic and the municipality using the hospital intranet and an advertisement in the news. A total of 18 participants were included in the study. We did not conduct a formal a priori sample size calculation. The sample size was based on recommended guidelines for a sample size of usability studies [21,22]. All diagnoses were confirmed by a consultant neurologist with headache expertise. Because there were only 10 pairs of sensors available for the study, participants were divided into two groups before completing a 4-week period of app testing at home (10 participants in the first group and 8 participants in the second group). The 4-week period was preceded by a preusability expectations interview and succeeded by a postusability experience interview. Participants also completed an evaluation questionnaire at weeks 2 and 4 of the test period. The study was approved by the regional committee for medical and health research ethics (REK Midt 7166) and the Norwegian Medicines Agency for trials of medical equipment (19/11730-9).

Inclusion criteria were aged 18 to 65 years; migraine with or without aura diagnosed according to the International Classification of Headache Disorders, Third Edition [23]; 2 to 8 attacks per month; experience with using a smartphone; and signed written informed consent. Exclusion criteria were lack of proficiency in the Norwegian language; reduced vision, hearing, or sensibility to a degree that hampered study participation; or any severe neurological or psychiatric disorders.

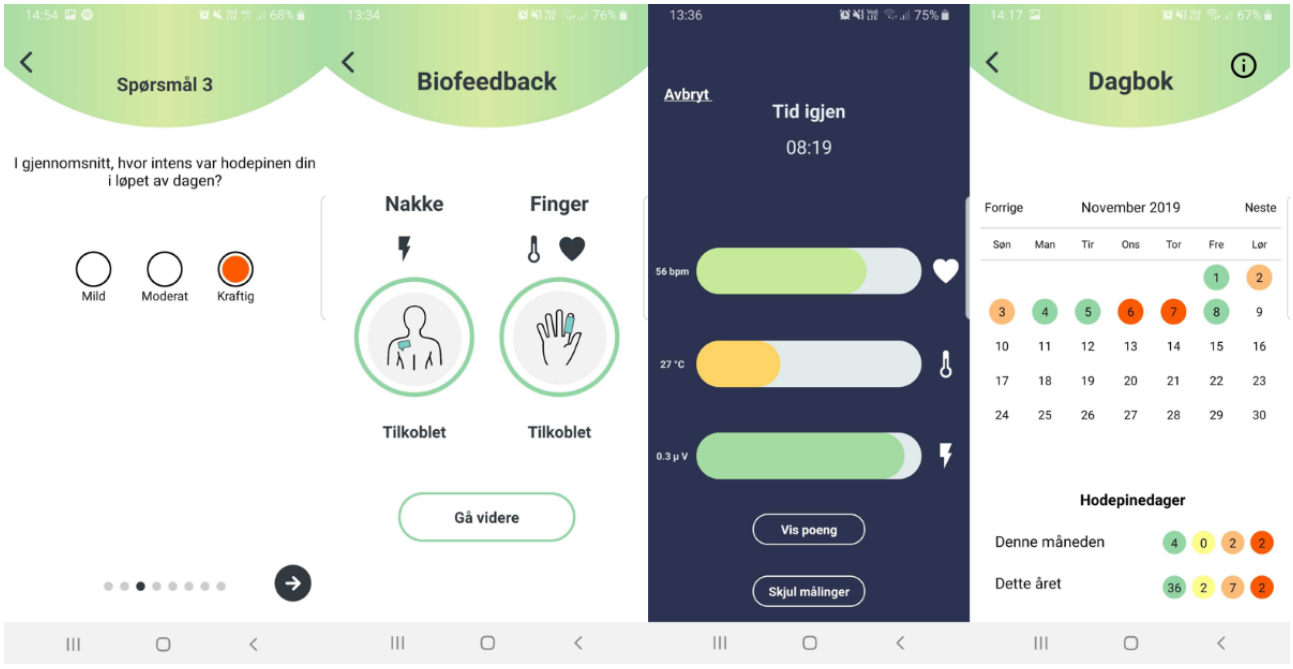
Biofeedback Setup

The Cerebri (Nordic Brain Tech AS) biofeedback setup consisting of a smartphone app connected to wearables was used for self-administered biofeedback treatment. The setup was developed based on similar equipment used in 2 previous studies at St. Olavs University Hospital. In the first of these studies, a biofeedback treatment app was developed in an iterative and incremental fashion, in which adolescents completed 3 cycles of usability testing, and improvements and changes to the app interface were completed between cycles [24,25]. A small compact SEMG sensor was used for measuring muscle tension from the upper trapezius muscle fibers. A combined device including 2 sensors was attached to the right index finger to measure peripheral skin temperature and heart rate (Figure 1 displays the sensors). Both devices transmitted signals to the app via Bluetooth Smart.

Figure 1. Photos of the wearable sensors. Top left: Combined sensor, measuring peripheral skin temperature and heart rate from the right index finger. Top right: Muscle tension sensor measuring surface electromyographic voltage from the upper trapezius muscle fibers. Bottom: Both sensors in use during a biofeedback session.

The app included biofeedback training, instructions for self-delivery, and a headache diary. Participants were given a push reminder daily to complete a headache diary entry and biofeedback session of 10 minutes. Prior to commencing treatment, participants were provided with a brief explanation of how biofeedback treatment works and how to complete the biofeedback training sessions. One of the investigators helped participants run through a trial session using both sensors and the app. Participants were encouraged to try to relax and sit comfortably during the sessions. No detailed instructions on how to perform the biofeedback were given. Figure 2 displays screenshots of the app. All participants were provided with a box containing both sensors, a power charger, and additional SEMG electrode patches. Participants used their own smartphones throughout the trial.

Figure 2. App screenshots. Left: Sample question in the headache diary where users are asked to rate headache intensity (On average, how intense was your headache during the day?). Center left: Instructions on how to connect the sensors. Center right: Visualization during the biofeedback session. Each of the three parameters is displayed as a horizontal column increasing in width with increasing score and correspondingly changing color. Right: Headache diary overview allowing for easy visualization of previous headache diary entries.



Usability Evaluation

Upon inclusion, participants met with one of the researchers to download and start using the app. A semistructured preusability expectations interview was completed (Multimedia Appendix 1) before starting a 4-week period using the app and sensors.

During the 4 weeks, participants were prompted to complete daily biofeedback sessions and daily headache diary entries (Multimedia Appendix 2). Participants were given an evaluation questionnaire at 2 weeks and 4 weeks after commencing use (Multimedia Appendix 3). The evaluation questionnaire was similar to the one used in a recent adolescent usability study of a similar biofeedback setup [25]. The evaluation questionnaire included the following 5 main domains, engagement, functionality, design, information, and biofeedback, corresponding to the mobile app rating scale [26]. Questions were answered on a 5-point Likert scale, ranging from 1 = completely disagree to 5 = completely agree. Also, participants were encouraged to take notes of any adverse events and discomforts during the treatment period.

At the end of the 4-week home use period, participants met with one of the researchers to return the equipment and complete a semistructured postusability experience interview (Multimedia Appendix 1). At this point, participants were explicitly asked to report any skin reactions, dizziness, and nausea and openly questioned on other adverse events. All adverse events were recorded with their seriousness and the potential grade of causality.

Data Analytic Strategy

We reported the number of completed sessions and calculated the adherence rate as the proportion of sessions completed within the first 28 days. Only sessions in which the full 10 minutes of biofeedback training was finished were considered as completed sessions. Sessions were automatically marked as completed within the app software, and the information was transferred to the database. No self-reported measure of adherence was made. We also described what weekdays and what time of the day sessions were completed.

Self-reported overall hours of phone use and familiarity with apps and sensors were averaged over the 2 evaluation questionnaires for each participant. Scores were averaged over each domain for all participants for the week 2 and week 4 evaluation questionnaires and summarized with medians and interquartile ranges. We only used complete data in the evaluation questionnaire analyses.

All usability interviews were recorded on an Olympus WS-853 recorder (Olympus America Inc). All recordings were transcribed and coded using NVivo 12 (QSR International) and stored in the software for qualitative analyses. A general inductive method was used to code transcripts. The transcripts were read repeatedly, and text segments were coded for potential themes. We used thematic content analysis to assess both preusability expectations and postusability experience [27]. We performed an inductive thematic content analysis for the expectations usability interview by generating codes that emerged naturally based on the participant responses to the semistructured interview guide. For the postuse usability interview, we conducted a problem-based deductive thematic content analysis to assess patterns of experience with the app and sensors and potential technical difficulties with the equipment. As the coding framework developed, transcripts were reanalyzed in light of new themes that emerged. Finally, we derived and summarized major themes that were relevant to the usability experience.

This is the primary analysis of data collected in this study. A priori, we planned for exploratory descriptive and qualitative analyses of usability data. No a priori hypothesis testing was planned, and none were conducted. Data were reported as means, standard deviations, medians, and interquartile ranges. Normality assumptions were based on visual inspection of histograms. Descriptive statistics were calculated, and figures were made using Python v3.7.7 (Python Software Foundation) with the following open-source packages: matplotlib 3.1.1, NumPy 1.17.2, pandas 0.20.3, and seaborn 0.9.0.

Results

Participants and Demographics

A total of 18 participants were recruited, attended, and completed the preusability and postusability evaluations. All participants had prior experience using health or wellness apps (such as headache diaries or meditation apps). Patient demographics are summarized in Table 1. Headache diary entry and biofeedback session data were not successfully transmitted to the data storage server for one participant and were thus not available for analyses.

Table 1. Patient baseline demographics.

Characteristic	Value (n=18)
Age (years), mean (SD)	40.6 (9.8)
Gender, female, n (%)	17 (95)
Migraine subtype (n=17)	
Migraine with aura, n (%)	7 (41)
Chronic migraine, n (%)	3 (18)
Comorbid headache disorders	
Tension type headache, n (%)	7 (39)
Trigeminal autonomic cephalalgias, n (%)	1 (6)
Self-reported monthly headache attacks, median (IQR)	4 (3.3-5)
Hours of daily smartphone use, mean (SD)	2.9 (1.0)
Familiarity with apps scored on a 5-point scale, median (IQR)	4 (4.0-4.25)
Familiarity with sensors scored on a 5-point scale, median (IQR)	1 (1-3)

Usability Metrics

Use Patterns

A total of 391 biofeedback sessions for 17 individuals were completed, with a median of 25 (IQR 17-28) per participant. The mean adherence rate was 0.76 (SD 0.26). Session completion was evenly spread through the week with 50, 56, 54, 62, 57, 56, and 56 sessions completed on Monday, Tuesday, Wednesday, Thursday, Friday, Saturday, and Sunday, respectively. More than 90% (358/391, 91.56%) of sessions were completed between 4 PM and 11 PM, and 52.43% (205/391) were completed between 7 PM and 10 PM.

Preusability Expectations Interview

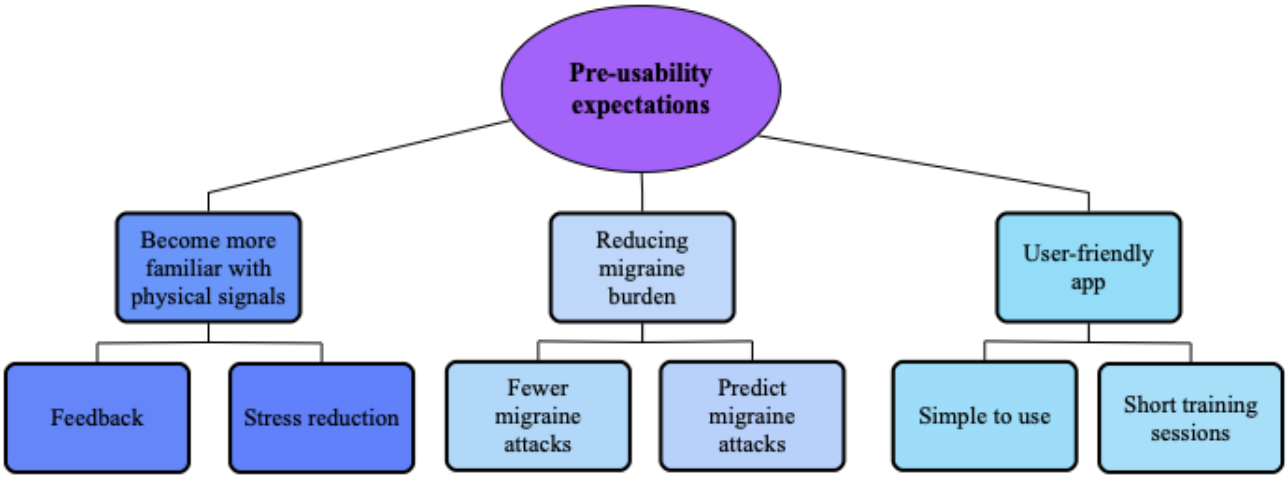
Coding of the preusability expectation interviews revealed 3 distinct major themes: becoming more familiar with physical signals, reducing migraine burden, and user-friendly app. Figure 3 is a diagram with an overview of themes and subthemes.

Almost all participants expressed a desire for the biofeedback sessions to help them become more familiar with bodily signals to understand what influenced their migraine and headache. Several participants had previously tried various relaxation and mindfulness exercises and reckoned the benefit of visualized feedback alongside such exercises. They expected that the explicit feedback in the app would enhance their motivation to use the equipment every day because it would show progress over time. Additionally, participants recognized the impact of stress on their migraine and thought the training would help them control and reduce stress levels.

All participants expressed that the main expectation of participating in the study was to reduce the migraine burden and improve their quality of life. Participants expressed that they wanted to understand their migraine better, learn to predict migraine attacks, and understand what triggered attacks. Some participants also noted that it would be interesting to see differences in the measurements on headache days compared to headache-free days.

Finally, as the third major theme, participants expressed the importance of a user-friendly app. The simplicity of use was essential if they were to use it while experiencing a headache so that the app would not worsen their headache. Some participants mentioned that short sessions would be beneficial due to the time constraints of a busy everyday life and the fact that the disease already consumes large amounts of their time.

Figure 3. Inductive thematic content analysis of preusability expectations. Three major themes with several subthemes were found: becoming more familiar with physical signals, reducing migraine burden, and user-friendly app.



Postusability Experience Interview

To assess postusability experience from a deductive problem-based approach, we used 3 major themes: sensor shortcomings, app shortcomings, and technical difficulties. The themes were based on the usability evaluation questionnaire (Multimedia Appendix 3) and interview answers. Inductive coding within each major theme revealed several subthemes (Figure 4).

Several of the participants felt that the temperature measurement did not reflect their skin temperature accurately. They also had difficulties understanding the association between finger temperature and stress/relaxation. Next, some participants had difficulties attaching the EMG sensor and found it too bulky to lie down and relax while performing the biofeedback sessions. Finally, some participants noted that the sensor design appeared prototype-like and that it might be easier to commercialize the sensors with a slimmer design.

Some participants wished for additional questions in the headache diary, such as associated symptoms and details on medication, to identify patterns in their migraine. Next, the app included limited information on biofeedback scores, and some participants found this information insufficient to understand the association between biofeedback performance and migraine burden. Some wanted an explicit overview of their scores and the direct association with headache occurrences, and one participant suggested an illustrative graph of score progression for each physiological measurement. Next, the app did not include specific instructions on biofeedback training, but several participants expressed a wish for relaxation techniques and/or tips to be included in the app. Finally, several participants said that the measures were inaccurate compared to how they felt. Some participants experienced that the measurements showed low scores on migraine-free days but high scores on days with migraine.

Some of the participants experienced technical difficulties. They had difficulties connecting the sensors to the app via Bluetooth and had to repeatedly switch sensors on and off during a session, which reduced the quality of the sessions. Additionally, several participants experienced that the session terminated early as their smartphone went into hibernation mode.

In addition to the thematic content analysis, results from the evaluation questionnaire illustrated postusability experience. The themes functionality and design showed the highest scores, whereas engagement and biofeedback scores were lower (Figure 5). A detailed visual presentation of the biofeedback ratings is provided in Multimedia Appendix 4.

Figure 4. Deductive thematic content analysis of postusability experience. Three major themes with several subthemes were defined: sensor shortcomings, app shortcomings, and technical difficulties.

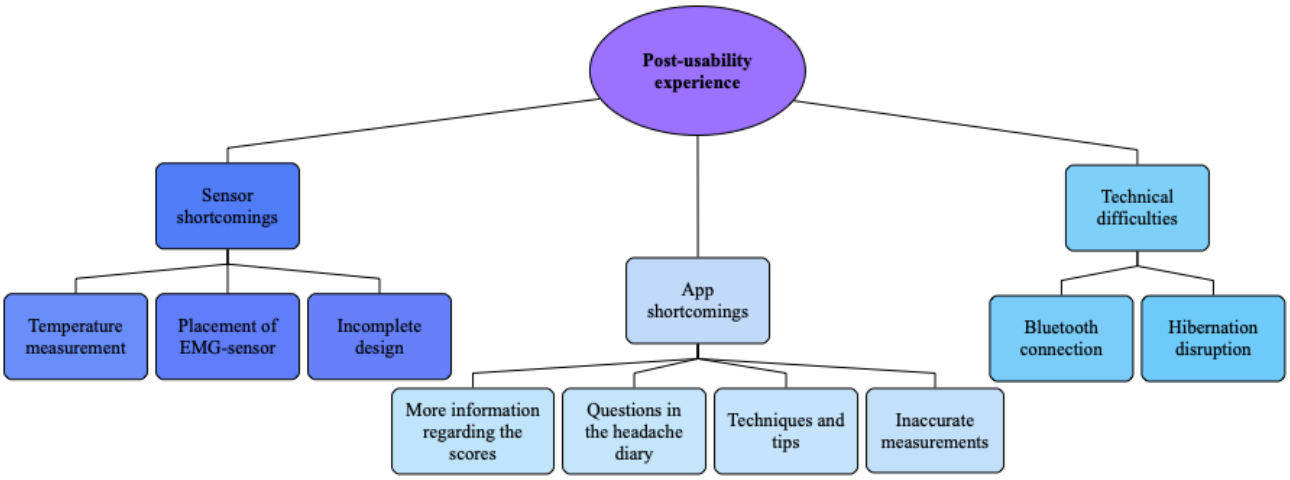
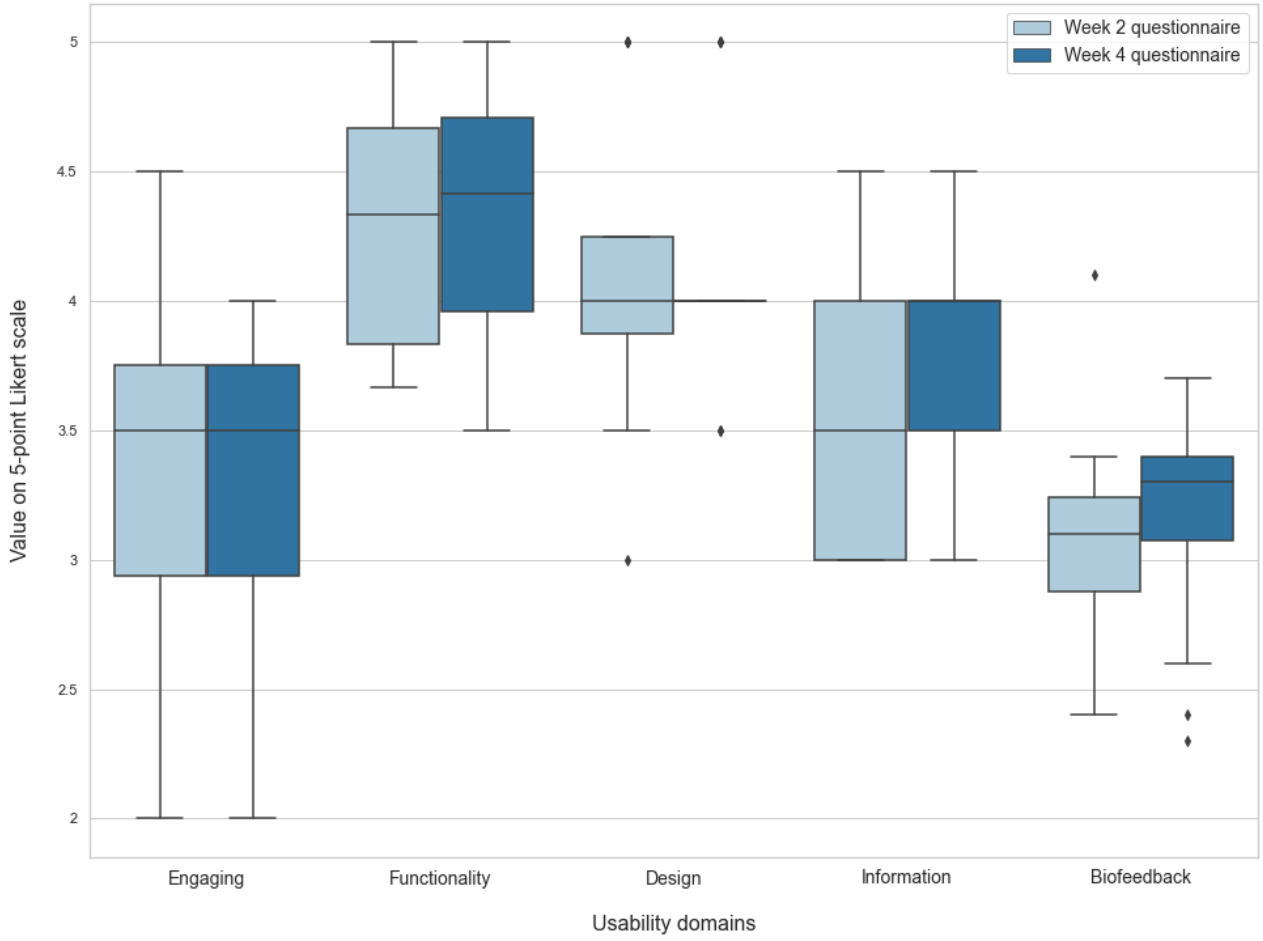


Figure 5. Boxplot of evaluation questionnaires. Horizontal lines represent medians, upper and lower box limits represent IQR, whiskers represent IQR*1.5, and diamonds represent outliers. Each pair of boxes shows the usability domain score after 2 (light blue) and 4 (dark blue) weeks of use. Note that functionality and design have the highest scores, whereas engagement and biofeedback scores are lower.



Safety and Tolerability

One case of prespecified adverse events was recorded, in which a patient developed a skin rash from the sticky SEMG electrodes. The rash was mildly painful and lasted for a week. No other adverse events were detected. Based on the evaluation questionnaire and qualitative analysis, some of the participants raised a discomfort concern regarding the bulkiness of the SEMG sensor when trying to lay down.

Discussion

Principal Findings

This study explored the usability and feasibility of a biofeedback app treatment for migraine using a mixed methods approach

with both quantitative and qualitative data. The preusability assessment indicated that all participants were positively attuned to the biofeedback app and expected to learn more about their bodily signals and how these affect their migraine. On the other hand, the problem-based postusability analysis revealed that the setup had several shortcomings, including technical difficulties and inaccurate measurements. Most participants had some recommendations for specific improvements to the setup but reported an overall positive user experience and good adherence rates.

Interpretation of Findings

Three main findings in this study illustrate the usefulness of usability testing when developing mHealth interventions. First, qualitative analysis revealed that participants felt they had difficulties with increasing their skin temperature. This is noteworthy because peripheral skin temperature appears to be one of the most effective biofeedback parameters for migraine [7,10] and is believed to provide an indirect measure of activity in the sympathetic nervous system, partially explaining the treatment effect of biofeedback [9,10,28]. A reduction in arousal and autonomic tone leads to increased peripheral blood flow and skin temperature, while increased arousal increases sympathetic outflow, thereby constricting peripheral blood flow and lowering skin temperature [29]. Migraine patients seem to have an interictal sympathetic impairment and ictal adrenoreceptor hypersensitivity [30], which suggest that regular training in reducing sympathetic tone could lower migraine burden [9]. Therefore, the importance of finger temperature in biofeedback training indicates that the perceived lack of influence over temperature lies in the app/sensor itself and not in the choice of the physiological parameter. An explanation for the mentioned difficulties with raising their finger temperature could be that the biofeedback sessions were completed during the cold winter in Norway. Thereby, the participants' index finger might have been colder than the average body temperature prior to the biofeedback sessions.

Second, our mixed methods approach revealed that participants required more guidance to understand the association between biofeedback and the app's illustration of the physiological measurements. The quantitative evaluation questionnaires revealed high scores for functionality and design but low scores for engagement and biofeedback, both in line with qualitative findings. Preexpectation analysis indicated that participants wished for the app to be simple and understandable. However, the postexperience analysis revealed that participants had difficulties perceiving how biofeedback is associated with migraine and better health outcomes. This suggests that upcoming iterations of the treatment should be focused on ensuring a tight correlation between users' perception of the biofeedback training and true physiological measurements. This is likely to increase motivation and potentially treatment effect further [31].

The third significant usability finding was the desire for relaxation training and stress management techniques to be included in the app. We decided not to include such features to investigate if a therapist might be omitted from the usual treatment and see if the app itself may replace the therapist [25]. However, both qualitative and quantitative findings indicated that more guidance would have improved user experience and adherence. On the other hand, previous studies investigating the use of minimal therapist contact treatments have discovered that they often generate results equivalent to therapist-led treatment [32] and are more cost-effective [33]. Andersson and colleagues [34] investigated the role of therapist-initiated contact in a telephone study where adults suffering from headaches were randomized to either a web-based self-help program or the same program with additional therapist-initiated telephone calls. They found that therapist-initiated phone calls did not influence the dropout rate or improvements in headache index. This indicates that therapist-assisted treatment is not necessarily superior to pure self-management. The immediate idea to counteract this uncertainty in app-based biofeedback treatment is to implement a combination of home training and therapist contact. The problem, however, with such an approach is that it is not much different from traditional treatment and will not ensure the desired cost-benefit and widespread distribution. To keep in line with trends of mHealth development, we propose a program where minimal to no guidance is included in the app for the first few sessions, and then specific tips and techniques are progressively included for participants who have problems with achieving improvement in their biofeedback scores.

As the mHealth approach to pain treatment has grown over the past year, several shortcomings in development processes have been identified. Lalloo and colleagues [16] found that only 8.2% of pain self-management apps included a health care professional in the development and the majority of the apps (58.5%) implemented only a single self-management function. Similarly, Rosser and Eccleston [20] found that 86% reported no involvement of health care professionals in the development process. This could explain some of the general deficiencies they found, such as a lack of psychological and behavioral components underlying many self-management interventions, thereby causing an absence of validated expertise and content underpinning the available pain apps [20]. We took several measures to combat these limitations by including a wide range of health care professionals, including medical doctors and psychologists, in the development process.

Even though there are no similar studies of biofeedback for migraine, development studies of biofeedback for other purposes highlight the importance of a thorough development processes. A study of a sensor-based exercise biofeedback system found that using a systematic combined quantitative and qualitative assessment improved the system [35]. Another study of a mHealth biofeedback device for borderline personality disorder was also significantly improved through user-centered design with usability assessment [36]. Together with this study, both of these studies demonstrate that meticulous usability and feasibility assessments can mitigate the unwanted effects of poor development processes that often hamper mHealth apps [37].

Limitations and Strengths

Several limitations should be considered when interpreting the results of this study. First, participants used the equipment over a relatively short period, whereas the International Headache

Society recommends 3 months for clinical trials [38]. Second, each group of participants only completed one cycle of usability testing. The study could have benefitted from iterative cycles with several rounds of testing for each individual to identify the effect of improvements in the app directly [39]. This was not possible at the time because there were only 10 available sensors for the study. Finally, the semistructured interview guide and evaluation questionnaire used in the study have not been systematically validated, which decreases confidence in usability findings. Nevertheless, the interview guide was based on recommended guidelines for the development of mHealth apps [18], and the evaluation questionnaire was based on a validated mHealth app rating scale [40].

The study also has several strengths. The greatest strength is the rigorous usability and feasibility development process. As discussed above, we believe this will mitigate the unwanted effects of poor development processes. In addition, the study was designed based on recommended guidelines for the development of mHealth apps and known shortcomings in existing mHealth usability studies. Finally, although the sample size was seemingly small, the authors feel that the study reached a level of data saturation with the high adherence rate and collecting quantitative and qualitative data from all participants. We believe this study has uncovered the majority of essential usability issues.

Conclusion

In this study, we performed usability and feasibility testing of a new biofeedback treatment app targeted at adults with migraine. The treatment underwent a rigorous development process specifically for the target population. Participants were overall satisfied with the treatment, had a high adherence rate, and provided several suggestions worthy of inclusion in future iterations. Our findings highlight the importance of usability testing, revealed shortcomings with the intervention that would otherwise have been difficult to discover, and built a solid foundation for future efficacy trials. Future research should assess the efficacy of the proposed biofeedback treatment app among adults with migraine.

Acknowledgments

The study received funding for cooperative projects between the Department of Neuromedicine and Movement Science and the Department of Psychology at Norwegian University of Science and Technology (NTNU).

Conflicts of Interest

NTNU and St. Olavs Hospital, Trondheim University Hospital, may benefit financially from the commercialization of the proposed treatment through future possible intellectual properties. This may include financial benefits to the authors of this article. ET, AO, AS are cofounders of the Nordic Brain Tech AS, a spin-off company that was established based on the proposed treatment in this and previous studies at NTNU. In addition, ET, AO, AS are coinventors of the proposed treatment in this study and may benefit financially from a license agreement between Nordic Brain Tech AS and NTNU. No conflicts were declared for SHI, EB, IW, and GBG.

Multimedia Appendix 1
Semistructured interview guide for preusability and postusability (translated to English).
[DOCX File , 23 KB - formative_v5i7e23229_app1.docx]

Multimedia Appendix 2
Headache diary questions.
[DOCX File , 23 KB - formative_v5i7e23229_app2.docx]

Multimedia Appendix 3
Usability evaluation questionnaire.
[DOCX File , 26 KB - formative_v5i7e23229_app3.docx]

Multimedia Appendix 4
Boxplot of evaluation questionnaires in the biofeedback domain. Horizontal lines represent medians, upper and lower box limits represent IQR, whiskers represent IQR*1.5 and diamonds represent outliers. Each pair of boxes show the score the usability domains after 2 (light blue) and 4 (dark blue) weeks of use.
[DOCX File , 73 KB - formative_v5i7e23229_app4.docx]

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Abbreviations

mHealth: mobile health
NTNU: Norwegian University of Science and Technology
SEMG: surface electromyography

Edited by G Eysenbach; submitted 24.12.20; peer-reviewed by P Knapp, M Connelly; comments to author 16.02.21; revised version received 17.03.21; accepted 31.05.21; published 28.07.21.

Please cite as:
Ingvaldsen SH, Tronvik E, Brenner E, Winnberg I, Olsen A, Gravdahl GB, Stubberud A
A Biofeedback App for Migraine: Development and Usability Study
JMIR Form Res 2021;5(7):e23229
URL: https://formative.jmir.org/2021/7/e23229
doi:10.2196/23229
PMID:34319243

Original Paper

Clinical Utility and Functionality of an Artificial Intelligence–Based App to Predict Mortality in COVID-19: Mixed Methods Analysis

Ahmed Abdulaal[1], MBBS, MRCS; Aatish Patel[1], MBChB, MRCP; Ahmed Al-Hindawi[1], MBBS, MRCA; Esmita Charani[2], MPharm, PhD; Saleh A Alqahtani[3,4], MD; Gary W Davies[1], MD, FRCP; Nabeela Mughal[1,2,5], BSc, MSc, MRCP, FRCPath; Luke Stephen Prockter Moore[1,2,5], MBChB, DTM&H, MSc, MPH, PhD, MRCP, FRCPath

[1]Chelsea and Westminster NHS Foundation Trust, London, United Kingdom

[2]National Institute for Health Research Health Protection Research Unit in Healthcare Associated Infections and Antimicrobial Resistance, Imperial College London, London, United Kingdom

[3]Johns Hopkins University, Baltimore, MD, United States

[4]King Faisal Specialist Hospital and Research Centre, Riyadh, Saudi Arabia

[5]North West London Pathology, Imperial College Healthcare NHS Trust, London, United Kingdom

Corresponding Author:
Luke Stephen Prockter Moore, MBChB, DTM&H, MSc, MPH, PhD, MRCP, FRCPath
National Institute for Health Research Health Protection Research Unit in Healthcare Associated Infections and Antimicrobial Resistance
Imperial College London
Commonwealth Building 8th Floor
Du Cane Road
London, W12 0NN
United Kingdom
Phone: 44 2033158273
Email: l.moore@imperial.ac.uk

Abstract

Background: The artificial neural network (ANN) is an increasingly important tool in the context of solving complex medical classification problems. However, one of the principal challenges in leveraging artificial intelligence technology in the health care setting has been the relative inability to translate models into clinician workflow.

Objective: Here we demonstrate the development of a COVID-19 outcome prediction app that utilizes an ANN and assesses its usability in the clinical setting.

Methods: Usability assessment was conducted using the app, followed by a semistructured end-user interview. Usability was specified by effectiveness, efficiency, and satisfaction measures. These data were reported with descriptive statistics. The end-user interview data were analyzed using the thematic framework method, which allowed for the development of themes from the interview narratives. In total, 31 National Health Service physicians at a West London teaching hospital, including foundation physicians, senior house officers, registrars, and consultants, were included in this study.

Results: All participants were able to complete the assessment, with a mean time to complete separate patient vignettes of 59.35 (SD 10.35) seconds. The mean system usability scale score was 91.94 (SD 8.54), which corresponds to a qualitative rating of "excellent." The clinicians found the app intuitive and easy to use, with the majority describing its predictions as a useful adjunct to their clinical practice. The main concern was related to the use of the app in isolation rather than in conjunction with other clinical parameters. However, most clinicians speculated that the app could positively reinforce or validate their clinical decision-making.

Conclusions: Translating artificial intelligence technologies into the clinical setting remains an important but challenging task. We demonstrate the effectiveness, efficiency, and system usability of a web-based app designed to predict the outcomes of patients with COVID-19 from an ANN.

(JMIR Form Res 2021;5(7):e27992) doi:10.2196/27992

KEYWORDS

app; artificial intelligence; coronavirus; COVID-19; development; function; graphical user interface; machine learning; model; mortality; neural network; prediction; usability; utility

Introduction

Clinical big data that are being collated in many health care settings have enabled prognostic scores to be developed on the basis of classical regression analysis, but these models frequently rely on laboratory parameters (which are not available in many primary care settings and in some low- and middle-income settings) [1]. Furthermore, because of a priori assumptions, these regression models may fail to leverage the data fully to create accurate prognostic models. Artificial intelligence (AI) techniques represent a potential solution [2], allowing more comprehensive use of big data, including the potential identification of proxy indicators (such as symptomatology and comorbidities) for laboratory parameters that may predict COVID-19 outcomes. Such systems have been shown to be accurate and reliable when compared to traditional regression models [3,4]. However, one of the principal challenges in leveraging AI clinically for COVID-19 has been in translating systems to the clinical setting [5].

Developing systems to accurately predict COVID-19 outcomes has several potential benefits at the patient, departmental, and organizational levels. At the patient level, predictive models would allow for early critical care reviews of high-risk patients and early discussions regarding treatment escalation plans. Medical departments could estimate bed requirements and account for intensive care unit (ICU) resource allocation issues more accurately. In turn, health care organizations could better manage staffing levels and health care resource procurement and distribution.

We describe here the clinical operationalization of an artificial neural network (ANN) that produces patient-specific mortality predictions for patients with COVID-19 [3,4] and explore the development of a graphical user interface (GUI) to facilitate the use of the system at the bedside. Subsequently, we assessed the utility and functionality (measuring effectiveness, efficiency, and satisfaction) of the GUI, which leverages this ANN, and analyzed the translational pathway for its integration and use in a clinical setting.

Methods

Development of the ANN

An ANN was developed, as previously described [3,4], to prognosticate for patients with COVID-19. A multilayer perceptron was trained and validated with 398 patients from a single London hospital, with an input of 22 features selected in accordance with previous studies [6-8], in turn developed after a review of existing evidence of contributory factors [9,10]. Demographics included gender and age. Smoking history was also included. Comorbidities included the presence or absence of asthma, chronic obstructive pulmonary disease, or chronic respiratory disease; hypertension; diabetes; congestive cardiac failure; ischemic heart disease; chronic kidney disease; hepatic cirrhosis; or a history of cerebrovascular events. Symptom data included the presence of absence of fever, cough, dyspnea, myalgia, abdominal pain, diarrhea, vomiting, altered mentation, collapse, and olfactory change or ageusia, as well as the duration of symptoms prior to hospital admission. Data were anonymized at the point of extraction and encoded from patient electronic health records by 3 health care practitioners (EC, AP, and A Abdulaal).

The model weights were initialized with Xavier normal initialization, and a dropout of 20% and 40% were used on the 2 hidden layers. Euclidean (L2) regularization was further added to the hidden layers to further prevent overfitting. The model was trained with 318 patients, and model hyperparameters were optimized on the basis of 10-fold cross-validation of the training set. The ANN was then trained on the full training set and validated on a held-out test set of 80 patients. For each patient input, the model produces a single output by using a sigmoid activation function (which demarcates results between 0 and 1). This output represents the probability of death during the current hospital admission for the patient. Discriminative ability was measured using the area under the receiver operating characteristic curve, and calibration was assessed both visually and by using the Brier score.

Data were collected as part of routine care by the responsible clinical team. No patient-identifiable data were used in this analysis. The study protocol was approved by the antimicrobial stewardship group at Chelsea & Westminster NHS Foundation Trust. The need for written informed consent was waived by the Research Governance Office of Chelsea & Westminster NHS Foundation Trust. The study was conducted in accordance with the tenets of the Helsinki declaration.

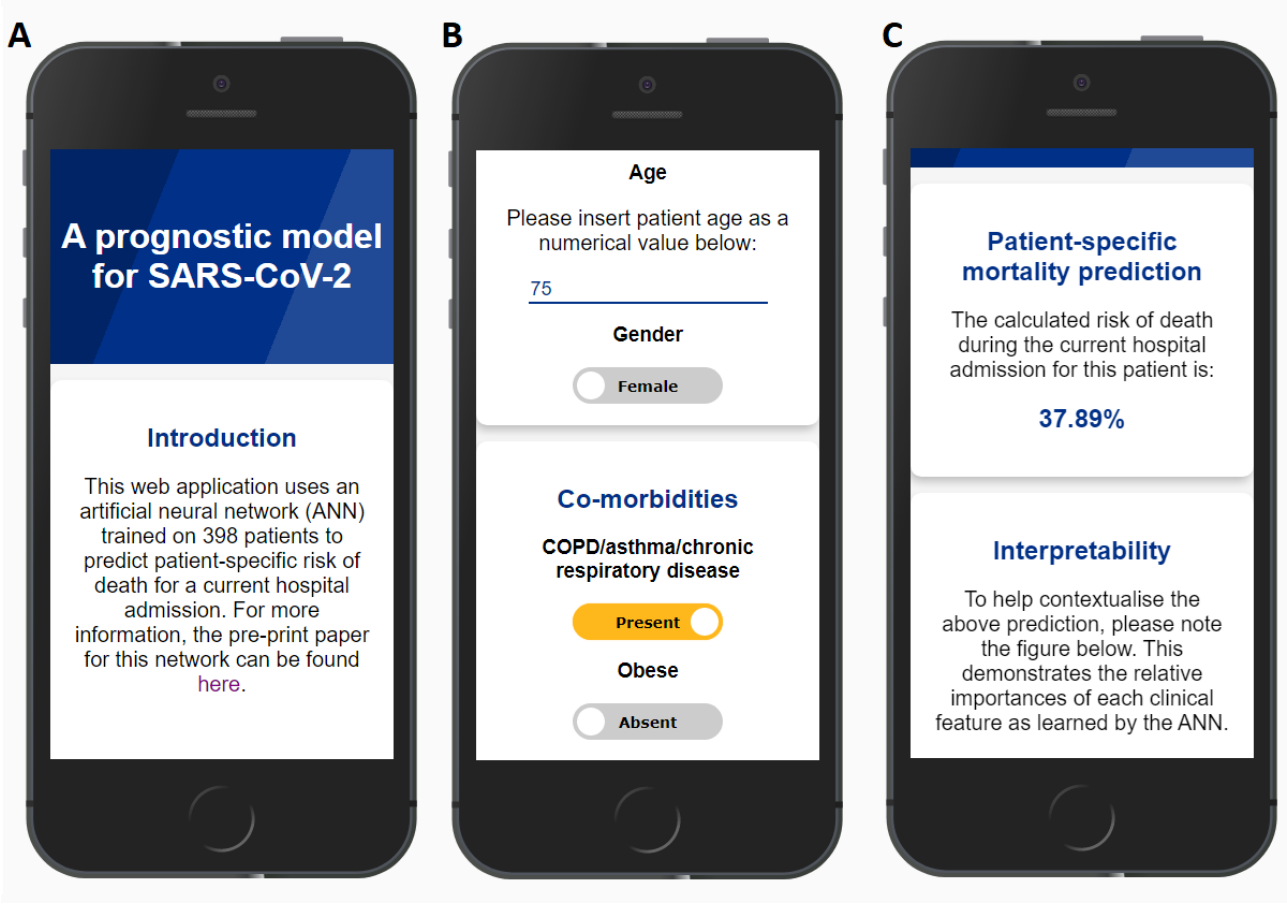
Development of GUI

A web-based app was developed using Node.js, an open-source, cross-platform, javascript runtime environment [11]. Express [12], a web-based framework for Node.js, which provides a set of tools for app development, was used to build the backend of the app. A combination of Nielsen and Shneiderman heuristics of user interface design were used to generate the initial GUI [13]. An iterative development process based on usability assessments throughout the design cycle was used to develop the interface further, thus ensuring its intuitiveness and ease of use. The app is currently developed as an English-language app.

The app collects patient demographics, comorbidities, and symptomatology data [4]. The data are then converted into a normalized tensor (a multidimensional array of data, which can be read by a machine learning algorithm [14]) in the browser. On the backend, these data are fed into the ANN [4] (the deep learning library Tensorflow.js [15] was used to transfer the data to the Node.js server), which makes a patient-specific mortality prediction, and the result is then returned to the user (Figure 1). The relative importance of patient-level factors with respect to the mortality prediction are displayed as a static figure on the results page. No patient data are stored by the app after a

prediction is made, and the app can be used for a new patient by navigating to the home screen.

Figure 1. Screenshots of the initial artificial neural network (ANN)–based COVID-19 prognostication app. (A) The introductory screen with a hyperlink to access more data on the ANN and its development. (B) The data input process with examples of numerical and categorical features. Selected categorical features are color-coded and labeled. Numerical features have input instructions above the data collection field. (C) A portion of the results screen. Patient mortality data are presented as a human-readable percentage.



Study Design

This was a between-subjects study with 1 condition: all participants used the app to predict the mortality risk for several patients. Effectiveness was defined as successful completion of a task. This was measured by assessing whether participants were able to insert a complete patient data set into the app GUI and successfully navigate to the results screen. Efficiency was defined as the duration to complete a task, which was measured by timing participants for each patient-specific data set that they inserted into the app. This time period was measured from when participants finished reading the introductory paragraphs until successful navigation to the results screen. Satisfaction was defined as a participant's perception of the effectiveness and efficiency of the app. Satisfaction was measured using the System Usability Scale (SUS) [16]. A semistructured interview format was used after the SUS assessment to gather additional feedback on the app. This allowed for flexible data collection with open-ended responses while ensuring that relevant topics were covered [17,18].

Participants

Several key informants [19] were selected across different clinical settings and seniority levels to represent the varied roles in managing patients with COVID-19. For example, initial assessment of the patient might be carried out by a junior physician in the emergency department, while a senior physician could be involved in critical decision-making, such as the establishment of treatment escalation plans.

Data saturation, defined as the point at which additional data would not add new information or require changes to be made to the developed findings, was estimated to occur at 30-35 interviews [20]. Participants were recruited in person at a single hospital site. We used maximum variation and snowball sampling to increase the likelihood that findings represent a wide range of perspectives with regard to the semistructured interviews [18,21].

Materials and Procedure

Informed written consent was obtained from all participants. Participants were made aware of their right to withdraw from the study at any point during data collection. Data were anonymized for all participants, except for designation and age because these data were considered important for contextualizing findings.

Demographic data and experience with electronics were recorded verbally, including baseline computer and smartphone app experience scores (on a scale of 1 representing novice experience, to 10 representing expert experience). Three

fictitious patient data sets in the form of clerking sheets (medical histories) were provided to each participant. Participants then entered the data into the app to generate a patient-specific mortality prediction on a computer device. This section of the assessment was timed.

While participants used the app, effectiveness and efficiency measures were collected. Once the tasks were completed, participants were provided with the SUS assessment on a web-based survey data collection platform, and the semistructured interview was then conducted. Audio recordings of the interviews were stored on a mobile device and transcribed using Otter.ai and then analyzed.

Ethical Approval and Consent to Participate

Data were collected, as part of service development work, by the responsible clinical team. Data were anonymized at the point of extraction by the care team. The analysis protocol was approved by the Antimicrobial Stewardship Group at Chelsea & Westminster NHS Foundation Trust and this was confirmed as a service development.

Data Analysis

Usability, as measured by effectiveness, efficiency, and satisfaction, was reported with descriptive statistics. Interview data were analyzed with a thematic framework method (by A Al-Hindawi, AP, and EC), which allowed for the development of themes from the interview narratives [22].

Availability of data and materials

The data sets analyzed during the current study and further details on gaining access to the intervention reported within this study are available from author AA on reasonable request, as long as the local ethics and research governance criteria are met. The app is currently available in the alpha version [23].

Results

Results Overview

In total, 31 health care workers were recruited from a single West London teaching hospital between June and August 2020; these included 5 (16.13%) foundation physicians (year 1-2 postgraduate), 5 (16.13%) senior house officers (years 3-4 postgraduate), 15 (48.39%) registrars or equivalent (year 5-10 postgraduate), 5 (16.13%) consultants (approximately >10 years postgraduate), and 1 (3.2%) primary care general practitioner (GP). None of them were excluded from the data analysis owing to equipment failure or withdrawal from the study. Of them, 12 (38.71%) participants were female. The mean participant age was 33.06 (SD 5.59) years. The mean baseline computer experience score was 7.71 (SD 2.07), and the mean baseline smartphone experience score was 8.58 (SD 1.70).

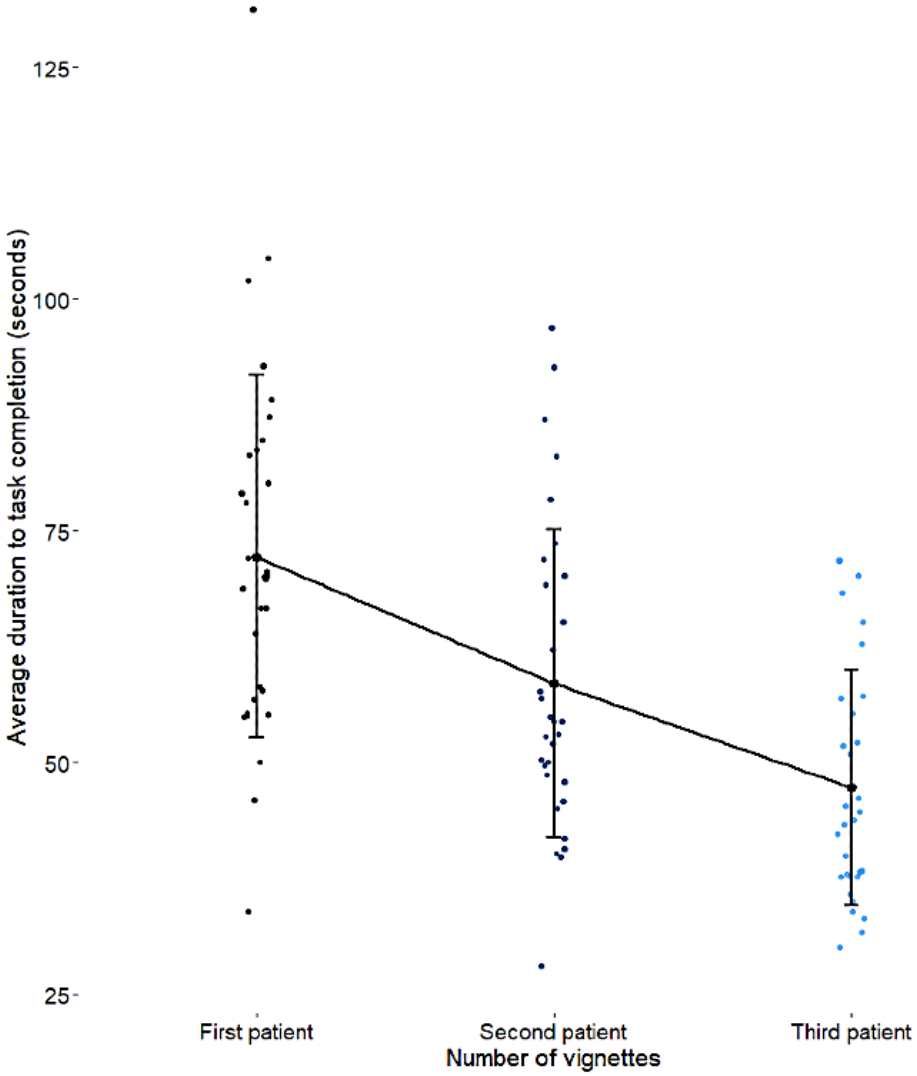
Effectiveness

All participants were able to complete the task. In total, 78 of 93 (83.9%) vignettes (3 vignettes provided to each participant) were completed correctly, which yielded the expected prediction results by the algorithm. The failure of participants to enter clinical parameters correctly into the GUI in 15 (16.1%) encounters was explored in the qualitative analysis explained below.

Efficiency

The mean time to complete each vignette was 59.35 (SD 10.35) seconds. Figure 2 shows the average duration of task completion for each patient vignette; participants completed the task more rapidly with each sequential attempt.

Figure 2. Efficiency of clinicians in using the artificial neural network–based COVID-19 prognostication app.



Satisfaction

The mean SUS assessment score was 91.94 (SD 8.54). This corresponds to a grade of "A" on the University Grading Scale that was used to help interpret SUS scores [16]. This score also corresponds to an adjective rating of "excellent" on the adjective rating scale [24].

Thematic Analysis of Semistructured Interviews

Uncertainty Over COVID-19 Prognostication Underpin Clinician Concerns

Regarding the management of patients with COVID-19, the physicians interviewed expressed a range of clinical concerns. Most concerns were about patient care, with the majority "worried about the deterioration of patients and their treatment escalation plan" [Participant #9, foundation physician]. Frontline physicians found themselves asking "is this the correct setting for the patient?" and "found [themselves] predicting where to manage patients" [Participant #4, consultant]. This highlighted a difference in focus depending on specialty. Physicians working in the emergency department or community were more focused on whether the patients "needed hospital admission" [Participant #18, registrar] or if they could "be managed at home" [Participant #31, GP]. In contrast, intensive care physicians were focused on "the mode of oxygen delivery needed" [Participant #25, foundation physician] and "which patients were likely to need intubation" [Participant #20, senior house officer].

In a group of physicians, there was uncertainty regarding communicating of prognoses with patients and their relatives: "Communicating that risk to the family and to the patient themselves is my biggest concern" [Participant #30, registrar].

Several physicians highlighted the fact that there was "a large amount of uncertainty in management and unpredictability in patient outcomes" [Participant #7, registrar] among patients with COVID-19. This was thought to arise from the fact that "current knowledge [of COVID-19] was poorly understood" [Participant #31, GP], and that this made "risk stratification in an unknown disease extremely difficult" [Participant #23, senior house officer].

Along with concerns about the general care of the patient and being in the appropriate care setting, there were some more specific questions that the physicians had regarding "renal, thromboembolic, and cardiac events secondary to COVID-19" [Participant #27, consultant].

Experience With the ANN-Based COVID-19 Prognostication App

Most physicians provided positive feedback, commenting that the app was "very well designed" [Participant #3, registrar], and "easy to pick up given I had never seen it before" [Participant #16, registrar] and that "the [GUI] is very intuitive" [Participant #1, registrar]. Many found it simple to navigate the GUI and input patient data, with the app being "not too wordy, easy to use" [Participant #9, senior house officer]. One participant liked that the application did not "need biochemical parameters," which rendered it more "useful in [the] ED setting" [Participant #22, foundation physician], as it negated the need to wait for the results of blood tests and allowed for more rapid quantification of the patient's risk. One clinician commented that the application allows you to "cut through noise" [Participant #24, senior house officer] when faced with a complicated case and helped to "pull different aspects together." The result was useful, as it was "nice to have numbers that are patient-specific" [Participant #24, senior house officer].

Interpretation of the Predictions of the ANN-Based COVID-19 Prognostication App

Mortality risk predictions for the different vignettes elicited a range of reactions from participants. In total, 29% of physicians felt surprised by the app's predictions. "I was surprised by how high the first mortality prediction was" [Participant #16, senior house officer]. Some clinicians felt that the app's mortality risk prediction was lower than they clinically expected. "I was surprised by some of the results, one lower than I thought" [Participant #2, registrar].

Other participants felt that the scores reflected their experience with patients with COVID-19: "Those numbers were relatively reasonable to what I have seen" [Participant #10, registrar]. One participant commented that "despite 2 of the scenarios appearing fairly similar, they had significantly different mortality predictions" [Participant #31, GP]. Overall, 6 participants felt that the mortality predictions were higher than expected, while 1 physician speculated that the app's predictions were lower than expected. Four physicians felt that the predictions were closely aligned to their clinical judgement.

Impact of the ANN-Based COVID-19 Prognostication App on Clinical Practice

In cases with a clear prognosis according to the clinician, the app positively reinforced clinical decision-making. Some physicians noted that "in clinical practice, it's quite obvious who's going to go off" [Participant #3, registrar]. Nonetheless, some underscored the potential benefit of concordance between their clinical decision-making and the app's predictions:

> *If I was planning to admit someone to ICU, this app might be useful in helping me make that decision. I'd base my management on my clinical judgement, but this might be a useful adjunct.* [Participant #6, consultant]

Other participants felt that the app provided them a sense of positive reinforcement:

> *I think it gives reassurance regarding your clinical judgement, especially if the app is roughly in agreement with your inclination.* [Participant #7, registrar]
>
> *Several critical care physicians focused on integrating [the score] into their own clinical judgement, and if the tool then validates [their] suspicion, it gives [them] a good positive predictive value.* [Participant #17, registrar]

With strong disparities, most physicians commented that they would revisit the case:

> *It would help you take a step back and look at the patient again irrespective of the score; I think that's the main use of predictive calculators to me.* [Participant #13, registrar]

Many participants explained that when they strongly disagreed with the algorithm, they would base their management on their personal clinical judgement:

> *If I looked at the tool and it said to me 'okay, she's got a 4% chance of mortality', but I look at the patient at the end of the bed and they appear incredibly frail, in that instance my judgement would overrule the application's prediction.* [Participant #17, registrar]

When a case was speculated to be borderline, the app helped as an "adjunct to the doctor" [Participant #25, registrar], to aid in forming a general impression of the case. Furthermore, some participants felt that the app could actively "help with clinical decision-making in more complicated or borderline patients" [Participant #23, senior house officer].

Several physicians commented that the app would act as an additional tool in their decision-making process, thereby complementing their clinical judgement. In total, 14 physicians explained that the app's results may help them stratify the risk to their patients more effectively, thus ensuring the right care setting. For example, one physician indicated that "It would allow me to risk stratify patients who are coming in; I might contact ICU earlier on" [Participant #16, registrar], and "it would be good as a screening tool to risk-stratify patients" [Participant #19, foundation physician], and "it would help me stratify future risk in an unknown disease" [Participant #20, registrar].

Many physicians felt that the app's predictions could be used to "better communicate patient outcomes" [Participant #24, foundation physician] to the patient and their family members, as well as "between medical colleagues" [Participant #26, registrar]. Topics that physicians felt would benefit from the app's results included "communicating disease severity" [Participant #27, consultant] and "the need for intensive care" [Participant #30, registrar] to the patient and their relatives.

Five physicians felt that the use of this app would not impact their clinical management, and one was unsure of the utility of the app:

> *It's tricky; I'm not sure whether it would alter my decision making in any appreciable way, but the numbers are interesting to see.* [Participant #11, consultant]

However, most agree that given COVID-19 is a "new disease, having any source of prediction would be useful for guiding management, and might help as an adjunct to decide on escalation" [Participant #8, senior house officer].

User-Driven Evolution of the ANN-Based COVID-19 Prognostication App

Many participants noted that it would be more intuitive to elicit symptoms before comorbidities, as this workflow more closely aligns with the clinical practice of many physicians: "I found myself scrolling down to fill in some details and then scrolling up to fill in the rest" [Participant #1, registrar]. However, other participants tended to prefer inserting comorbidity data prior to symptomatology: "The flow makes more sense for my clinical practice" [Participant #2, registrar]. Two physicians felt that there were many required variables for use of the app:

> *It might be easier to reduce the number of variables from 20 without reducing the model's predictive power too dramatically. This might make it easier to use.* [Participant #3, registrar]

However, one participant explained that this was not an important issue as the data were easy to accrue from the initial clerking:

> *There are a lot of yes/no boxes relative to other medical calculators, but that was alright because they were very easy to answer; data entry is elicitable from the clinical history.* [Participant #4, consultant]

One physician expressed being unable to find a disclaimer to explain that the app should only be used for patients with confirmed COVID-19. Similarly, 1 physician suggested the inclusion of a "disclaimer regarding the use of the app on first use" [Participant #17, registrar] and noted that the app should not be used in "isolation." Another physician suggested the "addition of ethnicity in future" [Participant #6, consultant] iterations of the model as an important prognostic factor. Another physician suggested "linking trust-based guidelines for COVID-19 management" on the results page of the app, or "integrating the results into the patient's electronic health records" [Participant #13, registrar].

Two physicians noted that it should be made clear that duration of symptoms is always recorded from the onset of first symptom by the app: "I think you should specify that the duration of symptoms is from the first symptom, as sometimes symptoms develop at different time points" [Participant #16, registrar]. Finally, being able to predict "intensive care requirements" [Participant #6, consultant] and "prolonged hospital stay" [Participant #4, consultant] were considered useful improvements to the algorithm.

User-Derived Concerns Regarding the ANN-Based COVID-19 Prognostication App

The principal concern expressed by users was the use of the predictions as an exclusive decision-making tool by, for example, making "management setting and treatment escalation decisions based solely on the results" [Participant #5, senior house officer] of the app.

> *I think a discussion may be required with ICU before deciding on ward-based care, and I'd worry if a high mortality prediction led to an automatic decision to not admit to ICU.* [Participant #2, registrar]

There were concerns that "generalizability would be difficult" [Participant #1, registrar] since the data are accrued from admissions to a single center: "Different patients in the UK will have different cohorts and so it should be generalized with caution" [Participant #8, senior house officer].

The model underlying this app was trained with patients during the first wave of COVID-19 in the United Kingdom. There were no established management guidelines or prognostic scoring system relating to this disease. Several physicians noted the importance of retraining the model with more recent data from patients with COVID-19 to reflect recent developments in the management of this condition: "The guidelines are changing, and so the data itself may change" [Participant #14, consultant]; therefore, "the application may not be calibrated to new waves, given newer treatments" [Participant #29, registrar]. The same physician indicated that "there is little concern if this is used as part of the big picture but shouldn't be used in a binary sense" [Participant #29, registrar]. This sentiment was echoed by several other physicians who felt that "you have to be responsible and realize no predictive calculator is a substitute for clinical judgement- I don't think anyone should be under the impression that a calculator can replace their judgement entirely" [Participant #7, registrar].

Discussion

Principal Findings

We tested the clinical utility of a responsive web-based app or GUI, which interfaces to an ANN to predict the outcomes of patients with COVID-19 at the bedside. All clinician-users were able to use the GUI with a mean time of 59.35 (SD 10.35) seconds to derive a mortality prediction. We found that clinician-users assigned a mean SUS score of 91.94 (SD 8.54), which corresponds to an adjective rating of "excellent." Clinician-users found the app intuitive and easy to use, and the majority described its predictions as a useful adjunct to their clinical practice. The main concerns were related to the use of the app in isolation rather than in conjunction with other clinical parameters. However, most clinicians felt that the app could positively reinforce or validate their clinical decision-making. Effectiveness and efficiency measures indicated that the app could be used easily with little technical support or prior explanation with respect to system function. The app is therefore highly productive, while maintaining low costs and learnability times. No participant took longer than 2.2 minutes to successfully input all required patient data and retrieve a prediction.

Thematic framework analysis provided further insight into the implications of the use of this app. The identification of deteriorating patients with COVID-19 was a key concern for most physicians. From a clinical perspective, accurate risk stratification underpins hospital admission decisions, as well as appropriate ceilings of patient management. Furthermore, an understanding of risk allows physicians to better communicate

prognoses to the patient and their relatives. Hence, a large majority of participants in this study felt that a scoring system can be a useful as an adjunct to their clinical workflow and could aid in communicating risk to patients and their families. However, most physicians agreed that the use of a predictive scoring system alone cannot surmount the decision-making by a clinician.

The spectrum of opinions regarding mortality risk predictions when faced with the same clinical scenario highlighted variations among clinicians. This emphasizes the potential role of an easy-to-use, widely accessible predictive system in minimizing biases such as experiential bias and the availability heuristic in prognostication.

Strengths and Limitations

A strength of this study is that both usability assessments and a qualitative framework were used to evaluate the app, thereby providing a deeper insight into all aspects of its use and implications. In addition, multiple researchers analyzed the thematic framework data, ensuring consensus with regard to the results and their interpretation.

However, there are limitations to consider in this analysis. The study participants had high self-reported levels of expertise in using computers and smartphones. If this app were to be used in settings where users had limited experience in using clinical decision-making tools, it may impact usability, and subsequently affect results and result interpretation. Furthermore, the underlying algorithm is trained with patients from a single West London hospital site during the first wave of COVID-19 in the United Kingdom. The generalizability of its predictions is therefore reduced among other populations, and further studies need to evaluate the app in other health care settings.

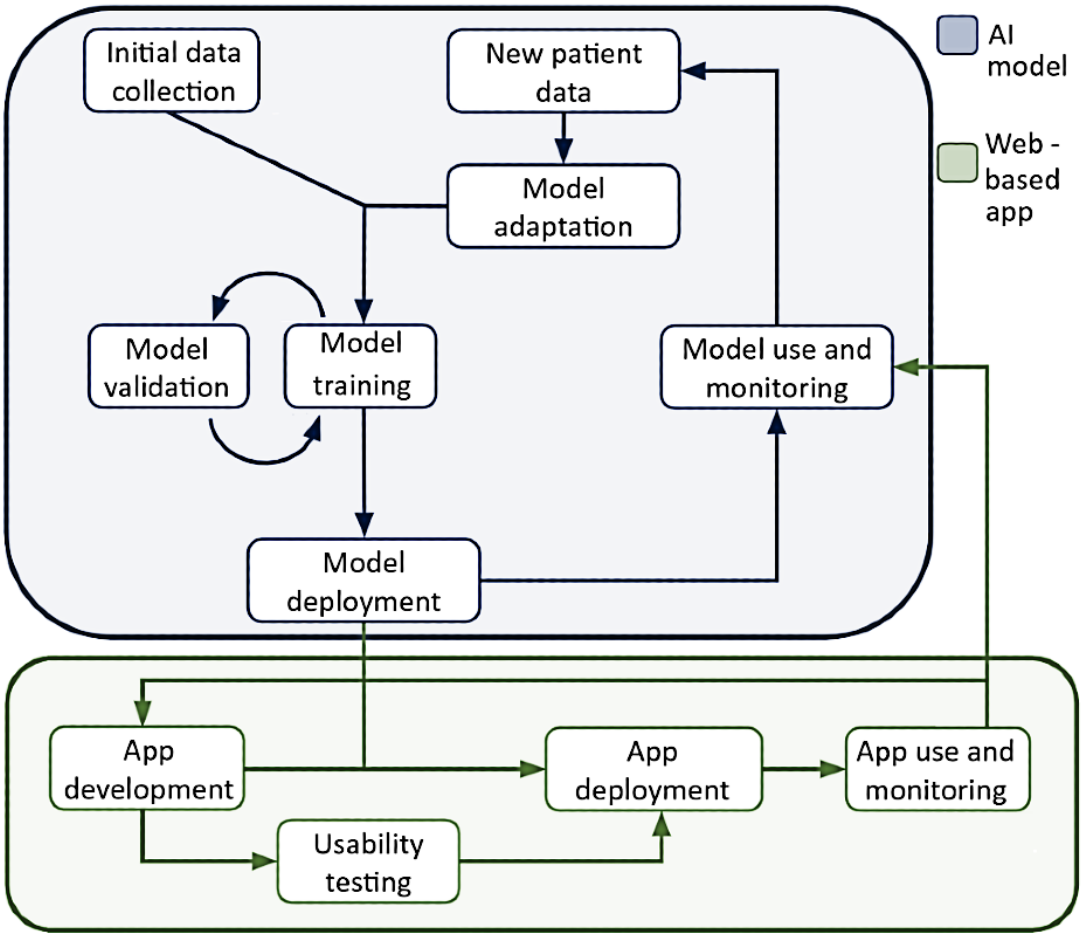
Comparison With Prior Studies and Future Prospects

Given that treatment for COVID-19 has progressed—for example, a recent study reported that dexamethasone reduces mortality in hospitalized patients with COVID-19 [25]—it is important to retrain or update the algorithm with new data to maximize the prognostic accuracy of the app. The adaptive nature of ANNs with their ease of retrainability, and the continued deposition of clinical big data for patients with COVID-19, implies that these latter limitations can be mitigated with future iterations.

The principal challenges in deploying AI technologies in a pandemic include the rapidly shifting clinical needs that the models need to address, and in translating these models to local environments [5]. While numerous recent studies have been using machine learning processes for aspects of COVID-19 clinical care in various settings [26-30], few use co-design, as we have in this study, to optimize the utility of the app among clinicians. Furthermore, beyond user interface and utility challenges lie ethical and legal issues that are inherent when smartphone apps are used as health care decision support systems [31]. The ethical aspects of integrating computerized decision support systems in to the management of infectious diseases remain unclear, but the importance in co-design with clinician-users early on in the preimplementation phase (as in this study) takes precedence to ensure that clinicians use them as part, rather than the entirety, of their overarching clinical assessment [32,33].

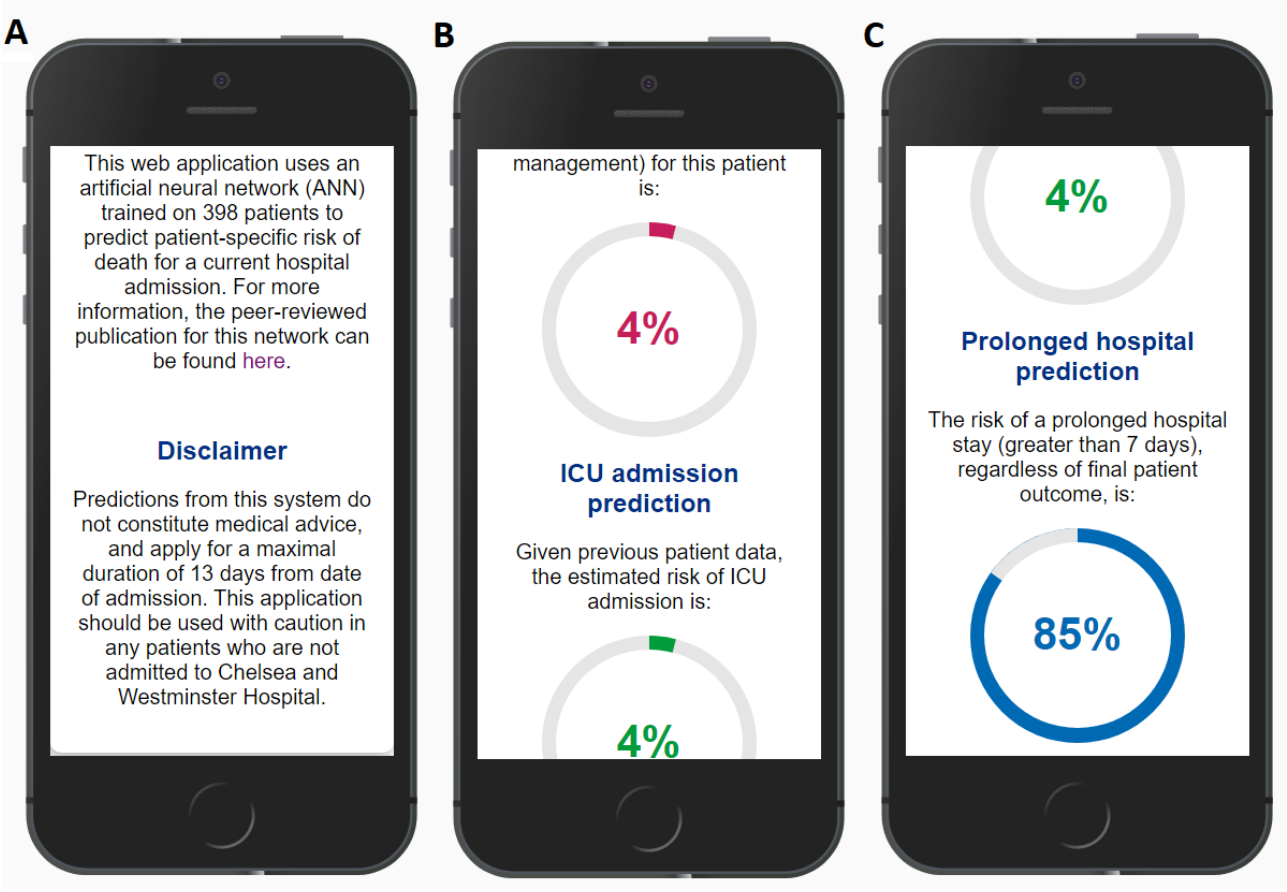
Based on our development of the ANN [4] and the clinical utility and feasibility assessment undertaken in this analysis, we propose an adaptive translational pathway for predictive systems for COVID-19 (Figure 3). This workflow recognizes the need for feedback mechanisms in the development and deployment of both the GUI and its underlying AI algorithm. As management strategies shift, new data must be incorporated through web-based learning or retraining of the algorithm to maintain accurate predictions. The new models then require further validation on test data sets to ensure reliability. In tandem, the application must be actively monitored for usability and security issues and updated as appropriate. Utilizing interconnected feedback mechanisms in this way can ensure that both the algorithm and the interface to it remain robust to changing trends in patient cohorts and the management of COVID-19.

Figure 3. Proposed translational network for the artificial neural network and web-based app, including model training, validation, and adaptation, as well as app development, testing, and deployment. AI: artificial intelligence.



Following this framework, because of the usability assessment and thematic framework analysis, our current app was modified to include several of the suggested improvements. These included, but were not limited to, the addition of a disclaimer on the index page and retraining the algorithm to estimate mortality, probability of admission to an intensive care unit, and probability of a prolonged hospital stay (defined as a stay of at least 1 week). These changes are shown in Figure 4. Future improvements include model retraining from patient samples across multiple hospital sites, and the potential integration of the app to patient electronic health records to facilitate its use in the context of clinicians' workflow, although the barriers to integration into electronic medical records are numerous [34].

Figure 4. Screenshots of the matured artificial neural network–based COVID-19 prognostication app. (A) The introductory screen and an added disclaimer for use. (B) and (C) A portion of the results screen. Predictions regarding mortality, intensive care unit, and prolonged hospital stay are presented as human-readable percentages and are color-coded to reflect retraining of the underlying algorithm.



Conclusions

Developing, validating, and deploying AI technologies in health care is associated with a variety of challenges. In this single hospital study, we tested a responsive web-based app, which leverages an ANN to produce multiple outcome predictions for patients with COVID-19 without the need for laboratory parameters. It demonstrates potential utility among patients with an initial presentation of COVID-19 and for those without diagnostic capability in the community. The application is intuitive and requires minimal training for use. Clinicians interviewed in this study found that the system represents a useful adjunct to their daily clinical practice, and we propose a translational workflow for future predictive systems that leverage similar technologies. We demonstrate that both model and interface adaptation can be used to meet the developing needs of clinicians in the context of a pandemic.

Acknowledgments

EC is supported by Economic and Social Science Research Council and the National Institute for Health Research (NIHR) Health Protection Research Unit (HPRU) in Healthcare Associated Infections and Antimicrobial Resistance, UK Department of Health [HPRU-2012-10047], in partnership with Public Health England. LSPM acknowledges support from the NIHR Imperial Biomedical Research Centre and the NIHR HPRU in Healthcare Associated Infection and Antimicrobial Resistance at Imperial College London in partnership with Public Health England. The views expressed in this publication are those of the authors and not necessarily those of the National health Service, the NIHR, or the UK Department of Health. This study did not receive any grant from funding agencies in the public or commercial sectors.

Authors' Contributions

A Abdulaal, AP, and LSPM conceptualized the study. A Abdulaal, AH, AP, and EC curated the data. A Abdulaal, AP, and LSPM carried out formal analysis. A Abdulaal, AP, and LSPM designed the study methodology. A Abdulaal, AP, and LSPM were responsible for study validation. A Abdulaal and AP were responsible for data visualization. A Abdulaal and AP drafted the manuscript. A Abdulaal, AP, AH, EC, NM, and LSPM critically reviewed and revised the manuscript. All authors have read and approved this manuscript and agree as to its contents.

Conflicts of Interest

All authors have completed the ICMJE (International Committee of Medical Journal Editors) form to disclose potential conflicts of interest and declare the following: EC has received speaker fees from bioMerieux (2019). NM has received speaker fees from Beyer (2016) and Pfizer (2019) and received educational support from Eumedica (2016) and Baxter (2017). LSPM has consulted for and received honoraria from DNAelectronics (2015-2018), Dairy Crest (2017-2018), Profile Pharma (2018-2019), Umovis Lab (2020), bioMerieux (2013-2021), Pfizer (2018-2021), Eumedica (2016-2021), and Shionogi (2021) and received research grants from Leo Pharma (2016), NIHR (2013-2020), and CW+ Charity (2018-2021). A Abdulaal and AP declare no conflicts of interest.

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Abbreviations

AI: artificial intelligence
ANN: artificial neural network
GP: general practitioner
GUI: graphical user interface
HPRU: Health Protection Research Unit
ICU: intensive care unit
NIHR: National Institute for Health Research
SUS: system usability score

Edited by G Eysenbach; submitted 16.02.21; peer-reviewed by M Sayed, K Braune; comments to author 26.02.21; revised version received 19.03.21; accepted 31.05.21; published 28.07.21.

Please cite as:
Abdulaal A, Patel A, Al-Hindawi A, Charani E, Alqahtani SA, Davies GW, Mughal N, Moore LSP
Clinical Utility and Functionality of an Artificial Intelligence–Based App to Predict Mortality in COVID-19: Mixed Methods Analysis
JMIR Form Res 2021;5(7):e27992
URL: https://formative.jmir.org/2021/7/e27992
doi:10.2196/27992
PMID:34115603

Original Paper

Determining Acceptance of e-Mental Health Interventions in Digital Psychodiabetology Using a Quantitative Web-Based Survey: Cross-sectional Study

Mirjam Damerau[1], MSc; Martin Teufel[1], Prof Dr; Venja Musche[1], MSc; Hannah Dinse[1], MD; Adam Schweda[1], MSc; Jil Beckord[1], BSc; Jasmin Steinbach[1], MSc; Kira Schmidt[1], MSc; Eva-Maria Skoda[1], MD; Alexander Bäuerle[1], PhD

Clinic for Psychosomatic Medicine and Psychotherapy, LVR-University Hospital Essen, University of Duisburg Essen, Essen, Germany

Corresponding Author:
Mirjam Damerau, MSc
Clinic for Psychosomatic Medicine and Psychotherapy
LVR-University Hospital Essen, University of Duisburg Essen
Virchowstr. 174
Essen, 45147
Germany
Phone: 49 201 438755 228
Email: mirjam.damerau@uni-due.de

Abstract

Background: Diabetes is a very common chronic disease that exerts massive physiological and psychological burdens on patients. The digitalization of mental health care has generated effective e-mental health approaches, which offer an indubitable practical value for patient treatment. However, before implementing and optimizing e-mental health tools, their acceptance and underlying barriers and resources should be first determined for developing and establishing effective patient-oriented interventions.

Objective: This study aims to assess the acceptance of e-mental health interventions among patients with diabetes and explore its underlying barriers and resources.

Methods: A cross-sectional study was conducted in Germany from April 9, 2020, to June 15, 2020, through a web-based survey for which patients were recruited via web-based diabetes channels. The eligibility requirements were adult age (18 years or older), a good command of the German language, internet access, and a diagnosis of diabetes. Acceptance was measured using a modified questionnaire, which was based on the well-established Unified Theory of Acceptance and Use of Technology (UTAUT) and assessed health-related internet use, acceptance of e-mental health interventions, and its barriers and resources. Mental health was measured using validated and established instruments, namely the Generalized Anxiety Disorder Scale-7, Patient Health Questionnaire-2, and Distress Thermometer. In addition, sociodemographic and medical data regarding diabetes were collected.

Results: Of the 340 participants who started the survey, 261 (76.8%) completed it and the final sample comprised 258 participants with complete data sets. The acceptance of e-mental health interventions in patients with diabetes was overall moderate (mean 3.02, SD 1.14). Gender and having a mental disorder had a significant influence on acceptance (P<.001). In an extended UTAUT regression model (UTAUT predictors plus sociodemographics and mental health variables), distress (β=.11; P=.03) as well as the UTAUT predictors *performance expectancy* (β=.50; P<.001), *effort expectancy* (β=.15; P=.001), and *social influence* (β=.28; P<.001) significantly predicted acceptance. The comparison between an extended UTAUT regression model (13 predictors) and the UTAUT-only regression model (*performance expectancy*, *effort expectancy*, *social influence*) revealed no significant difference in explained variance ($F_{10,244}$=1.567; P=.12).

Conclusions: This study supports the viability of the UTAUT model and its predictors in assessing the acceptance of e-mental health interventions among patients with diabetes. Three UTAUT predictors reached a notable amount of explained variance of 75% in the acceptance, indicating that it is a very useful and efficient method for measuring e-mental health intervention acceptance in patients with diabetes. Owing to the close link between acceptance and use, acceptance-facilitating interventions focusing on these three UTAUT predictors should be fostered to bring forward the highly needed establishment of effective e-mental health interventions in psychodiabetology.

(JMIR Form Res 2021;5(7):e27436) doi:10.2196/27436

KEYWORDS

e-mental health; acceptance; UTAUT; mental health; diabetes; e-mental health intervention; psychodiabetology

Introduction

Background

Diabetes is a common chronic disease that exerts a heavy physiological and psychological burden on patients. In 2017, approximately 451 million adult patients were affected worldwide, and the number is steadily increasing [1]. As diabetes is considered to be "one of the most psychologically demanding of chronic medical illnesses" [2], the integration of psychological care in the management of diabetes is crucial [3,4].

Living with diabetes means facing day-to-day challenges and complications resulting in considerable emotional distress [5], which can lead to a higher risk of psychological disorders. Indeed, patients with diabetes show disproportionately higher rates of psychological disorders than those without diabetes [5], including depression and anxiety [6,7]. Considering psychological comorbidity, diabetes mellitus is often accompanied by depression (18.8%-24%) [8-10]. They occur twice as frequently together as predicted by chance alone and worsen each other because of underlying biological and behavioral mechanisms such as diabetes-related symptoms and sleep disorders [11,12]. A meta-analysis including more than 50,000 participants confirmed the major role of depression as a comorbidity of diabetes, and found that participants with type 2 diabetes had significantly higher depression rates than those without diabetes (17.6% vs 9.8%; odds ratio 1.6, 95% CI 1.2-2.0) [13]. Regarding the prevalence of anxiety, a systematic review found that 14% of patients with diabetes who participated in clinical studies with generalized anxiety disorder and 27% with subsyndromal anxiety disorder [14]. Considering that 40% of their participants expressed the elevated symptoms of anxiety (N=1283 in 7 studies), anxiety turned out to be a major mental health threat to people with diabetes.

The psychological vulnerability of people with diabetes manifests itself in the heightened risks of psychological disorders; for example, the risk of developing depression is 24% higher in patients with type 2 diabetes than in individuals without diabetes [15]. However, diabetes and mental health appear to exert a bidirectional effect on each other because poor mental health is associated with an increased risk of developing type 2 diabetes [16]. Psychological support and self-empowerment are crucial, as diabetes impairs the psychological well-being and quality of life [17]. Although diabetes-related self-management education programs can reduce diabetes-related as well as emotional distress [5,18], help foster self-efficacy [18] and have proven their effectiveness [19] and cost-effectiveness [20] as demonstrated by web-based structured education programs, they are still not implemented to a sufficient extent in routine diabetes care [21]. Therefore, improving diabetes-related knowledge and self-care practices should be a major goal in diabetes management to reduce the risks of developing and chronifying psychological disorders [5,22].

The digitalization of mental health care has generated effective e-mental health approaches, which have an indubitable practical value for patient treatment [23-26]. The effects of e-mental health interventions for some mental disorders are comparable with those of a traditional face-to-face therapy [26]. Nonetheless, web-based interventions offer several advantages that cannot be provided by offline interventions, for example, offering an anonymous, low-threshold, cost-effective, time- and location-flexible alternative [27]. However, limited accessibility, negative treatment expectancies, and concerns about anonymity create serious challenges in the implementation of e-mental health approaches. To date, existing e-mental health interventions have mainly focused on psychosomatic inpatients and provide information and interactive tasks based on cognitive behavioral, psychodynamic, or acceptance and commitment therapy [28]. Unfortunately, clinical e-mental health interventions are still scarce and are not well known among patients in Germany [29]. Although patients with diabetes can make use of several apps and at least some (web-based) diabetes education programs that help in disease management [30,31], only a few web-based e-mental health interventions exist. A recent systematic review from 2021 found 9 studies offering digital interventions for psychological comorbidities in patients with diabetes [32]. Two of these studies were conducted in Germany [33,34] and both offered the guided self-help web-based intervention GET.ON Mood Enhancer Diabetes for depression in people with diabetes. Furthermore, 7 out of these 9 studies found the offered e-mental health intervention to be effective in terms of improvements in depressive symptoms [33-39] and 4 found the intervention effective with respect to diabetes (specific emotional) distress [34,37-39]. Given the current situation concerning the COVID-19 pandemic, the need for innovative and easily accessible approaches in psychological care is evident and has also increased. There is a scientific consensus that depression, anxiety, sleeping problems, and stress have increased over the course of the ongoing pandemic [40-45]. With the knowledge of the vulnerability of people with diabetes and in light of the pandemic and its mental health implications, we conducted a study to investigate the acceptance of e-mental health interventions in patients with diabetes.

As previous research suggests that patients with diabetes having depression symptoms might have a low motivation to participate in a screening program or psychological care [46], the acceptance of (future) interventions is a major variable that research should be considered. Thus, before implementing and optimizing e-mental health tools, their acceptance and underlying barriers and resources should first be examined and understood. In terms of usefulness, even the best intervention can only be beneficial to those patients using it. Therefore, the determinants of acceptance and uptake of e(-mental) health interventions need to be further analyzed. The research on eHealth acceptance has harnessed the Unified Theory of Acceptance and Use of Technology (UTAUT) for assessing the predictors of behavioral intention and acceptance [28,47-51]. The UTAUT model contributed to the analysis of factors that

influence the acceptance of e-mental health interventions in patients with diabetes [52]. This model and its e-mental health specific extensions [28,52] enabled researchers to tailor interventions properly to specific patient groups, because acceptance-influencing determinants were known from analysis with the UTAUT. Unfortunately, barely any validation of the UTAUT has been investigated in e-mental health programs for patients with diabetes. However, there is some evidence in disease management programs. For example, a survey of 116 patients with diabetes used the UTAUT model to identify the factors that influence the acceptance of telemedicine services. Researchers have found that performance expectancy (PE), effort expectancy (EE), and social influence (SI) are significant factors that contribute to the acceptance of telemedicine services for diabetes management. In addition, gender and age were identified as moderators between PE and acceptance as predicted by the UTAUT model [53].

The UTAUT postulates four core predictors: *PE*, *EE*, *SI*, and *facilitating conditions* (*FC*) [54]. Acceptance itself is operationalized as *behavioral intention*, which is predicted by the first three core predictors, whereas actual use is predicted by *behavioral intention* and *FC*. *PE* describes the degree to which an individual believes that using a system will be helpful. *EE* is defined as the degree of ease associated with the use of a system. *SI* describes the degree to which an individual perceives that important other, such as family or friends, would approve of the use of the system. *FC* are defined as the degree to which an individual believes that an organizational and technical infrastructure exists to support the use of a system. By applying UTAUT as a method of measuring acceptance, the notable values of explained variance (70%) can be achieved [54]. To prove external validity and generalizability, UTAUT needs to be explored in different target groups. Given the massive physiological and psychological burdens caused by diabetes, this study focused on investigating the acceptance of e-mental health interventions in a sample of patients with diabetes.

Objectives

This study aims to determine the acceptance of e-mental health interventions among patients with diabetes and explore the underlying factors influencing patients' intentions to use such interventions. The acceptance of e-mental health interventions is associated with sociodemographic characteristics such as gender, age, and education [28,55] and mental health, such as anxiety and current or past mental disorders [48,55]. Therefore, we extended the UTAUT model and added sociodemographic, medical, and validated mental health variables as the direct predictors of acceptance. In addition, this study aims to examine the viability of the UTAUT model with its three predictors of acceptance (*PE*, *EE*, and *SI*) in assessing patients with diabetes' acceptance of e-mental health interventions and to investigate whether this extended UTAUT model proves to be superior and more effective. Furthermore, an additional goal is to examine whether age and gender modulate the relationship of *PE*, *EE*, *SI* and acceptance, respectively, as postulated by the UTAUT [54]. Thus, the following research questions are addressed:

1. To what extent do patients with diabetes accept e-mental health interventions and does acceptance differ significantly regarding sociodemographic or medical characteristics of the participants?
2. Is the proposed extended UTAUT model suitable to predict the acceptance of e-mental interventions in patients with diabetes and which factors are significant predictors?
3. Is the proposed extended UTAUT model superior to the UTAUT model and do age and gender modulate the relationship between each UTAUT predictor and acceptance?

Answers to the research questions above might contribute to the process of implementing and improving e-mental health interventions. Especially during the ongoing COVID-19 pandemic, these results may be beneficial to individuals with mental health problems or those at a higher risk of developing psychological disorders.

Methods

Study Design and Participants

A cross-sectional study was conducted to assess the acceptance of e-mental health interventions and its underlying predictors in patients with diabetes. The Checklist for Reporting Results of Internet E-Surveys was used to report the methods and results of our web-based open survey [56]. From April 9 to June 15, 2020, participants were recruited via web-based diabetes channels and social media. The eligibility requirement was adult age (18 years or older), a good command of the German language, internet access, and a diagnosis of diabetes. All participants gave electronic informed consent before the survey began and were told about the length of time of the survey, which took approximately 15 minutes to complete. Participation was anonymous and voluntary, and the participants could withdraw from it at any time without harm. No financial compensation was offered, and no personal information was collected or stored. Of the 340 participants, 261 (76.8%) completed the survey, thereby forming the total sample of 261 participants. Three participants who stated not to have diabetes were excluded; hence, the final sample comprised 258 participants (192/258, 74.4% female and 66/258, 26.6% male) with complete cases. Multiple entries from the same individual were prevented by using cookies. The study was conducted in accordance with the Declaration of Helsinki and approved by the ethics committee of the medical faculty of the University Duisburg-Essen (19-89-47-BO).

Measures

Overview

The web-based survey contained items on sociodemographic, medical, and mental health data. In addition, we used the validated and well-established UTAUT questionnaire, which assesses health-related internet use, acceptance of eHealth interventions, and barriers and resources of eHealth use [54], and modified it to our research questions based on previous adaptations (Textbox 1). To assess mental health, validated measures were used, such as the Patient Health Questionnaire-2 (PHQ-2) [57], the Generalized Anxiety Disorder Scale-7 (GAD-7) [58], and the Distress Thermometer (DT) [59].

Textbox 1. Adapted items of the Unified Theory of Acceptance and Use of Technology model and references of original studies. Italicized verbalizations have been adapted.

Behavioral Intention (=acceptance)

- "I would like to try a *psychological web-based intervention*." [52,60,61]
- "I would use a *psychological web-based intervention* if offered to me." [52,60,61]
- "I would recommend a *psychological web-based intervention* to *my* friends." [48]

Social Influence

- "People close to me would approve *the use of* a *psychological web-based intervention*." [52,54,60,61]
- "My general practitioner would approve the *application* of a *psychological web-based intervention*." [52,60,61]
- "My friends would approve a *psychological web-based intervention*." [28]

Performance Expectancy

- "A *psychological web-based intervention* could improve my *general* well-being." [52,60,61]
- "A *psychological web-based intervention* could help me with *distress*." [52,60,61]
- "A *psychological web-based intervention* could help me improve my personal *(psychological)* health." [52,60,61]

Effort Expectancy

- "The use of a psychological web-based intervention would not be an additional burden to me." (Self-constructed)
- "A *psychological web-based intervention* would be easy to operate and comprehend." [49,52,54,60,61]
- "I could arrange using a *psychological web-based intervention* in my everyday life." [28]

Sociodemographic and Medical Data

Sociodemographic and medical data were assessed using items on gender, age, marital status, having children (aged<18 years), educational level, occupational status, and community size. Age was measured in six categories (18-24, 25-34, 35-44, 45-54, 55-64, and 65 or above). Regarding their medical condition, participants were asked whether they had a mental disorder, diabetes type, how well their diabetes was controlled, how their diabetes was treated, and since when they knew of their diabetes diagnosis. In terms of diabetes treatment, participants could state whether their diabetes was treated with oral medication, insulin, other treatment methods, or not treated, and multiple answers were possible.

Acceptance and UTAUT Predictors

Acceptance was operationalized as behavioral intention in accordance with the UTAUT and was measured using three items (Textbox 1). In terms of its specific content, acceptance was defined as the acceptance of a general psychological web-based intervention, which had neither been specified and tailored to patients with diabetes nor offered during this study or later. The underlying UTAUT predictors *PE*, *EE*, and *SI* were measured using three items each (Textbox 1). Answers were indicated on a 5-point Likert scale ranging from 1 (totally disagree) to 5 (totally agree). As *FC* are based on the UTAUT just as a predictor of use (*use behavior*) and not acceptance itself [54], *FC* have not been included in the statistical analyses. Cronbach α values in this study were .87 for acceptance, .96 for *PE*, .81 for *EE* and .87 for *SI*, proving a high internal consistency.

GAD-7 Anxiety

The GAD-7 comprises seven items measuring the frequency of anxiety symptoms over the past 2 weeks on a 4-point Likert scale (0=never to 3=nearly every day). According to previous validation samples, a sum score of ≥5, ≥10, and ≥15 points to mild, moderate, and severe generalized anxiety symptoms, respectively. This assessment instrument has demonstrated high reliability and validity in health care and research [58]. Cronbach α in this study was .91, indicating a high internal consistency.

PHQ-2 Depressive Symptoms

The PHQ-2 comprises two items that screen the frequency of depressive symptoms over the past 2 weeks on a 4-point Likert scale (0=never to 3=nearly every day). A sum score of ≥3 serves as a cutoff for major depressive symptoms [57]. In our study, the internal consistency was sufficient, with Cronbach α=.84.

DT Distress

The DT [59] involves one visual analog scale from 0 (no distress) to 10 (extreme distress) experienced in the past week. A score of ≥4 indicated increased psychological distress [62].

The items were not randomized or alternated among individuals. The participants were able to change and review their responses while answering. Only completely answered questionnaires could be sent off and were analyzed.

Statistical Analyses

Overview

Data analysis was performed using SPSS 26 (IBM), the macro process by Andrew F Hayes (version 3.3) [63] and the software R [64] (version 3.6.3; R Foundation for Statistical Computing).

The level of significance was set at α=.05 (two-sided tests) except for two-tailed *t* tests and analysis of variances (ANOVAs; see *Research Question 1*). First, the internal consistencies and descriptive statistics were calculated. Second, general acceptance was computed and its distribution was assessed (research question 1). In accordance with previous research [28], acceptance (1-5) was categorized by mean in low (1-2.34), moderate (2.35-3.67), and high (3.68-5) acceptance, and the respective frequencies were calculated.

Research Question 1: Acceptance and Its Differences by Sociodemographic and Medical Data

Next, the means of acceptance were compared between groups regarding sociodemographic and medical data using *t* tests and ANOVAs to include variables with multiple categories (research question 1). Bonferroni correction was applied to keep the α error low for multiple pairwise comparisons. To prevent the inflation of the α error caused by multiple *t* tests and ANOVAs, we adjusted the respective α level for each *t* test and each ANOVA. For each *t* test, the level of significance was .017 and .007 for each ANOVA.

The normal distribution of acceptance was examined with the Kolmogorov-Smirnov test, skewness, and kurtosis and graphically via a histogram including a normal distribution curve. All these measures detected violations against a normal distribution. Parametric tests were still performed for two reasons. First, according to the central limit theorem, the sampling distribution of the mean of a variable can be safely assumed to be normal if the variable and its mean are normally distributed in the population and the sample size is sufficiently large. We consider our sample size of 258 to be sufficient, because some literature suggests that such an effect already emerges with a sample size of n=30 [65]. In addition, other researchers found acceptance distributions that did not seem to differ from the normal distribution [48], thereby indicating that variable acceptance might be normally distributed in the population. Second, *t* tests and ANOVAs are considered to be robust against violations assuming normal distribution [66].

Research Question 2: Predictors of Acceptance

Using multiple hierarchical regression analyses, the predictive models of acceptance were tested and compared (research question 2). The following predictors were included blockwise: (1) sociodemographic and medical variables, (2) mental health variables, and (3) UTAUT predictors. The categorical variable age was dummy coded before being included in the regression analyses; the category with the highest n (age 45-54, n=70) was used as a reference. In addition, the full model was tested against a restricted model (UTAUT predictors only) (research question 3). No multicollinearity could be detected, because all values of the variance inflation factor were <5. To examine the normality of residuals, the Kolmogorov-Smirnov test was computed (P=.20) and q-q plots were visually inspected; both showed no signs of violations against normality. Homoscedasticity was proven based on a scatter plot of the standardized residuals and adjusted predicted values.

Research Question 3: UTAUT Versus Full Regression Model and Moderator Analyses

In the final step, bootstrapped moderation analyses (model 1) were performed with acceptance as the dependent variable; UTAUT predictors *PE*, *EE*, and *SI* as the respective independent variable; and age or gender as a potential moderator (research question 3). The number of bootstrap samples was set to 10,000. Independent variables were centered, because the value 0 was not defined on a 5-point Likert scale ranging from 1 (totally disagree) to 5 (totally agree).

Results

Sociodemographic and Medical Data

Of the 258 participants, 192 (74.4%) women and 66 (25.6%) men participated in the study. Most participants (n=234, 90.7%) were middle age (25-64 years), whereas the most frequent age category was 45-54 years (70/258, 27.1%). Marital status was classified as either mostly *married* or *in a relationship* (174/258, 67.4%). The majority (200/258, 77.5%) had no children aged <18 years. Our sample was highly educated, because 62.5% (162/258) had higher education entrance qualifications or university education; most were employed (160/258, 62%). The community size was nearly balanced, meaning that none of the four community size categories occurred predominantly. Table S1 in Multimedia Appendix 1 provides a comprehensive summary of sociodemographic information.

A mental disorder was present in 27.5% (71/258) participants. Regarding the type of diabetes, 67.4% (174/258) participants had type 1 diabetes, 28.7% (74/258) patients had type 2 diabetes, and 3.9% (10/258) had other types of diabetes. In total, 49.6% (128/258) participants rated their diabetes control as being *good* and 5.4% (14/258) as *not good*. In terms of medical treatment for diabetes, 76% (196/258) used oral medication, 84.1% (217/258) injected insulin, 3.9% (10/258) had other treatment, and 3.5% (9/258) had no treatment. On average, patients had known of their diabetes disease for approximately 17 years (mean 16.98, SD 13.64).

The GAD-7 (mean 6.12, SD 5.20) measures revealed that 29.1% (75/258) of participants had mild, 16.6% (43/258) had moderate, and 7.8% (20/258) had severe anxiety symptoms (Tables S2-S4 in Multimedia Appendix 1). The analyses of measures of PHQ-2 (mean 1.52, SD 1.75) and DT (mean 4.72, SD 2.90) resulted in 21.7% (56/258) and 65.9% (170/258) participants, respectively, reaching the cutoff values of 3 and 4, respectively (Tables S2-S4 in Multimedia Appendix 1). Further information about GAD-7, PHQ-2, and DT measures stratified by gender, age, and diabetes type are displayed in the Multimedia Appendix 1 (Tables S2-S7).

Research Question 1: Acceptance and Its Differences by Sociodemographic and Medical Data

The general acceptance of e-mental health interventions was moderate, with a mean of 3.02 (SD 1.14). Its distribution can be roughly estimated as one-third for each category; 34.1% (88/258) participants showed low, 37.2% (96/258) showed moderate, and 28.7% (74/258) showed high acceptance.

Acceptance differed significantly between female and male participants (t_{256}=4.21; P<.001), with a higher acceptance in women than in men. Having a psychological illness was also significantly associated with higher acceptance ratings (t_{256}=−4.47; P<.001). No differences in acceptance regarding age groups, marital status, having children aged under 18 years, educational status, occupational status, community size, diabetes type, and diabetes control were observed. Table S1 in Multimedia Appendix 1 illustrates acceptance scores as a function of sociodemographic and medical data.

Research Question 2: Predictors of Acceptance

The multiple hierarchical regression analysis revealed that the sociodemographic and medical variables included in the first step explained 14.2% of the variance in acceptance (R^2=0.142; $F_{7,250}$=5.903; P<.001). Therefore, gender (β=−.20; P=.001) and having a mental disorder (β=.24; P<.001) significantly predicted acceptance. The mental health variables included in the second step (R^2=0.204; $F_{10,247}$=6.347; P<.001) significantly increased the explained variance (ΔR^2=0.063; $F_{3,247}$=22.166; P<.001), even though none of these variables were significant predictors of acceptance. However, generalized anxiety (GAD-7) was very close to statistical significance (P=.05). The UTAUT predictors included in the last step (R^2=0.770; $F_{13,244}$=62.966; P<.001) changed the explained variance significantly by 56.6% (ΔR^2=0.566; $F_{3,244}$=200.451; P<.001), further resulting in a total percentage of explained variance of 77%. *PE* (β=.50; P<.001), *EE* (β=.15; P=.001), and *SI* (β=.28; P<.001) significantly predicted acceptance. In addition, the DT was a significant predictor of acceptance in the full regression model (β=.11; P=.03). Table 1 presents the regression parameters of the hierarchical regression model of acceptance.

Table 1. Hierarchical regression model of acceptance. N=258.[a]

Predictor	Standardized coefficient β	Unstandardized coefficient β, B	T	Determination coefficient, R^2	Changes in R^2, ΔR^2	*P* value
Step 1: sociodemographic and medical predictors				0.142	0.142	
Gender	−.204	−.533	−3.368			.001
Age[b]	−.053, .083	−.327, .260	−0.696, 1.193			.42
Mental disorder	.240	.612	4.056			<.001
Step 2: mental health variables				0.204	0.063	
GAD-7[c]	.216	.047	1.934			.05
PHQ-2[d]	−.028	−.018	−0.273			.76
Distress Thermometer [59]	.119	.047	1.383			.17
Step 3: UTAUT[e] predictors				0.770	0.566	
Performance expectancy	.503	.487	10.340			<.001
Effort expectancy	.150	.181	3.366			.001
Social influence	.282	.328	6.268			<.001

[a]In Steps 2 and 3, only the newly included variables are presented.

[b]Age was measured in categories and therefore has been included as a dummy variable. The category with the highest n (age: 45-54 years, n=70) was used as a reference. For β, B, and T minima, the maxima of each group contrast are presented. The *P* value was aggregated using the statistical software R; no single *P* value of each contrast reached statistical significance.

[c]GAD-7: Generalized Anxiety Disorder Scale-7 [58].

[d]PHQ-2: Patient Health Questionnaire-2 [57].

[e]UTAUT: Unified Theory of Acceptance and Use of Technology.

Research Question 3: UTAUT Versus Full Regression Model and Moderator Analyses

The comparison between our extended UTAUT model (13 predictors) and the UTAUT-only model (three predictors) revealed no significant difference in explained variance in acceptance ($F_{10,244}$=1.567; P=.12).

Several moderation analyses have been computed to prove whether age and gender work as moderators, as postulated by the UTAUT [54]. None of them turned out to be statistically significant. Thus, neither gender nor age moderated the relationship between acceptance and the respective UTAUT predictor *PE* (gender: P=.61, $F_{1,254}$=0.269; age: P=.34, $F_{1,254}$=0.922), *EE* (gender: P=.33, $F_{1,254}$=0.962; age: P=.28, $F_{1,254}$=1.162), or *SI* (gender: P=.10, $F_{1,254}$=2.726; age: P=.53, $F_{1,254}$=0.400).

Discussion

Principal Findings

This study examined the acceptance of e-mental health interventions among patients with diabetes and explored factors influencing patients' intention to use such interventions. The overall acceptance of e-mental health interventions was

moderate. Acceptance was associated with gender and mental illness, because women and participants with mental illness had a significantly higher acceptance than men and participants without a stated mental disorder. No difference in acceptance regarding other sociodemographic and medical data were observed, whereas diabetes type only failed to show a statistical significance based on an adapted level of significance (see *Statistical Analyses* section). In the full regression model, the acceptance of e-mental health interventions was significantly predicted by mental health variable *distress* (DT) as well as the UTAUT predictors *PE*, *EE*, and *SI*. The UTAUT predictors (restricted model with UTAUT predictors only) reached a similar explained variance (75%) in acceptance as the full regression model (13 predictors). Neither gender nor age were moderators of the relationship between each UTAUT predictor and acceptance, which contradicts one postulation of the UTAUT [54].

Comparison With Previous Work

Our results confirm the high psychological vulnerability of patients with diabetes, which previous studies had emphasized [5-15], as approximately 21.7% (56/258) and 65.9% (170/258) of our participants expressed indications of major depression (PHQ-2≥3) and elevated distress (DT≥4), respectively. Measures of the GAD-7 showed that 16.7% (43/258; GAD-7≥10) and 7.8% (20/258; GAD-7≥15) had moderate and severe levels of anxiety, respectively.

Despite the proven high psychological vulnerability of patients with diabetes, for example, the increased risk of developing depressive symptoms caused by, for example, heavy demands and major distress or medical complications and constraints this disease and its treatment poses [67,68], research on determining the acceptance of e-mental health interventions, which could have provided help flexibly, and its underlying barriers and resources have been scarce. In particular, research using validated measures (eg, UTAUT) assessing the acceptance of e-mental health interventions in people with diabetes has been lacking. To our knowledge, only one study took on this major research subject [52] and conducted important research groundwork by doing so. Nevertheless, our study was imperative and is of great significance for the following reasons. First, their focus was on determining acceptance and examining the effectiveness of an offered acceptance-facilitating intervention (AFI) and not on assessing acceptance and its predictors and testing the viability of the UTAUT model. Second, the sample size of patients with diabetes was smaller, and the study was conducted 7 years ago. Third, their measurement methods implied noteworthy deficiencies; although relying on the UTAUT, *FC* were regarded as a predictor of acceptance, and not just a predictor of use [54]. In addition, behavioral intention as an operational construct of acceptance is measured using four items instead of three, which is also discordant to the UTAUT [54]. In particular, by deviating in this matter and adding a fourth self-generated item covering willingness to pay for e-mental health interventions, the authors diverge from previous research and respective UTAUT adaptations [28,47,49], not taking advantage of the viability and validity of the UTAUT and its adaptations to the field of e-(mental) health acceptance.

As stated above, the research group investigated patients with diabetes' behavioral intention to use internet-based interventions for depression [52]. The measured acceptance ratings differed from our results (mean 3.02, SD 1.14). Transforming their acceptance scale (4-20) to our acceptance scale (1-5), the average acceptance was lower than that observed in our diabetes sample (control group: mean 2.42, SD 1.07; intervention group: mean 2.64, SD 1.18), but the variance was comparable. Different selection methods may have contributed to these differences. In contrast to the recruitment in the aforementioned study, recruitment was conducted via the internet, resulting in a sample of patients with diabetes that may have been more open to and interested in e-mental health interventions. On the other hand, the passage of time and increasing digitalization and experiences with and knowledge of e(-mental) health tools may also have accounted for these differences. In addition, by adding a fourth finance-based self-generated item of behavioral intention, acceptance ratings might not be comparable. Contrary to the expectations of the researchers, their AFI had no significant effect on acceptance and its predictors. However, subgroup analyses revealed a significant effect for female participants and yielded a trend for younger (<59), depressed, diabetes-related distressed participants, and for those with a low frequency of internet usage to benefit from their AFI [52]. Therefore, future AFIs should probably be tailored to the specific needs of the respective subpopulations.

Studies assessing the acceptance of e-mental health interventions in general found the following variables to be significantly associated with acceptance: gender [55], age [55], education [55], anxiety [48], internet anxiety [48], prior e-mental health use [55,69], and current or past mental disorders [55]. An investigation of acceptance of a web-based aftercare in a mixed inpatient sample with subgroups from different medical clinics revealed that acceptance was significantly associated with (younger) age, (higher) education, stress due to permanent availability, private internet access, and prior eHealth use [28]. With regard to a diabetes-specific web-based platform for patients with type 2 diabetes, stating interest was significantly associated with being male, younger age, higher education, and shorter duration of type 2 diabetes [70].

In line with previous research, acceptance ratings in this study were significantly associated with gender and current or past mental illness. However, contrary to previous studies [25,52], acceptance ratings in this study were significantly higher for women than for men. Age and educational background were not significantly associated with acceptance. Nevertheless, acceptance in this study showed a descriptive trend toward a higher acceptance in younger participants.

Exploring the underlying predictors of eHealth acceptance, previous research adapted the UTAUT and identified the following significant predictors: the UTAUT predictors *PE* [28,50,51,71], *EE* [28,50,51,71] and *SI* [28,50,51] and other predictors namely *perceived reliability* [51], *stress due to permanent availability* [28], *perceived security* [71], *technology anxiety* [50], and *resistance to change* [50]. *FC* are the fourth core predictors of UTAUT, which is supposed to significantly predict the actual usage, but not the behavioral intention (=acceptance) [54]. However, some studies incorporated *FC* as

a fourth UTAUT predictor of acceptance [28,50,51,71], generating inconsistent results. In 2 studies, *FC* was a significant predictor of acceptance, whereas others were not. In case of significance, its predictive value can be regarded as rather low, for example, reaching correlations of r=0.12 with acceptance [71].

Our results support the viability of UTAUT in determining e-mental health acceptance. The proportion of explained variance by *PE*, *EE*, and *SI* was high in this study (75%) and comparable with those of the original UTAUT validation study (70%) [54]. Confirming previous research, in this study *PE* was the key predictor of acceptance [28,49,50,54,72].

Acceptance operationalized as *behavioral intention* can be regarded as a significant and highly valid predictor of actual usage behavior. According to the UTAUT, *behavioral intention* is a significant predictor of actual use, and both correlate with r=0.59 [54]. In addition, prior eHealth research emphasized the major role of acceptance regarding a valid prediction of the actual eHealth usage: predicting the usage of mobile health services, *behavioral intention* had a significant effect and reached notable standardized regression coefficients of β=.415 [50] and β=.372 [51] in the respective structural model. Moreover, acceptance can predict the future use of eHealth interventions, as higher ratings of acceptance led to higher use of an unguided web-based intervention for chronic pain [48]. Nevertheless, the majority of studies on e(-mental) health acceptance do not measure its actual use (eg, uptake rate of an offered intervention), and if so, usage behavior was assessed retrospectively. To prove the prospective validity of acceptance, future research should include actual use and uptake rates as an outcome measure and assess acceptance in advance.

Comparing the acceptance and use of eHealth in terms of significant associations with sociodemographic variables, the findings appear to be similar. For both age and education, significant associations are generated, as younger age and higher educational level are associated with higher acceptance and higher use [28,55,70,73-75]. In contrast to acceptance, eHealth use was found to be associated with income and living conditions, finding that not living alone and higher income were associated with higher usage behavior [73,74]. Gender with regard to eHealth use has resulted in inconsistent results. A recent review found 8 studies with no significant association between gender and eHealth use and 5 studies stating a significant association between gender and eHealth use in patients with chronic diseases [73]. Increasing the heterogeneity of these results, 3 of the 5 studies found that being female is associated with an increased usage behavior, whereas 2 studies revealed that males showed a higher use of eHealth services.

These heterogeneous findings are of central importance, as they are a valid reminder of the limitations of research on eHealth acceptance and eHealth use and the variety of (unknown) underlying factors. In our understanding, the following factors may influence the acceptance and use of eHealth and should be regarded in terms of interpreting research results: measurement method (eg, UTAUT or not), recruitment method (web-based or not), sociodemographic characteristics (gender, age, education, income, and living conditions), duration of illness, user type (inpatient, outpatient, staff, and public), technical type of delivery (app, mobile, tablet, and laptop), guidance (unguided vs guided), target population (healthy, type of illness, and chronic disease), type of eHealth service (intervention program, education, communication, and technical devices), and the specificity of the eHealth service (general health, general mental health, and specific for current disease).

Limitations

The following limitations should be considered while interpreting the results. First, because our study was a web-based survey, patients were required to have internet access. As the probability of internet access declines with age [76], we received a younger diabetes sample than that present in the general population. Consequently, we had more patients with type 1 diabetes (174/258, 67.4%) than patients with type 2 diabetes (74/258, 28.7%), because type 2 is an acquired form of diabetes in older age. Therefore, our sample does not reflect the typical distribution of 90% of patients with type 2 diabetes [77]. The composition of the investigated sample was mostly female (approximately 192/258, 75%). Owing to this selection bias, the generalizability of our results may be reduced.

Second, these compositional specifications may not only limit generalizability, but also bias acceptance ratings, because participants recruited via the internet may be more open to and interested in e-mental health interventions. In addition, female patients had significantly higher acceptance ratings than male patients. Furthermore, in a descriptive view, younger patients had higher acceptance ratings than older patients. In addition, acceptance may be overestimated, because patients with type 1 diabetes showed a higher acceptance than patients with type 2 diabetes, but only in a descriptive view based on our adapted level of significance of 0.007 (see *Statistical Analyses*).

Third, all data were self-reported. This method is prone to the *common method* bias because of the shared method variance [78]. Counteracting this limitation, the instruments used had a sufficient internal reliability, the survey had a short length, and the patients were well-educated because these points are known to mitigate the *common method* bias.

Fourth, we measured acceptance as the *behavioral intention*, which corresponds to previous studies [28,48,49,51,54,79-81]. However, direct conclusions from the intention to use an e-mental health intervention to its actual usage cannot be drawn because of the intention-behavior gap [82]. Thus, acceptance can be assessed as a predictive function of behavioral intention, and previous studies have proven its validity [48,50,51,54].

Fifth, our study design was based on assessing mental health only through symptom-based measures, which were oriented on diagnostic criteria. Although we used established and validated measures, which is one strength of our study (PHQ-2, DT, and GAD-7), it could also be beneficial to include the mental health–related quality of life measures.

Sixth, the cross-sectional study design is not suited to identify and account for factors and predictors of acceptance and use of eHealth interventions that may interact or change over time and depend on technological progress. In addition, because of the

cross-sectional design, no statements can be made regarding causality.

To overcome these limitations, future research should add the uptake rate as an outcome measure and focus on assessing acceptance and its barriers and resources in a longitudinal design with different target groups and a balanced composition of gender and age. Furthermore, future research should add health-related quality of life measures to investigate how predictive these measures can be regarding e-mental health acceptance and if those might be even more predictive than symptom-based validated measures of mental health. Moreover, qualitative or mixed methods research could help identify the unknown predictors of e-mental health acceptance and therefore add richness to the understanding of underlying barriers and resources of e-mental health acceptance in general, particularly for e-mental health interventions in patients with diabetes.

Conclusions

This study supports the viability of the UTAUT model and its predictors in assessing the acceptance of e-mental health interventions in patients with diabetes. The UTAUT model, comprising the predictors *of PE*, *EE*, and *SI*, reached a notable amount of explained variance in the acceptance of 75%. This UTAUT model was compared with a full model including 13 predictors including sociodemographic, medical, and mental health variables and explained a similar variance in acceptance.

To conclude, the UTAUT model (here, 9 items) turned out to be a very useful and efficient method for measuring the e-mental health acceptance of patients with diabetes. Due to the close link between acceptance and use, AFIs should be fostered to bring forward the establishment of effective e-mental health interventions in psychodiabetology. These AFIs should focus on *PE*, *EE*, and *SI* to increase the acceptance of easily accessible and location-flexible e-mental health interventions, which are even more vitally needed these days given the ongoing pandemic and in light of the high (psychological) vulnerability of patients with diabetes.

However, future research should also include the actual use behavior as an outcome measure to test the (prospective) validity of acceptance predictions for the actual use of e-mental health interventions.

Authors' Contributions

AB initiated and conceptualized the study. MD, JB, and JS performed the statistical analyses, interpreted the data, and wrote the manuscript. Data acquisition and statistical analyses were performed by AS, KS, JB, and JS. AS, KS, HD, and VM actively participated in the interpretation of the data and edited the manuscript. AB, MT, and EMS made major contributions to the study's conception and design, actively participated in the interpretation of data, and revised the manuscript critically for important subject-specific content. All authors contributed to the study and approved the final version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Statistical data tables of differences in acceptance and prevalence of anxiety, depressive symptoms, and distress.
[DOC File , 184 KB - formative_v5i7e27436_app1.doc]

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Abbreviations

AFI: acceptance-facilitating intervention
ANOVA: analysis of variance
DT: Distress Thermometer
EE: effort expectancy
FC: facilitating conditions
GAD-7: Generalized Anxiety Disorder Scale-7
PE: performance expectancy
PHQ-2: Patient Health Questionnaire-2
SI: social influence
UTAUT: Unified Theory of Acceptance and Use of Technology

Edited by G Eysenbach; submitted 25.01.21; peer-reviewed by S Liu, N Subedi, S Skovlund; comments to author 30.03.21; revised version received 21.05.21; accepted 31.05.21; published 30.07.21.

Please cite as:
Damerau M, Teufel M, Musche V, Dinse H, Schweda A, Beckord J, Steinbach J, Schmidt K, Skoda EM, Bäuerle A
Determining Acceptance of e-Mental Health Interventions in Digital Psychodiabetology Using a Quantitative Web-Based Survey: Cross-sectional Study
JMIR Form Res 2021;5(7):e27436
URL: https://formative.jmir.org/2021/7/e27436
doi:10.2196/27436
PMID:34328429

Original Paper

Prioritization of Features for Mobile Apps for Families in a Federal Nutrition Program for Low-Income Women, Infants, and Children: User-Centered Design Approach

Summer J Weber[1], PhD, RD; Elyse Shearer[2], PhD, RD; Shelagh A Mulvaney[3], PhD; Douglas Schmidt[4], PhD; Chris Thompson[5], BSc; Jessica Jones[6], MSc; Haseeb Ahmad[1]; Martina Coe[2]; Pamela C Hull[1], PhD

[1]Markey Cancer Center, University of Kentucky, Lexington, KY, United States
[2]College of Agriculture, Tennessee State University, Nashville, TN, United States
[3]School of Nursing, Vanderbilt University, Nashville, TN, United States
[4]School of Engineering, Vanderbilt University, Nashville, TN, United States
[5]233 Analytics, Nashville, TN, United States
[6]Meharry-Vanderbilt Alliance, Meharry Medical College, Nashville, TN, United States

Corresponding Author:
Pamela C Hull, PhD
Markey Cancer Center
University of Kentucky
2365 Harrodsburg Rd
Suite A230
Lexington, KY, 40504-3381
United States
Phone: 1 859 323 9965
Email: Pam.Hull@uky.edu

Abstract

Background: The Special Supplemental Nutrition Assistance Program for Women, Infants, and Children (WIC) is a federal nutrition program that provides nutritious food, education, and health care referrals to low-income women, infants, and children up to the age of 5 years. Although WIC is associated with positive health outcomes for each participant category, modernization and efficiency are needed at the clinic and shopping levels to increase program satisfaction and participation rates. New technologies, such as electronic benefits transfer (EBT), online nutrition education, and mobile apps, can provide opportunities to improve the WIC experience for participants.

Objective: This formative study applies user-centered design principles to inform the layout and prioritization of features in mobile apps for low-income families participating in the WIC program.

Methods: To identify and prioritize desirable app features, caregivers (N=22) of the children enrolled in WIC participated in individual semistructured interviews with a card sorting activity. Interviews were transcribed verbatim and analyzed using constant comparative analysis for themes. App features were ranked and placed into natural groupings by each participant. The sum and average of the rankings were calculated to understand which features were prioritized by the users. Natural groupings of features were labeled according to participant descriptions.

Results: Natural groupings focused on the following categories: clinics/appointments, shopping/stores, education/assessments, location, and recipes/food. Themes from the interviews triangulated the results from the ranking activity. The priority app features were balance checking, an item scanner, and appointment scheduling. Other app features discussed and ranked included appointment reminders, nutrition training and quizzes, shopping lists, clinic and store locators, recipe gallery, produce calculator, and dietary preferences/allergies.

Conclusions: This study demonstrates how a user-centered design process can aid the development of an app for low-income families participating in WIC to inform the effective design of the app features and user interface.

(JMIR Form Res 2021;5(7):e30450) doi:10.2196/30450

KEYWORDS

WIC; mobile technology; maternal-child health; childhood obesity; nutrition; government programs; mobile app; user-centered design; low income; women; infant; child; formative; development

Introduction

The Special Supplemental Nutrition Program for Women, Infants, and Children (commonly known as WIC) is one of the most successful [1] and cost-effective [2,3] nutrition programs aimed at improving maternal, infant, and child health in the United States. WIC is a federal program that provides nutritious food (eg, fresh and frozen produce, whole grains, milk, eggs), nutrition education, and health care referrals to low-income women during pregnancy and the postpartum period and to their children from birth up until their fifth birthday. WIC's services have been monitored and researched for decades and its contribution has been attributed to a myriad of positive health outcomes for its participants.

For example, better birth outcomes with WIC are well documented [4] and include beneficial interaction effects on birth weight [5-7] and significantly reduced probability of highly premature births [5]. Nutrition-related outcomes include—but are not limited to—positive changes in dietary intake [8], healthy food purchases [9], and reductions in obesity [10]. WIC has also been associated with improvements in household food security [10], childhood immunizations [11,12] and health care utilization [11].

Despite all the positive effects of WIC, barriers to the usage of the program and participation exist at the interpersonal (eg, family support), institutional (eg, prohibitive work schedules), clinical (eg, long wait times), shopping (eg, WIC items that are hard to find, not in stock, and inconsistent within and between vendors), and administrative/systems levels (eg, restrictive benefits and stigma surrounding government assistance) [13-17]. Addressing the issue of early exits from the WIC program has been identified as one of the key areas in a research needs assessment put forth by the National WIC Association (NWA) [18], and a national program retention campaign was rolled out in 2018 [19].

Technologies to improve and streamline the WIC experience for participants have been offered as a solution at the clinic and shopping level. These technologies have become particularly essential after the onset of the COVID-19 pandemic. In many states, participants can complete web- or app-based nutrition education in their own time, rather than attending in-person classes at the clinic to fulfill some of their nutrition education requirements [20-22].

At the shopping level, WIC state agencies were mandated to switch from a paper voucher system to an electronic benefits transfer (EBT) system for WIC by 2020, with some waivers of extension [23] in which participants make WIC purchases using an EBT card that resembles a debit card. Implementation of WIC EBT (or electronic WIC [eWIC]), as many state agencies refer to it) is a considerably large administrative undertaking that stands to benefit participants considerably owing to increased ease of use at checkout, elimination of the risk of theft or loss of paper vouchers, increased redemption of benefits, and decreased stigma associated with purchasing food using a discreet benefit card rather than cumbersome paper vouchers that can cause difficulties for customers and cashiers [14,24-26].

Although beneficial, modernization of the redemption process by eWIC comes with certain challenges for the participants in lieu of paper voucher usage. In the recent past, participants could utilize their paper vouchers (also called food instruments) to view and keep track of itemized WIC benefits, quantities, and sizes according to their food prescription. Without a source of guidance, shoppers may feel unclear about their eWIC benefit balance, especially if they are new to the program and unfamiliar with WIC foods and prescription changes that occur as children age or when women transition from pregnancy to the postpartum period. WIC families also face the same barriers when choosing the correct items while shopping.

A potential solution to the challenges outlined above are mobile apps that provide WIC families with balance checking features and barcode scanners to verify eligible WIC items [27-29]. The study described in this paper builds off a project that informed the development of a prototype mobile app called Children Eating Well (CHEW) designed to support WIC families prior to eWIC transition [28]. The objective of the current study was to conduct interviews with caregivers of WIC- enrolled children (referred to as "WIC caregivers") to inform the design and prioritization of the features for an enhanced version of the CHEW mobile app and other mobile apps for low-income families participating in the WIC program.

Although apps for WIC participants exist in many states [27], research studies on WIC apps are relatively sparse. A recent study found that usage of the most widely available commercial WIC app (WICShopper) was associated with higher levels of WIC benefit redemptions among WIC households in West Virginia [29]. Literature searches revealed only one previously published study that employed user-centered design principles to inform the development of WIC apps; that study focused on nutrition education and health behavior [30]. The objective of the current study was to conduct formative research applying user-centered design principles to inform the layout and prioritization of the features in mobile apps for low-income families participating in the WIC program that could target outcomes such as WIC family benefit redemption, diet quality, and obesity risk factors among preschool-aged children [31-33].

Methods

Recruitment

Caregivers/parents of children aged 2-4 years enrolled in WIC were recruited via fliers and posters at WIC clinics and health departments throughout Nashville, Tennessee, to participate in a 30-to-60–minute interview about mobile phone apps for WIC families. Participants were screened for eligibility via telephone. Eligible participants were 18 years or older, had a child aged

2-4 years enrolled in WIC, were the primary WIC shoppers in their households, and used a smartphone.

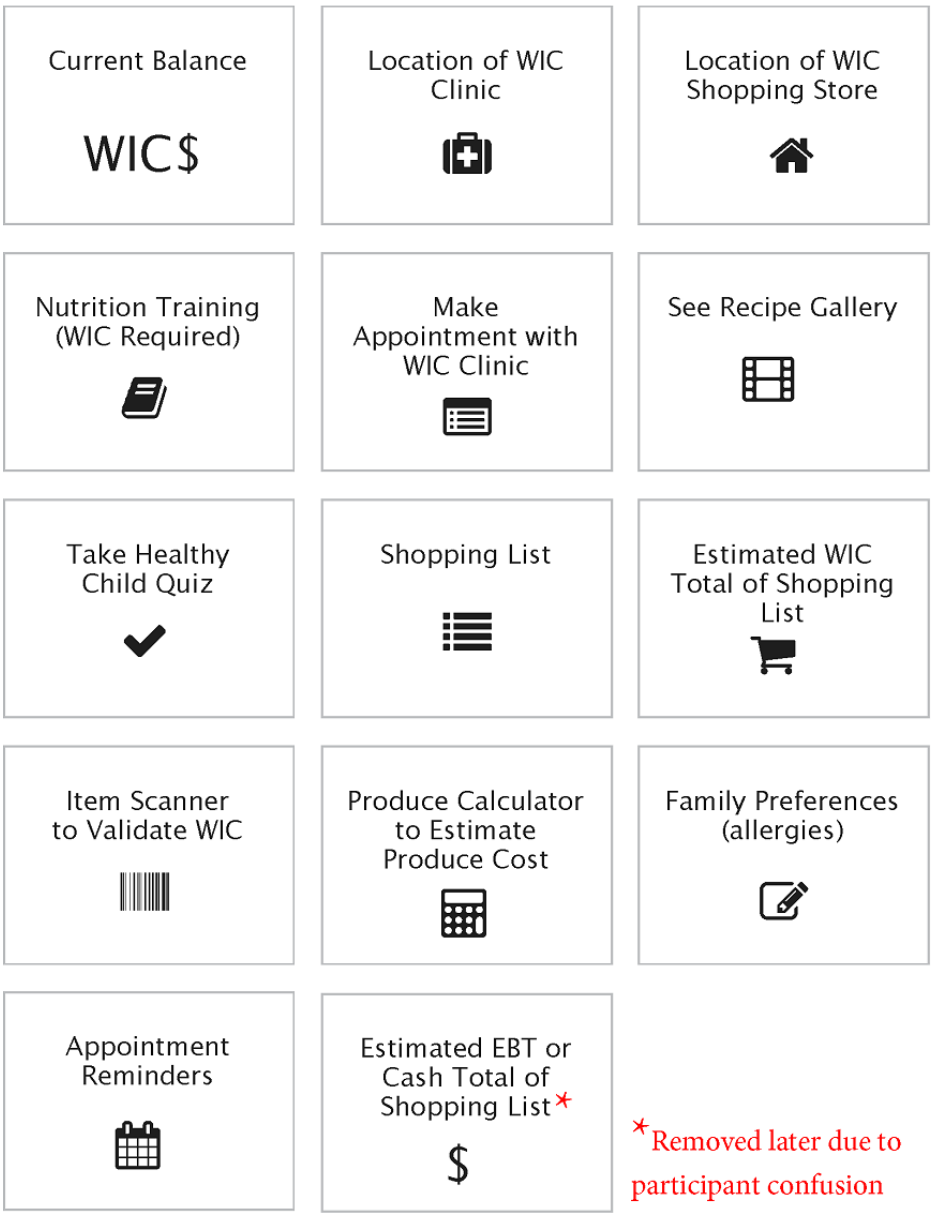
The interviews took place during July-August 2018, prior to the transition of the Tennessee WIC program to eWIC. Interviewees were informed at the beginning of the interview that WIC would be changing to eWIC over the course of the coming year. Therefore, the questions were framed around what features they would like to have in an app to use with eWIC.

Study Procedures

A semistructured interview protocol was developed based on a multilevel model of factors influencing the perceived value of WIC [14], as well as formative research [28] and a review of existing WIC apps and features [27]. Using the semistructured interview protocol, participants were asked to speak about their experiences using WIC services, shopping for WIC foods, and using mobile phone technology. Participants were also asked to form mental models about using recipes, shopping lists, using WIC benefits, and checking their WIC balance.

Potential in-app features were printed on 14 activity cards with icons to represent their function, as Figure 1 shows. Using a sorting activity, participants were first asked to sort the features by importance. They were then asked to place the cards into natural groupings of similar features. To record the prioritization of features and the natural groupings of features, photographs were taken during the card- sorting activity and labeled immediately following each interview.

Figure 1. App feature activity cards given to WIC caregivers for sorting by level of importance and placing into natural groupings. WIC: Special Supplemental Nutrition Assistance Program for Women, Infants, and Children.



Quantitative Analysis

For the feature prioritization task, a numerical ranking from 1 to 14 (1 being most important and 14 being least important) was applied to each feature description for each participant. To comprehensively analyze the rankings, the sum and mean of each ranking were calculated. For the natural groupings task, the card groups in each photograph were circled and labeled according to the participants' own descriptions, if any. A table of the card groupings and labels was created to track how participants would like to display and organize these features within an app.

Qualitative Analysis

Interviews were transcribed verbatim, read several times to obtain a clearer understanding, coded, and then analyzed by constant comparative analysis [34] to identify themes, using the ATLAS.ti qualitative data analysis software (version 8.0, ATLAS.ti Scientific Software Development GmBH). A list of codes and code groups was updated and maintained throughout the analysis. Codes and code groups were queried via like groupings and then compared within and between transcripts.

The identification of themes was informed by previous research on barriers and facilitators to using WIC in general (eg, difficulties while shopping, clinic location) [13-17]. Analysis also focused on themes that were based on potential app features and tools for families who use WIC (eg, scanner, balance checking, recipes). Participants were recruited until the data reached saturation and no new information resulted from the interviews. The main themes were summarized, and sample quotes were selected that illustrated the themes.

Interrater reliability was determined according to the procedures of Gough and Conner [35]. Three additional coders completed code allocations to all 429 quotations, which were then checked to ensure a high level of correspondence (96.5%, 94.1%, and 92.3%, respectively). Lincoln and Guba's criteria for trustworthiness of qualitative research [36] were applied to ensure credibility of the findings, which included the following:

- prolonged engagement (iterative interviews and correspondence with participants)
- persistent observation (staff and client interactions)
- peer debriefing (meetings and correspondence with the state agency and WIC site coordinators)
- triangulation of data (quantitative card sorting activity alongside qualitative interviews)
- negative case analysis (discussion of elements that contradicted patterns from the data)
- referential adequacy (archiving a portion of the data to be analyzed later to test the validity of the preliminary findings)
- member checks (verbal confirmations of accurate understanding conducted throughout the interviews and during follow-up interviews as part of the iterative process).

Results

Participant Characteristics

Table 1 shows the participant characteristics. All the interview participants were female except for 2 (WIC families' primary shoppers are predominantly female). Of the 22 participants, 11 identified their race as Black or African American, 8 White, 1 Asian Indian, and 2 selected "other race." Hispanic ethnicity was selected by 2 participants, and 6 participants reported that they were born in another country, which included Iraq (2), the Democratic Republic of Congo (2), Egypt (1), and India (1).

Just over half (12/22, 55%) of the participants were not married and had 1 or 2 children under the age of 18 years (13/22, 59%). Nearly one-third (7/22, 32%) of the participants also had an infant child aged below 2 years in addition to having 1 or more 2-to-4-year-old children. Most participants had high school degree or some college education (15/22, 68%).

Table 1. Characteristics of the Special Supplemental Nutrition Assistance Program for Women, Infants, and Children participants in Nashville, Tennessee, United States, determined via interviews (N=22).

Variable	Values, n (%)
Gender	
Female	20 (91)
Male	2 (9)
Race	
Black or African American	11 (50)
White	8 (36)
Asian Indian	1 (5)
Other	2 (9)
Hispanic ethnicity	
Yes	2 (9)
No	20 (91)
Born in the United States	
Yes	2 (9)
No[a]	20 (91)
Marital status	
Married	10 (45)
Single-never married	5 (23)
Single-never married-lives with partner	4 (18)
Single-divorced	1 (5)
Refused to state	2 (9)
Number of children under 18	
1	3 (14)
2	10 (45)
3	6 (27)
4	1 (5)
5	1 (5)
9	1 (5)
Employment	
Full-time	8 (36)
Part-time	4 (18)
Not employed	10 (45)
Type(s) of WIC[b] packages received	
Pregnant woman	1 (5)
Breastfeeding woman	2 (9)
Partially breastfeeding woman	1 (5)
Postpartum (not breastfeeding) woman	2 (9)
Infant (0-23 months old)	7 (32)
Child (2-4 years old)[c]	26 (100)
SNAP[d] recipient	
Yes	9 (41)

Variable	Values, n (%)
No	13 (59)
Type of smartphone	
Android	13 (59)
iPhone	9 (41)
How often do you have your smartphone with you?	
Almost all the time	19 (86)
Often	2 (9)
Some of the time	1 (5)

[a] Participants not born in the United States were from Iraq (21 and 22 years in US), Egypt (9 years in US), the Democratic Republic of Congo (4 and 8 years in US), and India (23 years).

[b]WIC: Special Supplemental Nutrition Assistance Program for Women, Infants, and Children.

[c] Some participant households (4/22) had 2 children aged between 2 and 4 years.

[d]Supplemental Nutrition Assistance Program.

Card Sorting Activity

Among the 22 participants, 4 did not complete the card sorting activity, 1 could not participate owing to literacy issues, and the last 3 participants reviewed these features in an app prototype with these features embedded to review instead of the card sorting activity. Figure 2 depicts the card sorting activity performed by 1 participant. Part way through the study (after 7 participant interviews), 1 app feature card "Estimated EBT or cash total of shopping list" was removed from the card-sorting activity owing to participant confusion.

Most participants (9/22) placed the app features into 3 or 4 natural groupings focused on "clinic/ appointments" (15/22), "shopping/store" (15/22), followed by "education/assessments" (6/22), "location" (4/22), and "recipes/food" (3/22). Some participants (4/22) did not label some of their groupings, whereas others (3/22) did not place the features into any natural groupings.

Prioritization of the app features resulting from the card sorting activity is summarized in Table 2. Card rankings were scored from 1 (highest priority) to 13 (lowest priority), then summarized as sums and means. For the sum and average scores, lower scores represent higher priority, and higher scores represent lower priority. The top 5 features ranked as the highest priority ones were closely tied to their WIC benefits, namely current balance (mean 2.9), item scanner to validate WIC (mean 4.1), make appointment with WIC clinic (mean 4.8), appointment reminders (mean 6.3), and required nutrition training (mean 7.2). The next group of moderately ranked features included shopping list (mean 7.8), location of WIC store (mean 8.0), recipe gallery (mean 8.1), estimated WIC total of shopping list (mean 8.9), and take Healthy Child Quiz (mean 9.1).

Figure 2. Card sorting activity in progress: sample prioritization (top) and natural groupings (bottom) of potential features in a smartphone app for WIC families by WIC caregivers. WIC: Special Supplemental Nutrition Assistance Program for Women, Infants, and Children.

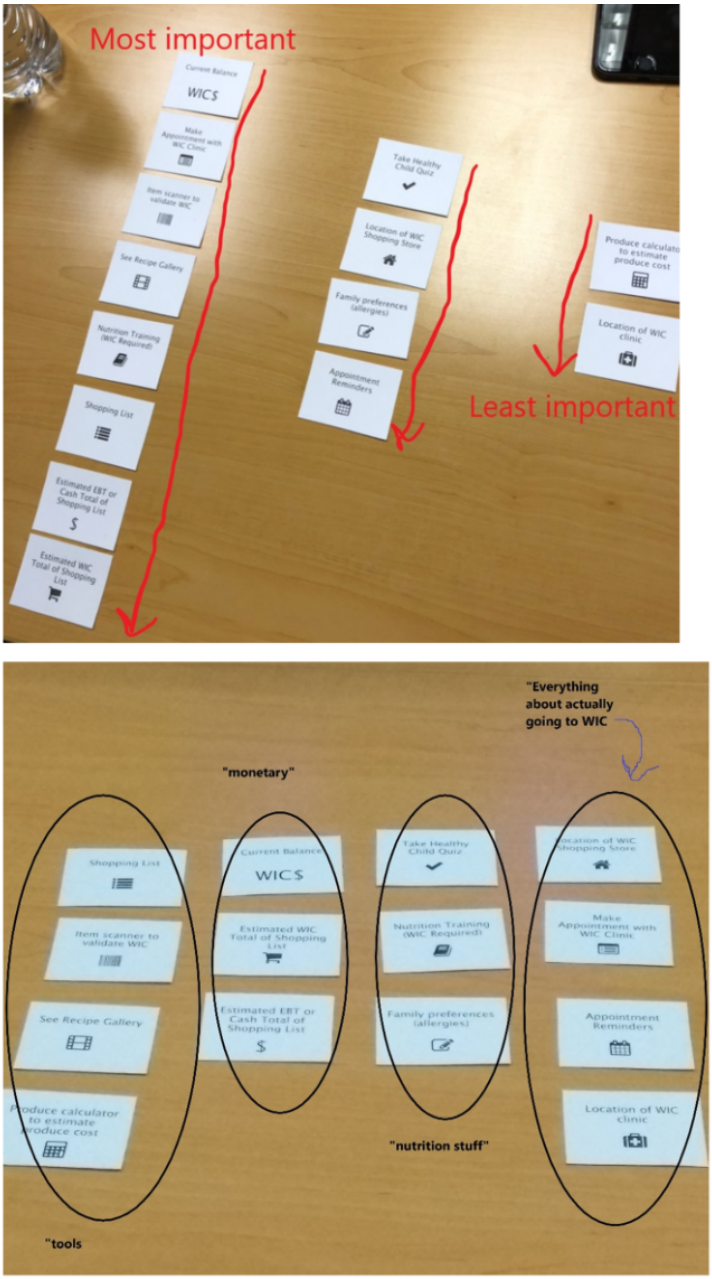


Table 2. Prioritization of potential features in a smartphone app for Special Supplemental Nutrition Assistance Program for Women, Infants, and Children families by caregivers (N=18).

Rank[a]	App features listed on cards	Sum	Mean
1	Current balance	52	2.9
2	Item scanner to validate WIC[b]	74	4.1
3	Make appointment with WIC Clinic	86	4.8
4	Appointment Reminders	113	6.3
5	Nutrition training (WIC Required)	130	7.2
6	Shopping list	141	7.8
7	Location of WIC shopping store	144	8.0
8	See recipe gallery	146	8.1
9	Estimated WIC total of shopping list	161	8.9
10	Take healthy child quiz	163	9.1

[a] Card rankings were scored from 1 (highest priority) to 13 (lowest priority). For the sum and mean scores, lower scores represent higher priority, and higher scores represent lower priority.

[b]WIC: Special Supplemental Nutrition Assistance Program for Women, Infants, and Children.

In-Depth Interview Results

Themes from the qualitative interview portion of the study mainly aligned with and confirmed the results from the card sorting activity. These themes provided deeper insights into the participants' reasoning, daily activities, and experiences with respect to the WIC program, which guided their opinions about the need for an app and app features designed for their use.

Balance Checker

Of the participants who expounded about this feature in the interviews to check their WIC balance (18/22), all described the feature positively saying that it was important, useful, and necessary for keeping track of their benefits.

> *My current WIC balance would be very important and something I would use all the time.* [Breastfeeding WIC Participant, mother of 3: 1 child and 1 infant enrolled in WIC]

Most participants were puzzled about how they would keep track of their benefits without an app. However, some (6/22) anticipated how they might try to keep track, citing that they would be able to "call a number" or view it on their receipts or "on a website." All these participants agreed that these alternatives would be less preferable to a detailed app feature displaying their balance with pictures. Many participants (7/22) described their preferred on-screen appearance of the balance feature, what details should be displayed about the foods, and which items they would want to see at the top of their balance.

Fewer participants expressed as much interest in a subfeature within the balance tracker that would help them calculate their fruit and vegetable balance. Although some described such a feature as potentially helpful (9/22), others (4/22) said the feature might be a "waste of time" or "not very useful" because they either calculated their fruit and vegetable costs themselves, or because it did not really seem important to keep close tabs on the small amount they were allowed ($8-$12 per month) by WIC. Participants (2/10) did describe the difficulty or hassle of trying to tabulate the correct amounts of certain WIC items other than fruits and vegetables (eg, cereal) for going over (or in some cases under) the amount allowed by WIC. Sometimes, participants described choosing cereal that comes in the largest boxes to avoid having to calculate ounces or lose the maximum benefit.

> *It's literally like playing, playing cards in the aisle with the kids and other people that are trying to get their cereal too. That's how you end up in the routine of getting the same over and over again. Because you're like ok, I know I can get the big box of (Brand Name A) and the smaller box of (Brand Name B) and just… Let's just go. So, they don't get to try the other things. I've literally always wanted to try (Brand Name C) and it's covered (by WIC) and I never incorporate it because the math will be off. I've heard it's like a really good cereal and really good for fiber and things of that nature.* [Mother of 2: 1 child enrolled in WIC]

Two participants mentioned the desirability of a feature, perhaps within the balance tracker that could show them which cereals and cereal combinations they could choose based on the remaining ounces of cereal in their WIC balance.

Scanner to Verify WIC Items

Most participants (17/22) felt a barcode scanner would be useful to verify whether an item is WIC-eligible and available on their WIC balance, especially "in the beginning" of their WIC enrollment. Some (4/22) were already familiar with using barcode scanners in shopping-related apps. Shopping for WIC was described as generally confusing, frustrating, and difficult by most participants (21/22) because WIC items must meet specific size, brand, and nutritional criteria.

Stores lacking labeling or clear labeling of WIC products posed a barrier even for experienced participants (8/22), who stated that stores would change their inventories and WIC-eligible brands. Participants (18/22) described problems at store

checkouts including bringing up the wrong item, items not present in the stores' systems, contentious cashiers, length of checkout time, and stigma from other customers. Conflicting information regarding the eligibility of WIC items was a common theme, where participants (10/22) mentioned that their WIC food brochure did not reflect what the store deems eligible or other instances where one store allows an item, whereas another does not.

The study participants described various strategies to make WIC shopping easier, including going to the store at specific non-busy times (2/22), shopping without children (2/22), separating WIC items from the rest of the groceries for a faster check-out (6/22), shopping with someone who has experience with WIC (2/22), asking store employees for help (3/22), and taking photographs of WIC-eligible items at the store to facilitate the next shopping trip (1/22).

> *The item scanner to validate WIC, that's pretty important because stores are always introducing new things and like I said, even when you have the ounces or you think you know what you're supposed to get on your voucher, it would always be good just to scan it, double-check it before you get up to the counter and then they tell you no, that's not WIC eligible.* [Breastfeeding WIC Participant, mother of 3: 1 child and 1 infant enrolled in WIC]

> *Oh, I like that right there- the item scanner to validate WIC- to make sure it is a WIC item. So, like if somebody said no this is not (eligible) then I'm like, "uhuh, watch this then. I'm gonna scan it.* [Mother of 2: 2 children enrolled in WIC]

Clinic-Related Features

Participants (11/22) were enthusiastic about a feature that would allow them to view, make, or change a WIC appointment online via an app. Although participants clearly valued the health benefits and information their families receive through WIC, most (11/22) considered the WIC clinic experience as an inefficient but a necessary burden. Long wait times and difficulties in contacting the WIC clinic (5/22) to enroll and make or reschedule an appointment were recurring themes among the interviewees.

Despite these clinic barriers, one area in which WIC has improved its efficiency over the years is the option for patients to complete the required nutrition education classes online. Most participants said they preferred the online option out of convenience (10/22), although some (2/22) did prefer in-person classes. Participants said they would use an in-app link to meet this requirement, although this feature was not rated high priority unless it allowed them to skip the sign-in process.

Shopping List Feature

Of those participants who expounded beyond the card sorting activity (12/22), most (7/12) commented positively about a shopping list feature that would allow them to add WIC and non-WIC items to a shopping list that was linked to their WIC benefits via the app , though some (5/12) remained indifferent to this feature . Most participants (12/22) mentioned that they already use apps or similar features in their smartphones to make shopping lists, whereas others said they prefer to use a pen and paper only for making lists (8/22).

Location Features

Participants commented positively (10/22) about a feature that would allow them to find a WIC store, whereas others said the feature was not important, citing that they "already know" where the WIC stores are (one participant even expressed concerns about allowing an app to access her location to enable these features). Participants (7/22) mentioned visiting the same store or stores often. Although proximity was deemed important (8/22), factors other than location were often considered in choosing a WIC store.

Many participants (11/22) said the store environment and customer service were more important than the location because certain stores are often crowded, making it hectic and frustrating to redeem WIC benefits. Participants talked about preferring to go "out of the way" to do their WIC shopping in a less stressful environment (9/22), where they can find better deals (6/22), and where they know that the items will be in stock (1/22).

> *I think this (WIC store locator) will help because if someone first time will use it he don't know where he will go.* [Mother of 5: 1 child and 2 infants (twins) enrolled in WIC]

Participants were also asked to provide their opinions about the inclusion of a WIC clinic locator. Although participants mentioned hypothetical situations in which a WIC clinic locator could be useful (eg, first-time patients, when someone moves), no participant regarded a clinic locator as an important feature. Participants said they "know where their WIC clinic is and where they are going."

However, WIC clinic proximity was regarded as a facilitator to participants' enrollment and ability to attend appointments. Participants (5/22) described the convenience of attending WIC appointments close to their home or at a location that temporarily—but regularly—serves as a "Mobile WIC Clinic" (eg, community center, library). Interviews revealed that in-app notifications about these types of services could serve participants better than a general clinic locator feature.

Recipes, Meal Planning, and Dietary Preferences

To gauge interest in a recipe feature within the app, participants were asked to describe their cooking routines. Most participants said they do use recipes (15/22) primarily sourced from the Internet (13/22). However, some participants (inside and outside of the recipe-using group) claimed they were mostly autonomous cookers (8/22) that already "knew how to cook" without relying on recipes for meal ideas.

Many participants described food traditions (10/22), such as learning to cook from a family member or preparing culture-specific foods. However, the most frequently mentioned influence on daily meals was what children wanted to eat (9/22). Health (3/22) and simplicity (3/22) were also factors that participants said influenced their cooking.

Most participants (15/22) said they were interested, would use, or would like to try recipes featured within an app. Some (2/22) mentioned they would not use such a feature, citing that they

already knew how to cook what their children liked to eat. Participants who liked the idea of a recipe feature said they would be interested in filtering or pushing recipes based on preparation time (9/22), WIC foods (6/22), keywords (eg, ingredient or recipe name) (5/22), dietary preferences (eg, vegetarian, food allergens) (5/22), kid-friendly recipes (1/22), and meal type (1/22).

Participants (3/22) also mentioned the importance of an attractive layout and photographs within a recipe feature. Although a feature to set dietary preferences and allergies in their family profile was not ranked as high priority, many participants acknowledged that being able to do so would be a "good thing" (10/22).

> *I would want the recipe gallery because while I'm shopping, if I am trying to be creative and think, "well what else can I get to put with this to actually make a meal?"- go to the quick gallery and you know, see what I already have and you know, see what else I could pick up to make a different meal.* [Mother of 2: 1 child enrolled in WIC]

> *I'm visual. If I have a list of food, what to do, yeah- I love to look, and the steps they do. It helps me. I'm like okay. I go back, oh, well I need to put this in. You know? I'm visual. I don't know. Yeah, I like to look, to get pictures, or the video of it.* [Mother of 1: 1 child enrolled in WIC]

Health Assessments and Goal Tracking

All participants expressed that they valued health (either their own, their child's, or their family's), and many participants (7/22) described WIC as a program that promotes health and nutrition. Many of these participants (6/22) expressed interest in receiving health information, tips, and child-feeding advice through the CHEW app. Picky eating was a theme among many participants (11/22) and some expressed a desire to address this issue in their children (6/22) either through the app or otherwise.

Participants were divided on whether they deemed a "child health quiz" as an important feature in the app. Those who said they would use the feature (5/22) described themselves as curious and interested in finding out new information, whereas others (5/22) said the feature was good but not a priority. Others said such a feature would not be something they would use, citing their busy schedules with children and that it was not necessary for redeeming WIC benefits. Certain participants (3/22) said they would consider a quiz feature important if its use counted toward their required WIC nutrition education.

> *To take healthy child quiz, if they want it to be a priority, they should do it like nutrition training- like required.* [Mother of 2: 2 children enrolled in WIC]

Ancillary Themes Related to App Usefulness

It was apparent from the participant interviews that an app designed to help WIC participants shop should be easier and clearer, as well as contain better information, than existing paper food brochures given at the clinic. Participants (5/22) emphasized that such an app should be straightforward and easy to use.

> *In general, I just kind of do pretty simple things. Yeah, and I think the pictures is a good way, too (…) make sure the pictures are there. (…) It would make you feel like you're doing something elaborate, but it would be simple and quick, so that's good.* [Mother of 1: 1 child enrolled in WIC]

Others (6/22) described the existence of language barriers, native languages other than English, and the importance of supporting several languages in the app. A desire to make the app easy to use for those with limited or low literacy was also mentioned (6/22).

Regarding participants' smartphones and data issues, some (8/22) described barriers to usage, such as having limited data or experiencing slow data speeds. Connecting to available Wi-Fi networks to limit data usage costs was a common strategy for addressing these data issues. Participants mentioned several reasons for deleting an app from their smartphone, the most frequent reasons being infrequent usage (10/22) and limited space/memory (6/22) on their phones. Additional reasons that the participants cited for deleting an app are presented in Table 3.

Table 3. Reasons for deleting an app from a smartphone mentioned by Special Supplemental Nutrition Assistance Program for Women, Infants, and Children (WIC) caregivers (N=22) during qualitative interviews about an app for such families.

Reason for deleting an app	Frequency of participant mentions (n)
Do not use it often enough	10
App takes up too much space on phone	6
Children misuse the app	3
App drains battery life of the phone	2
App crashes	2
App is slow to load	1
App is not user friendly/ presents hassles during usage	1

Discussion

Principal Results and Comparison With Prior Work

The participants in this study acknowledged the need for a smartphone app with features that would help WIC families keep track of their food benefits and make shopping for WIC easier, especially following the program transition from paper-based food vouchers to EBT cards for redemption of benefits. For the participants in this study, the balance checker and barcode scanner were the most important app features to include in an app for WIC families. This finding confirmed our observations in a previous review [27] of apps and app features for participating WIC families, where these shopping management features were the most commonly present features, and the importance of these features was demonstrated in positive user reviews.

In a previous study that surveyed WIC participants' current technology usage and preferred methods for interacting with the program, access to the EBT balance (6678/8144, 82%) was reported as highly useful [20]. Nationwide support of EBT for WIC was mandated by 2020 and this technology is not new for some states, although the rollout in most states began within the last 5 years. Wyoming was the earliest adopter of offline EBT for WIC almost 2 decades ago in 2002, whereas New Mexico adopted it in 2007 [23].

A study conducted by the Altarum Institute on behalf of the United States Department of Agriculture (USDA) Economic Research Service that examined the impact of EBT in Kentucky, Michigan, and Nevada (three early adopter states) found positive effects for vendors (less responsibility in policing WIC items for eligibility and quicker receipt of payment) and participants (faster and more discreet checkouts) [25,37]. Focus group participants in the same study expressed that they would like to receive alerts when their benefits are about to expire and would like to access their WIC benefit balance on their smartphones [37]. Similar to the desire for app simplicity and availability in languages other than English among the participants in the current study, the ability to check the WIC balance was notably important for the Spanish-speaking participants in the Altarum study owing to communication barriers with the cashiers when there was an error [37].

The barcode scanning feature was considered important to the participants in this study mainly owing to their negative experiences with WIC item eligibility. Bensley et al also demonstrated that WIC participants would find universal product code (UPC) scanning and verification of WIC items useful (5782/8144, 71%) [20]. Issues at checkout and conflicting information regarding WIC item eligibility remains a barrier to using WIC [13] and is one of the key factors that decrease participants' perceived value of the program [14]. A barcode scanning feature to verify item eligibility and confirm whether or an item remains on the WIC balance could provide a solution to this common barrier to redeem WIC benefits.

Clinic management features, such as receiving appointment reminders, and viewing, requesting, or making a WIC appointment, were popular options among the participants of his study. In a review of WIC apps, the ability to view an upcoming appointment was an available feature in 8 apps and 3 apps could provide appointment reminders. However, only 1 app at the time of the review provided a feature where participants could request an appointment change through the app [27].

Clinic management features like those outlined above require synchronization with participant information within the clinic's management information system (MIS) and efforts from the scheduling staff in the clinics. Access to these systems can pose hurdles for third-party providers of digital tools (such as mobile apps) owing to interface design issues, the inability of an older MIS to support secure communication, or WIC agency data security standards [38]. Guidelines from the NWA put forth for WIC agencies wishing to adopt new technologies urges consideration for interoperability between systems or software before adopting or procuring digital tools and mobile apps [38].

In a review of WIC apps available in other states, vendor location or "Find a WIC Store" features were common in 7 WIC apps, and clinic locators were available in 5 apps [27]. Participants in the current study were more enthusiastic about vendor location features than clinic location features, and those that did respond favorably to having a vendor locator did not consider rate it as high priority in the card sorting activity. This result was perhaps due to the participants' experience with WIC in that none of the participants were new to the program.

Mediocre prioritization of the vendor locator feature may have also been due to the way participants in this study and others did their shopping. Most participants in this study kept their WIC shopping to one or two stores, especially if they received good customer service at a particular store. This finding aligns with Altarum's EBT transition study [37] that reported participants generally shopped at between one and three major stores.

The clinic locator feature was among the lowest prioritized feature by the participants in this study, which was likely because the participants do not change their home WIC clinic unless they move or choose to recertify elsewhere. Recertification is a lengthy process compared to a typical WIC visit, which has been viewed as a burden by some participants [13]. Participants must recertify their eligibility for WIC every 6-12 months depending on the participant category (eg, pregnancy vs. infant vs. child). If participants' household incomes fluctuate, placing them in and out of WIC eligibility, they must recertify each time they become eligible for WIC if they desire to remain in the program.

The recipe gallery, meal planning, and dietary preference setting features in a WIC app were received positively in the qualitative interviews but were ranked with medium priority in the card sorting activity among participants in the current study. Searching for and using online recipes were not novel concepts to the participants, especially compared to the shopping management features for WIC. Similar results were found in the study by Bensley et al, where more participants rated the possibility of EBT balance checking and UPC scanning as useful compared to web-based recipes and cooking demos [20].

In a 2018 review of WIC apps, only 2 other apps (WICShopper and Alabama WIC) included a recipe feature. However, user reviews of other apps in the review did voice a desire for a "healthy eating" section [27]. Medium prioritization of this recipe feature in the current study may have also stemmed from the fact that participants were not yet able to see an actual gallery of recipe photographs during the interviews. Healthy recipe ideas and recipes using WIC foods are not new to the WIC program and are often utilized by WIC nutritionists to share with their clientele or posted on local agency websites [39].

NWA newsletters and reports frequently feature testimonials from WIC participants, exclaiming the positive impacts of the WIC program, staff, and services, including healthy recipe ideas [40]. Cooking Matters [41] and EatFresh [42] are resources that gather cooking ideas, recipes, food budgeting, meal planning, and healthy eating information for low-income families online. Incorporating recipes from resources such as these—along with WIC staff knowledge—into a shared space that WIC participants can access through their smartphones could significantly benefit low-income families.

As with the recipes, health assessments and goal tracking features received lower prioritization and enthusiasm compared to shopping management features from our participants. Engagement with the target audience remains a challenge with respect to nutrition education [43]. Introducing an intervention or health tool through a reputable program such as WIC is thus desirable not only for the ability to reach its eligible audiences, but also for the potential impact it can provide to public health [44].

A 2010 workshop summary entitled Planning a WIC Research Agenda cites that most WIC nutrition education research targets the needs of pregnant or postpartum women, and few studies target the needs of preschool children [44]. Other digital tools and apps focusing solely on WIC nutrition education exist [22,30], as do validated web and paper tools targeting preschool children [45,46]. However, delivering nutrition education–based features paired with an app that participants primarily download to help them with their WIC shopping has the potential to impact more participants than a stand-alone tool.

The participants in this study emphasized the importance of delivering a WIC app that is easy to use, hassle free, and available in many spoken languages. Publicly available user reviews of current WIC apps also demonstrate the desire for simplicity, seamlessness, and ease [27]. Although WIC is a federal program, it is administered at the state level, as are the apps available to participants in each state [27]. WIC is multifaceted at the administrative, vendor, and clinic levels, so an app to help participants is only useful if these systems are well integrated, as noted in a recent WIC app study by Zhang et al [29].

In the current study, the participants mentioned the need to delete apps that required too much storage space on their phones or apps that were "slow to load." Although several low-income households have access to smartphone technology [47], many remain underconnected in that they are only able to access the Internet via their mobile devices [48]. This study highlights many barriers to the successful usage of WIC in its current form and the opportunity to overcome many of these with the transition to an efficient and a useful digital program. However, as revealed by the participant who could not complete the task owing to literacy issues, there might be a risk that some program participants could be left behind owing to low information technology (IT) literacy or limited access to appropriate or suitable devices and the Internet. App developers must be mindful of these issues when designing tools meant to help low-income families.

As our current and ever-changing health care landscape becomes increasingly dependent on technology, the five A's of access (affordability, availability, accessibility, accommodation, and acceptability) must be considered when implementing these systems to ensure equitable care for those who need it the most [49].

Limitations

The current study is not without limitations. Owing to the lack of research on apps that reduce the risk factors of childhood obesity among preschool children, only caregivers of WIC children aged 2 to 4 were recruited, which restricted the enrollment of those newer to the program (ie, pregnant women enrolling for the first time or those enrolling with their first infant). This limitation could have altered the prioritization and desire for certain shopping features (eg, scanner or store locator), though this effect was partially remedied by participants' reflections on the difficulties of being new to the program, compared to navigating the program with experience.

Although all the interview participants spoke English, this was the secondary language for some (6/22) participants in the study. Language barriers that may result from conversing in participants' secondary language can limit the understanding, intention, and interaction between the interviewer and interviewee. As this study was conducted with WIC families in Tennessee, participant responses may not be empirically generalizable for the WIC population in other states or at the national level.

Conclusions

By combining in-depth interviewing with a card sorting activity to prioritize features, this study demonstrates how user-centered design can aid the development of an app for low-income families participating in WIC. As WIC continues to modernize, digital tools (such as mobile apps) are becoming increasingly available to streamline WIC services and improve participant experience [38].

The participants in this study were interested in (1) health and nutrition information (they want to eat nutritious food), (2) a modern and graphic-heavy app (eg, something that feels familiar), and (3) app features that increase the accessibility of the program. WIC agencies in states are tasked with procuring and providing digital tools that are user-friendly for participants, supported by staff, affordable, and cost-effective [38].

The following are a summary of recommendations we identified as a result of conducting this study:

- To increase WIC program participation, states should endeavor to work with vendors that provide user-friendly software applications with user-focused features.
- States should attempt to meet users where they are [50] by considering what will drive value for their users, rather than just meeting the requirements of the program.
- Agencies must consider what long-term maintenance and upgrades their digital tools require, as well as their interoperability between systems [38] (eg, EBT vendor or client information systems).
- As WIC is an evidence-based federal nutrition program, WIC agencies should strive to partner with researchers, developers, and vendors that support apps and other digital tools providing avenues to evaluate their potential impact on public health.

Acknowledgments

This study was funded by a grant from the USDA (grant 2017-68001-26352). The authors would like to acknowledge Vanderbilt University's Qualitative Core and Maureen Nwizu for assisting with interview transcriptions, Healthmade Design for the consultation work on the card sorting activities and interview protocol, and Calvin Harris for assisting with survey data entry.

Authors' Contributions

SJW, ES, SAM, DS, CT, JJ, and PCH contributed to the study design, interpretation of results. SJW, JJ, and PCH conducted participant interviews. SJW developed the qualitative coding structure, conducted the analyses, and wrote the main draft of the article. ES, HA, and MC conducted secondary coding to assure interrater reliability. PCH oversaw the study. All authors contributed to editing and approve the manuscript for publication.

Conflicts of Interest

None declared.

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Abbreviations

CHEW: Children Eating Well
EBT: electronic benefits transfer
eWIC: WIC electronic benefits transfer
IT: information technology
MIS: management information system
NWA: National WIC Association
SNAP: Supplemental Nutrition Assistance Program
UPC: universal product code
USDA: United States Department of Agriculture
WIC: Special Supplemental Nutrition Program for Women, Infants, and Children

Edited by G Eysenbach; submitted 17.05.21; peer-reviewed by L Tully, Q Zhang; comments to author 09.06.21; revised version received 14.06.21; accepted 16.06.21; published 30.07.21.

Please cite as:
Weber SJ, Shearer E, Mulvaney SA, Schmidt D, Thompson C, Jones J, Ahmad H, Coe M, Hull PC
Prioritization of Features for Mobile Apps for Families in a Federal Nutrition Program for Low-Income Women, Infants, and Children: User-Centered Design Approach
JMIR Form Res 2021;5(7):e30450
URL: https://formative.jmir.org/2021/7/e30450
doi:10.2196/30450
PMID:34328432

Original Paper

An Avatar-Led Digital Smoking Cessation Program for Sexual and Gender Minority Young Adults: Intervention Development and Results of a Single-Arm Pilot Trial

Jaimee L Heffner[1], PhD; Noreen L Watson[1], PhD; Edit Serfozo[1], MPH; Megan M Kelly[2,3], PhD; Erin D Reilly[2,3], PhD; Daniella Kim[4], PhD; Kelsey Baker[1], MS; N F N Scout[5], PhD; Maria Karekla[6], PhD

[1]Fred Hutchinson Cancer Research Center, Seattle, WA, United States
[2]Veterans Affairs Bedford Healthcare System, Bedford, MA, United States
[3]University of Massachusetts Medical School, Worcester, MA, United States
[4]University of Washington, Seattle, WA, United States
[5]National LGBT Cancer Network, Providence, RI, United States
[6]University of Cyprus, Nicosia, Cyprus

Corresponding Author:
Jaimee L Heffner, PhD
Fred Hutchinson Cancer Research Center
1100 Fairview Ave N, M3-B232
Seattle, WA, 98109
United States
Phone: 1 2066677314
Email: jheffner@fredhutch.org

Abstract

Background: Sexual and gender minority young adults have a high prevalence of smoking and unique barriers to accessing tobacco treatment.

Objective: To address these challenges as well as their preferences for sexual and gender minority–targeted interventions and digital programs, we developed and evaluated the acceptability, preliminary efficacy, and impact on theory-based change processes of an acceptance and commitment therapy–based digital program called Empowered, Queer, Quitting, and Living (EQQUAL).

Methods: Participants (n=22) of a single-arm trial conducted to evaluate the program were young adults, age 18 to 30 years, who self-identified as sexual and gender minority individuals and smoked at least one cigarette per day. All participants received access to the EQQUAL program. Participants completed web-based surveys at baseline and at a follow-up 2 months after enrollment. We verified self-reported smoking abstinence with biochemical testing; missing data were counted as smoking or using tobacco.

Results: For young adults who logged in at least once (n=18), the mean number of log-ins was 5.5 (SD 3.6), mean number of sessions completed was 3.1 (SD 2.6), and 39% (7/18) completed all 6 sessions. Overall, 93% of participants (14/15) were satisfied with the EQQUAL program, 100% (15/15) found it easy to use, and 100% (15/15) said it helped them be clearer about how to quit. Abstinence from smoking or using tobacco was confirmed with biochemical testing for 23% of participants (5/22). Both quantitative and qualitative results suggested a positive overall response to the avatar guide, with areas for future improvement largely centered on the avatar's appearance and movements.

Conclusions: Treatment acceptability of EQQUAL was very promising. The rate of abstinence, which was biochemically confirmed, was 3 times higher than that of the only other digital program to date that has targeted sexual and gender minority young adults and 6 to 13 times higher than those of nontargeted digital smoking interventions among sexual and gender minority young adults. Planned improvements for the next iteration of the program include making the avatar's movements more natural; offering multiple avatar guides with different on characteristics such as race, ethnicity, and gender identity from which to choose; and providing a support forum for users to connect anonymously with peers.

(JMIR Form Res 2021;5(7):e30241) doi:10.2196/30241

KEYWORDS

LGBT; embodied agent; tobacco cessation; nicotine dependence; user-centered design; avatar; digital health; minority; young adult; teenager; smoking; cessation; intervention; development; pilot trial

Introduction

The prevalence of tobacco use among sexual and gender minority young adults is twice as high as that among non–sexual and gender minority young adults across all tobacco products: 29% vs 15% for cigarettes and 8% vs 4% for both electronic nicotine delivery systems and noncigarette tobacco, respectively [1]. Compounding their risk for tobacco-related diseases, sexual and gender minority young adults also encounter unique barriers to accessing treatment. Almost half of sexual and gender minority young adults lack health insurance to pay for traditional treatments such as counseling and pharmacotherapy [2], and there is substantial underuse of existing public health interventions such as tobacco quitlines among this group [3]. There is tremendous unrealized opportunity to reach these young tobacco users via digital means, because they are high adopters of technology [4] and would benefit from the availability of a high-reach, no-cost intervention due to the multiple barriers they face in accessing traditional forms of treatment. However, only one study [5], published recently, tested a targeted digital intervention—a professionally moderated intervention delivered via Facebook—that was specifically for sexual and gender minority young adults. Although the study showed low biochemically confirmed quit rates overall, it demonstrated the potential efficacy of sexual and gender minority–targeted content, with quit rates for the targeted social media intervention (7%) almost double that of the nontargeted social media intervention (4%) [5].

To address the need for an engaging, effective, and accessible treatment approach for sexual and gender minority young adult tobacco users, we engaged in a user-centered design process to develop a digital cessation program targeted for this group and subsequently conducted a single-arm pilot trial to evaluate its acceptability (primary outcome) and preliminary efficacy (secondary outcome) for motivating and supporting smoking cessation. Acceptability, as well as intervention impact on change processes and outcomes (ie, efficacy), are standard benchmarks in intervention development [6]. Together, they help provide proof-of-concept evidence that users will engage with the intervention and that it can impact theory-based change mechanisms and, ultimately, the outcome of interest. The purpose of this study was to evaluate components of the novel program requiring further refinement and to plan a future randomized clinical trial as a next step in treatment development and evaluation.

Methods

Part 1: User-Centered Design of EQQUAL

The Empowered, Queer, Quitting, and Living (EQQUAL) program is a cultural, linguistic, and sexual and gender minority–targeted adaptation of Flexiquit, a web-based acceptance and commitment therapy (ACT) program designed for young adults at all stages of readiness to quit tobacco use [7]. In addition to focusing on increasing acceptance of smoking triggers and facilitating values-guided action as cessation treatment mechanisms, ACT also teaches generalizable emotion regulation skills that can increase resilience and buffer minority stress [8] among sexual and gender minority young adults. This generalizability stems from a transdiagnostic focus on building psychological flexibility—defined as willingness to experience the full range of emotional, physical, and cognitive experiences without trying to change them and to do things that are difficult in service of one's values [9,10]. EQQUAL also employs another exciting innovation in digital tobacco treatment: an avatar guide designed to make the program more engaging and effective. The original avatar-led Flexiquit program (not sexual and gender minority–targeted) showed great promise in motivating cessation in a pilot randomized controlled trial with young adults in Cyprus, with a 29% posttreatment quit rate for Flexiquit versus 11% for the waitlist [7]. Importantly, the majority (65%) of participants were in the precontemplation or contemplation stages of change, demonstrating the program's utility for smokers who are at lower levels of quit readiness [7].

To adapt the original version of the program, which was created for the general population of young adults in Cyprus, to one for a US young adult population self-identifying as sexual and gender minority, 3 major modifications were needed: (1) translation from Greek to English, (2) adaptation of content for US culture (eg, providing examples and metaphors that are more relevant to life in the US), and (3) adaptation of content to sexual and gender minority young adults. After translation, which occurred from August to September 2018, we followed a user-centered design process to adapt the program for the US culture and to a sexual and gender minority young adult population. This included 2 rounds of preliminary user testing (n=7 participants; 2 self-identified as female, 4 self-identified as male, and 1 did not self-identify as male, female, or transgender; 3 self-identified as bisexual and 4 self-identified as gay or lesbian; 2 self-identified as non-Hispanic White, 1 self-identified as non-Hispanic Asian, 1 as self-identified as non-Hispanic Asian and White, and 3 did not provide their race and ethnicity) and a diary study in which participants used the program for 1 week and provided feedback about it via daily diary entries and a final interview (n=8; 2 self-identified as female, 1 self-identified as male; 5 self-identified as transgender or nonbinary; 1 self-identified as bisexual, 2 self-identified as gay, 2 self-identified as queer, and 2—who self-identified as gender minority—did not provide their sexual orientation; 3 self-identified as non-Hispanic White, 2 self-identified as non-Hispanic Asian, and 3 did not provide their race and ethnicity).

A major focus of the user-centered design work to create EQQUAL was updating the appearance, voice, and persona of the avatar guide. The most recent version of the avatar used in the original, nontargeted Flexiquit program was presented as a young woman (Figure 1). As part of the testing, we evaluated users' reactions to this avatar as well as to several other potential

program guides, including both human and nonhuman representations. Users unanimously preferred a human guide, with desired qualities being inspiring, fun, and sensitive. Users also indicated that they preferred having a visual representation of the program guide, rather than just a voice, as something concrete that they could count on consistently while they completed the program. Visually, users preferred cartoon-like over realistic-looking avatars. They also preferred avatars that appeared to be androgynous or gender ambiguous. Among the possible human representations presented to users, the previous Flexiquit avatar was not preferred. Users agreed that the avatar should have a backstory and share it and that the tone of the avatar should be conversational and informal. Participants wanted to be able to hear and read the content simultaneously. Several options for voices of the avatar were presented, and a preferred voice was selected on the basis of user testing, which was the voice of a young adult woman. Participants also expressed a desire for an avatar that could be customized or selected based on their ability to identify with it or be inspired by it. With the exception of the customizable avatar, which was cost-prohibitive for this phase of development, all of these user preferences were incorporated into the design of the EQQUAL program.

Aside from the new appearance and backstory of the EQQUAL avatar (Figure 2), user-centered design for sexual and gender minority targeting included development of user stories about sexual and gender minority young adults sharing their motivations and successes in quitting smoking. These stories were written by the research team and evaluated during user testing. During the interviews, users also noted a preference for a social component to the program that would allow users to connect anonymously, such as a quit buddy or support group, as well the ability to give and receive kudos for reaching smoking-related milestones. Similar to avatar customization, this functionality was outside of the scope for this phase but is a planned direction for future versions.

In accordance with stated user preferences of accessing the program on a mobile device, we developed EQQUAL as a responsive mobile-optimized website designed to be used primarily on mobile and tablet devices. Programming was completed in May 2020, at which point we launched a single-arm pilot trial to evaluate its acceptability and preliminary efficacy for cessation and impact on theory-based change mechanisms.

Figure 1. Avatar from original, nontargeted Flexiquit.

Figure 2. New sexual and gender minority–targeted Empowered, Queer, Quitting, and Living (EQQUAL) program avatar.

Part 2: Single-Arm Pilot Trial

Participants

Eligibility criteria were individuals (1) between 18 and 30 years of age who (2) self-identified as sexual or gender minority (ie, a sexual orientation other than straight, gender that doesn't match sex assigned at birth, or both); (3) resided in the United States; (4) smoked at least 1 cigarette per day over the past 30 days; (5) had at least weekly internet access and were willing and able to stream video online during the 2-month study period; (6) used text messaging; (7) were not engaged in any other smoking cessation treatment at the time of screening, including pharmacotherapies or behavioral counseling, but excluding e-cigarettes or other vaping devices, which are not approved by the US Food and Drug Administration for smoking cessation; and (8) were comfortable reading, writing, and speaking in English.

Procedures

All study procedures were reviewed and approved by the Scientific Review Committee and the Institutional Review Board of the Fred Hutchinson Cancer Research Center.

Participants were recruited online between May and June 2020 via Facebook and Craigslist advertisements and directed to a screening survey administered via REDCap (Vanderbilt University). To prevent potential fraudulent participation, study staff reviewed the responses of individuals who were potentially eligible for duplicate entries and email addresses were verified. Individuals who were eligible were sent an email indicating their eligibility that required a reply. Individuals who did not reply after 3 attempts (2 reminders were sent over a 14-day period) were no longer contacted for potential recruitment and were sent an email with alternative quit-smoking resources (eg, referrals to 1-800-QUIT-NOW to reach their state quitline and the National Cancer Institute's Smokefree web and mobile app programs).

Individuals who responded to the email were sent another email (and up 2 reminders over a 14-day period, as needed) inviting them to complete a confidential, secure online survey to provide informed consent and complete the baseline assessment. After submitting the baseline assessment, participants received an email indicating that they were enrolled in the study that provided log-in credentials for EQQUAL and information about technical support, study payment, and the follow-up survey. Individuals who did not consent or complete the online enrollment process within 14 days were sent an email notifying them that they were not enrolled; the email provided them with the smoking cessation resources mentioned above.

Two months after enrollment, participants were sent an email inviting them to complete a web-based follow-up survey. A text message was sent on the same day as the email survey invitation to alert participants that the survey would be arriving via email that day. To maximize data retention, participants were sent up to 2 email reminders within 9 days indicating that the follow-up survey was available. Participants who did not complete the survey were called once daily for 5 days and were given the opportunity to complete the follow-up survey by phone. A final attempt was made—a postcard with just 2 follow-up questions (ie, the primary acceptability and efficacy outcome questions) was sent out to those who had not responded by the fifth phone call. Baseline and follow-up survey data were collected and stored in a secure REDCap database.

Participants were compensated US $25 for completing the follow-up survey. To maximize data retention, respondents received a $10 bonus if they completed the survey online within 24 hours of the initial email. Participants who self-reported smoking abstinence were asked to submit saliva cotinine test results and received an additional $25 for doing so. Thus, participants could receive up to $60 in total.

Assessments

The baseline survey collected information on demographic characteristics, use of alcohol and electronic cigarettes, and smoking history and current smoking behaviors, including the Fagerström Test for Nicotine Dependence score [11]. To assess sexual and gender minority identity, we used 3 items based on consensus recommendations [12-14]. Two gender minority items focused on sex and gender identity: "What was your assigned sex at birth, on your original birth certificate?" (response options: male, female); "What is your current gender identity (check all that apply)?" (response options: man/male, woman/female, trans male/trans man, trans female/trans woman, genderqueer/gender nonconforming, different identity, not sure). To assess sexual minority identity, participants were asked: "Do you think of yourself as: (check all that apply):" (response options: straight (heterosexual), bisexual, gay, lesbian, queer, different than listed, not sure). We considered participants whose current gender identities differed from their birth sex or who answered that they were trans male/man, trans female/woman, genderqueer/gender nonconforming, different, or not sure as gender minority. We considered participants who gave any response to the sexual orientation question other than straight/heterosexual as sexual minority. Since recruitment occurred during the early period of the COVID-19 pandemic, we also included 1 question on the baseline survey (ie, "Since learning about the coronavirus—also known as COVID-19—has your smoking decreased, increased, or stayed the same?") and 1 question on the follow-up survey (ie, "Since you started this study, to what extent has the coronavirus—also known as COVID-19—played a role in motivating you to reduce or quit smoking?" Response options were "not at all," "slightly," "somewhat," "moderately, and "extremely") to assess the impact of COVID-19 on baseline smoking and motivation to quit during the treatment period.

Primary treatment acceptability endpoints were (1) server-recorded number of log-ins and number of sessions completed during the 2-month study period, and (2) treatment satisfaction, which was assessed using 12 study-specific items on the follow-up survey (eg, "Overall, how satisfied were you with EQQUAL?"). Secondary endpoints were (1) biochemically confirmed 7-day point prevalence smoking abstinence at 2 months, and (2) changes in readiness to quit smoking from baseline to follow-up 2 months later assessed via the 11-point Contemplation Ladder [15], which ranges from 0 ("No thought about quitting") to 10 ("Taking action to quit (eg, cutting down, enrolling in a program)". Self-reported 7-day point prevalence

abstinence (PPA) from smoking was assessed via the question: "When was the last time you smoked, or even tried, a cigarette?" Responses of "8-30 days ago" and "over 30 days ago" were classified as 7-day PPA. All participants who self-reported 7-day PPA at follow-up and no other nicotine use in the past 7 days were sent Alere iScreen saliva kits via overnight mail to verify their smoking status. The iScreen offers qualitative detection of cotinine in saliva at a cut-off level of 30 ng/mL. Participants were sent instructions to complete the test at home and submit test results via a photo of the completed test uploaded in a REDCap form.

Changes in psychological flexibility, as the theory-based mechanisms of change, from baseline to 2 months were exploratory endpoints. This included (1) changes in acceptance of smoking triggers (emotional and physical subscales of the adapted Avoidance and Inflexibility Scale [16,17], 18 items), (2) overall psychological flexibility (24-item short version of the Multidimensional Psychological Flexibility Inventory [18], which has 2 composite scores representing psychological flexibility and psychological inflexibility), and (3) valued living (10-item Valuing Questionnaire [19], which has 2 subscales representing values progress, 5 items, and values obstruction, 5 items).

We also explored acceptability of the EQQUAL avatar, called Jen, at follow-up 2 months after enrollment using the Agent Persona Inventory [20], which contains 25 items rated on a 1 (strongly disagree) to 5 (strongly agree) scale, with 4 subscales: facilitating learning (10 items; eg, "Jen kept my attention"), credible (5 items; eg, "Jen was knowledgeable"), human-like (5 items; eg, "Jen showed emotion"), and engaging (5 items; eg, "Jen was expressive"). We also included a set of items assessing the avatar's attributes, drawing in part from items on the Robotic Social Attributes Scale [21]. On these items, the avatar's attributes were rated on a 1 (definitely does not describe Jen) to 9 (definitely describes Jen) scale and included the following: pleasant, likable, agreeable, trustworthy, sincere, supportive, relatable, credible, scary, strange, awkward, and judgmental. We also included 4 open-ended, study-specific questions to assess acceptability of the avatar: (1) "Based on your experiences, what were the least important or least useful parts of Jen?" (2) "Based on your experiences, what were the most important or most useful parts of Jen?" (3) "What, if anything, would you change about Jen? Why?" (4) "What additional feedback would you like to provide us about the avatar in the program?"

EQQUAL intervention

Consistent with the original, nontargeted program, EQQUAL contained 6 sessions designed to be completed in order, with a minimum of 3 days between sessions and automated pacing and prompting from the program. Sessions took approximately 10 to 30 minutes to complete. A single text message reminder was used to prompt availability of the next session. Session 1 PDF handouts were emailed to participants 2 days after enrollment, along with instructions for requesting technical support. At the end of the program, participants were sent an email with session handouts.

Content followed the ACT treatment model [9,22]. Session 1 introduced the avatar guide Jen who provided an overview of the program and shared their own story of quitting. Users completed an interactive game to identify personal values guiding quitting and reviewed stories from other sexual and gender minority young adults who quit smoking. Session 2 focused on trigger awareness through interactive questions, graphs, pictures, and experiential exercises and metaphors, and it introduced the ACT concept of creative hopelessness—recognizing that efforts to control thoughts, feelings, or sensations related to smoking can be counterproductive. Session 3 completed the topic of creative hopelessness and introduced cognitive defusion—psychological distancing from thoughts—as an alternative to thought control as a means of achieving goals and living a valued life. Session 4 completed the topic of cognitive defusion, encouraged setting a quit date in the subsequent week, and prompted users to practice defusing from thoughts (eg, "I won't be able to quit") as part of quit planning. Session 5 started with a reflection on the past week's successes and difficulties, introduced acceptance and willingness to have unwanted thoughts and emotions as a means of handling smoking triggers, and covered relapse prevention via self-compassion and recommitment to quitting. Session 6 also started with a reflection on the past week's successes and difficulties, reviewed content from previous sessions, and ended with a video emphasizing the importance of letting go of the need to control internal experiences such as feelings, sensations, and thoughts as a means to achieve goals. EQQUAL also included information about US Food and Drug Administration–approved smoking cessation medications and encouraged users to consider using a medication to support quitting. EQQUAL was accompanied by daily text messages that provided (1) motivational messages, (2) new session availability prompts, and (3) reminders of information discussed in the program.

The sexual and gender minority–targeted treatment content in EQQUAL focused on (1) unique motivations for quitting among sexual and gender minority individuals, such as the desire for freedom to live one's life openly (eg, not having to hide smoking from family, as sexual and gender identity may have been hidden); (2) tools for coping with minority stress and its mental health sequelae (eg, evidence-based ACT skills for depression and anxiety); (3) self-compassion exercises focused on managing internalized shame, which can serve as a trigger for tobacco use; and (4) targeted videos and infographics describing the impact of tobacco use on the LGBTQ+ community. The appearance and backstory of the EQQUAL avatar guide was also designed to suggest that the avatar identified as a sexual and gender minority young adult (Figure 2). Figure 3 shows the program home screen (desktop view), along with examples of the sexual and gender minority–targeted quit stories (Figure 4) and interactive games to promote engagement with the program (Figure 5).

Figure 3. Home page screenshot.

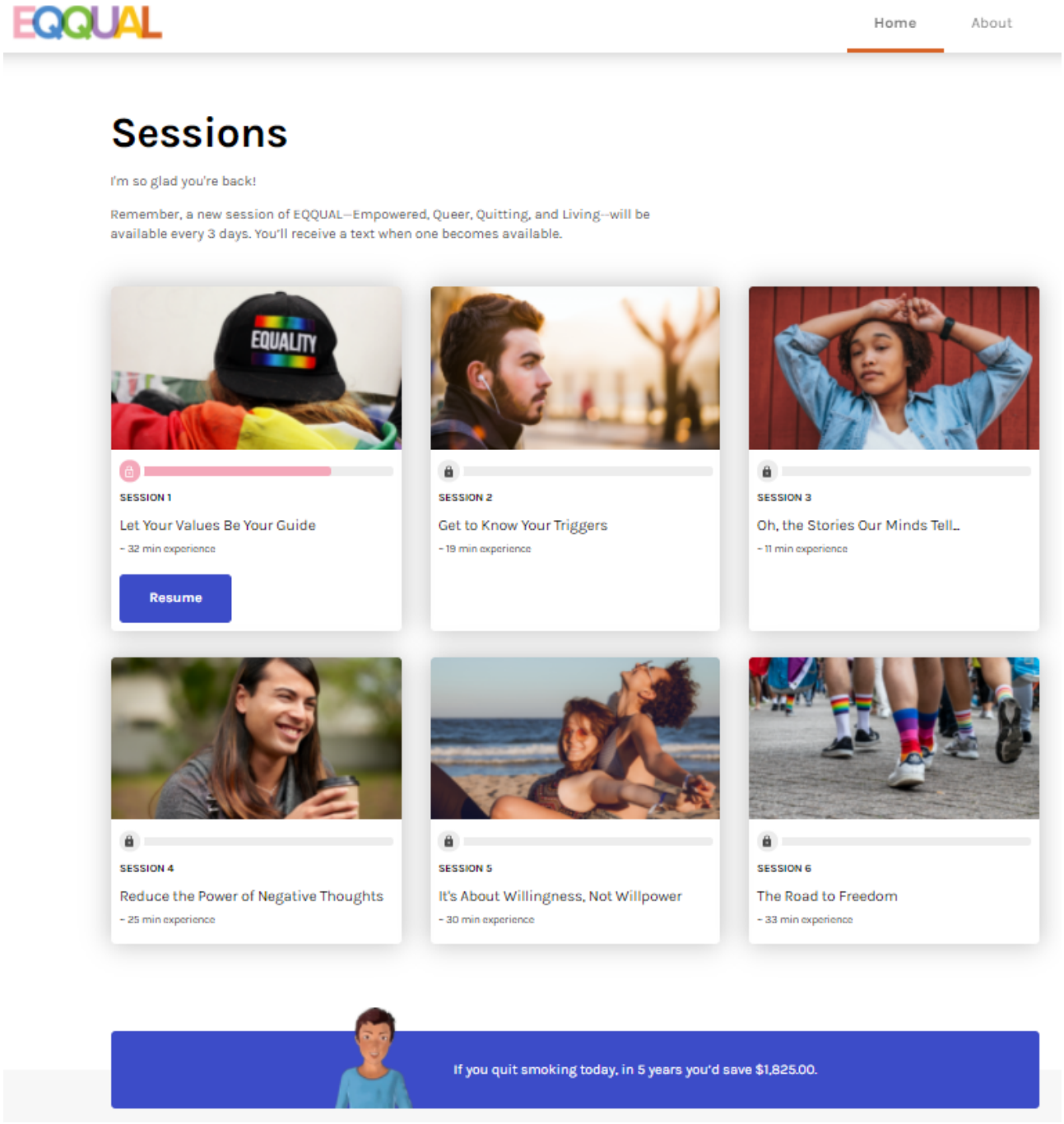
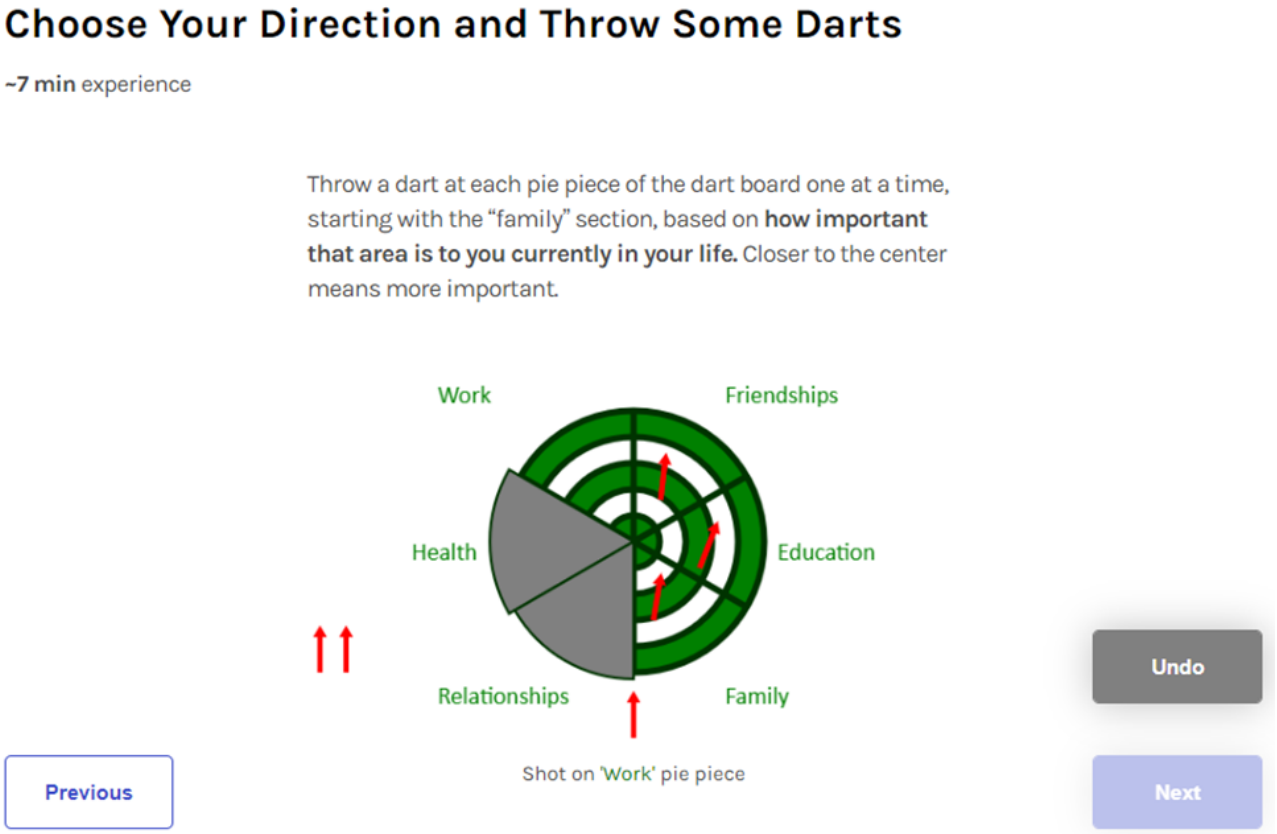


Figure 4. Sexual and gender minority–targeted quit story.

Figure 5. Interactive exercise screenshot.



Analysis

Sample Size

Because pilot trials differ from efficacy trials in their aims and scope, techniques that are employed for sample size determination in an efficacy trial (ie, power analysis) are not appropriate for a Stage 1 pilot trial [23]. The stage model of behavioral treatment development suggests that pilot treatment development trials should include approximately 15 to 30 participants per arm to test feasibility [23]. A sample size of 25 was chosen on the basis of this recommendation. Because this is a single-arm pilot trial, this study is not designed for power to detect statistically significant changes in response to treatment. However, we planned to preliminarily and descriptively assess the outcomes of the intervention to inform further refinements of EQQUAL and obtain the information necessary to optimize the study design in preparation for a subsequent Stage 2 efficacy trial.

Statistical Analysis Plan

Given the pilot nature of the study, all statistical analyses are descriptive. Frequencies (for categorical variables) or means and standard deviations (for continuous variables) are reported for all endpoints, including change scores. Categorical ratings for treatment satisfaction questions were dichotomized as useful ("somewhat," "mostly," or "very") versus lower ratings based on a priori analysis plans (clinicaltrials.gov, NCT04194918). For smoking abstinence outcomes, we report results (1)

including only participants who provided data on smoking abstinence at follow-up (complete-case) and (2) including all participants and imputing missing smoking data as nonabstinence.

Results

General

As planned, we enrolled 25 participants, but we excluded 3 participants postenrollment due to suspected fraudulent behavior (eg, providing different dates of birth at baseline and follow-up), leaving a final sample of 22 (Multimedia Appendix 1). Of these 22 participants, all identified as sexual minority (n=22, of whom 13 self-identified as bisexual, 3 self-identified as gay, and 6 self-identified as lesbian; 5 selected "queer" in addition to one of the other options) and a portion also self-identified as gender minority (n=7, of whom 3 self-identified as a trans man, 3 self-identified as genderqueer, and 1 self-identified as not sure). Over half (12/22; 55%) reported vaping as well as smoking. Ages ranged from 18 to 30, with a mean of 23.5 (SD 3.9). Over one-quarter (6/22; 27%) self-identified as racial minorities (n=1 self-identified as American Indian/Alaska Native, n=3 self-identified as Asian, n=2 self-identified as more than one race). The majority were employed (16/22; 73%) or in school (4/22; 18%) and were in a committed relationship (14/22; 64%). Average number of cigarettes smoked per day was 7.6 (SD 9.5), with a mean Fagerström Test for Nicotine Dependence score of 3.9 (SD 2.3). Baseline readiness to quit smoking ranged from 0 to 10 on the Contemplation Ladder, with a mean of 6.2 (SD 2.7). Regarding the impact of the COVID-19 pandemic on participants' smoking, at baseline, the majority of participants (12/22; 54.5%) indicated that their smoking had stayed the same, 7/22 (31.8%) indicated that it increased, and 3/22 (13.6%) indicated that it had decreased. At follow-up, participants reported the extent to which COVID-19 played a role in motivating them to reduce or quit smoking as not at all (3/17; 17.6%), slightly (6/17; 35.3%), somewhat (2/17; 11.8%), moderately (3/17; 17.6%), or extremely (3/17; 17.6%).

Design Feasibility

We screened 118 individuals over a 1-month period to enroll 22 participants. Recruitment occurred via Facebook (61% of those screened) and Craigslist advertisements (39%). Seventeen participants completed the follow-up survey (77% data retention). All 17 completed the survey online; 8 participants completed the survey within 24 hours of receiving the link, 3 participants completed the survey after 1 or 2 email reminders, and 6 participants completed the survey after 2 email reminders and 1 or more phone call reminders. Six participants who self-reported 7-day PPA from smoking and indicated using no other sources of nicotine during those 7 days were sent a cotinine kit, and all 6 (100% adherence) submitted a photo of the completed test as requested. One participant reported abstinence from cigarettes but use of other nicotine-containing products and was not sent a cotinine test kit.

Primary Endpoint

Among those with at least 1 log-in (n=18), the mean number of log-ins was 5.5 (SD 3.6), mean sessions completed was 3.1 (SD 2.6), and 39% of participants (7/18) completed all 6 sessions. Among follow-up respondents who provided satisfaction ratings (n=15), 93% (14/15) rated EQQUAL as useful, 93% (14/15) reported being satisfied with the program, and 87% (13/15) said they would recommend it to a friend. Considering specific program components, 71% (10/14) felt that text messages were useful and 93% (14/15) reported that PDF handouts (eg, health benefits of quitting, smoking and the LGBTQ+ community) were useful. All but 1 participant (93%; 14/15) said they felt as though the program was made for them. All participants (15/15; 100%) said the program was easy to navigate, 100% (15/15) reported that they felt more clear about how they might quit as a result of using the program, and 93% (14/15) said it gave them new ways of looking at quitting.

Secondary Endpoints

Biochemically confirmed 7-day PPA was 22.7% (5/22) with missing data imputed as continued smoking (missing=smoking), and 31.3% (5/16) using the complete-case method. Self-reported 7-day PPA was 31.8% (7/22) in the missing=smoking analysis and 41% (7/17) in complete-case analyses. Participants also showed an overall increase in readiness to quit, averaging a 2.1-point increase (SD 3.0) on the 11-point Contemplation Ladder from baseline to 2 months.

To understand the relationship between smoking abstinence and "dosage" received of the EQQUAL program, we descriptively examined, as a post hoc analysis, differences in program usage between those participants who achieved biochemically confirmed, missing=smoking 7-day PPA (n=5) to those who didn't (n=17). Smoking abstainers had numerically higher program usage metrics than nonabstainers, including number of log-ins (mean 7.2, SD 3.9 for abstainers; mean 3.7, SD 3.6 for nonabstainers), number of sessions completed (mean 4.8, SD 2.7 for abstainers; mean 1.8, SD 2.3 or nonabstainers), and completion of all 6 sessions (80% of abstainers; 18% of nonabstainers).

Exploratory Endpoints

Exploration of changes in values-based action on the Valuing Questionnaire [19]) showed a modest increase in Values Progress (mean +2.9, SD 4.4) and decrease in Values Obstruction (mean –3.3, SD 7.3). Acceptance of smoking triggers on the Avoidance and Inflexibility Scale [16] showed minimal average change from baseline to follow-up (mean +0.2, SD 0.8 for the emotions subscale score, mean –0.03, SD 0.9 on the physical sensations scale). On the Multidimensional Psychological Flexibility Inventory, the change in the psychological flexibility composite score from baseline to follow-up was + 0.3 (SD 0.8), and the change in the psychological inflexibility composite score was –0.3 (SD 1.2). In sum, the mean changes in the ACT-based measures of psychological flexibility were almost all in the hypothesized direction (ie, representing increased psychological flexibility and decreased inflexibility), albeit with low overall magnitude.

On the Agent Persona Inventory, all subscale scores suggested positive overall impressions of the avatar: facilitating learning (mean 41.9, SD 9.8, on a scale of 10-50), credible (mean 20.7, SD 5.2, on a scale of 5-25), human-like (mean 19.7, SD 5.1, on

a scale of 5-25), and engaging (mean 20.4, SD 5.1, on a scale of 5-25). On items where participants rated the avatar's attributes on a 1 to 9 scale from "definitely does not describe Jen" to "definitely describes Jen," all of the positive attributes were rated highly: pleasant (mean 7.4, SD 2), likable (mean 7.5, SD 2), agreeable (mean 7.5, SD 2), trustworthy (mean 7.3, SD 2.1), sincere (mean 7.7, SD 2), supportive (mean 7.7, SD 2), relatable (mean 7, SD 2.3), and credible (mean 7, SD 2). Negative attributes all had lower scores: scary (mean 1.8, SD 1.4), strange (mean 2.4, SD 2), awkward (mean 2.5, SD 2.3), and judgmental (mean 2.3, SD 2.6).

Qualitative responses confirmed and extended the quantitative findings as well as suggesting specific areas for avatar improvement. Overall, we saw evidence that efforts to present Jen as human-like, supportive, nonjudgmental, and credible were effective. For example,

> *She encouraged me when I thought I couldn't quit smoking.*
>
> *...[I liked] how she seemed very intelligent.*
>
> *She made it feel like a real person was there.*
>
> *...[I liked] her approachable, nonjudgmental tone.*

One participant even reported of Jen,

> *I'm in love with her.*

When asked what they would change about Jen, 2 dominant themes emerged: (1) making the body movements more natural

> *She just kinda moved a little awkwardly*

and (2) the need for the participant to be able to see themselves in the avatar's appearance and voice

> *She should be a person of color so I can relate to her more.*

Discussion

The aim of this work was to develop and evaluate the acceptability and preliminary efficacy of an avatar-led digital smoking cessation program targeted for sexual and gender minority young adults. The product of our user-centered design work, the EQQUAL program, demonstrated strong acceptability and efficacy in a single-arm pilot trial with 22 sexual and gender minority young adults. For example, 93% of participants (14/15) were satisfied with the EQQUAL program, 100% (15/15) found it easy to use, and 100% (15/15) said it helped them be clearer about how to quit. Both quantitative and qualitative results suggested a positive overall response to the avatar, with areas for future improvement largely centered on the avatar's appearance and movements. Regarding treatment utilization, including only those who logged in at least once (n=18), participants logged in an average of 6 times and completed an average of 3 sessions, with 39% completing all 6 sessions. This suggests that there is room for improvement in keeping users engaged with the program as a means of enhancing outcomes [24]. Indeed, our post hoc analysis suggested that there may be a relationship between engagement and outcomes given that 80% (4/5) of the participants who quit smoking completed all 6 sessions compared with only 18% (3/17) of the participants who did not quit. In addition to avatar improvements (eg, making the avatar's body movements more natural) and customization options (eg, offering choice of avatars with varying gender expression, race, ethnicity, etc), in future iterations of the program, we also plan to implement a social feature that was suggested by users in the initial user-centered design work but was out of scope for the present work. Social connectedness has been demonstrated to increase engagement in other digital programs [25] and was associated with better engagement and abstinence outcomes in an online tobacco treatment program [26,27]. In addition, to prompt continued program use, we plan to include multiple session availability reminders rather than relying on a single reminder when a new session becomes available.

Compared to the only other targeted digital intervention for sexual and gender minority young adults—a professionally moderated Facebook intervention—the self-guided EQQUAL program's biochemically confirmed quit rate was over 3 times higher (22.7% vs 7.1%) [5]. It is also 6 to 10 times higher than biochemically confirmed quit rates for the nontargeted Facebook intervention (3.7%) and the Smokefree website (1.7%) arms in the same study [5]. It is worth noting that study participants' readiness to quit smoking at baseline spanned the full range of the Contemplation Ladder, from 0 to 10, suggesting that even sexual and gender minority young adults with very low motivation to quit may be willing to engage with, and may benefit from, an intervention that is designed for smokers at all levels of quit readiness. This was the case in the original Flexiquit trial, where a 29% quit rate was obtained even though 65% of the sample reported low readiness to quit at baseline [7].

In order to understand the impact of the EQQUAL program on ACT's key theory-based change mechanisms, we included several measures of psychological flexibility, which generally showed modest theory-consistent improvements. The largest improvements were observed for the Values Questionnaire. Greater change on the Values Questionnaire may be due to the heavy emphasis on values in the first 2 sessions, with the treatment dosage of later acceptance-based content limited by less engagement with the latter sessions. Alternatively, it could be that the values-based action component of psychological flexibility precedes changes in other processes that take longer to develop in this new context of ACT for smokers across all stages of quit readiness, as has been observed in studies of ACT for other conditions [28].

This study had a number of limitations that should be considered when interpreting the results. Primary limitations stem from the small sample size and that causality cannot be determined from a single-arm pilot trial; therefore, conclusions about EQQUAL's efficacy or impact on theory-based change mechanisms are tentative and require evaluation in a larger, controlled clinical trial. Due to the small sample size, representativeness and generalizability are limited. For example, although 25% of the sample identified as a racial or ethnic minority, not every race and ethnicity could be represented. Another limitation concerning the generalizability of findings is that the data were collected during the early period of the COVID-19 pandemic, which may have impacted participants' perceptions of the

EQQUAL program and their willingness and ability to quit smoking. Based on the COVID-19-related questions that we included in the baseline and follow-up surveys, there were mixed findings regarding the pandemic's impact on smoking and motivation to reduce or quit, with some participants reporting little or no impact, some increasing their smoking, and some decreasing their smoking or experiencing increased motivation to reduce or quit smoking. Overall, the reported intensity of smoking at baseline (ie, averaging 7.6 cigarettes per day) is not atypical, as a majority of young adults smoke less than one-half pack (ie, less than 10 cigarettes) per day [29]. Another limitation is that it was not feasible in this pilot trial to conduct the testing that would allow us to biochemically verify smoking abstinence among participants who used other nicotine and tobacco products (eg, e-cigarettes). In future work, we plan to use a multimethod approach combining remote carbon monoxide monitoring with cotinine testing to address this limitation.

In spite of the study's limitations, this work is significant and innovative in 5 key respects: (1) It focuses on a tobacco-related health disparities group that has been underserved in health-related research to date and in tobacco treatment research in particular. (2) It is the first evaluation of a self-guided digital cessation treatment for sexual and gender minority young adults, maximizing scalability and addressing sexual and gender minority youths' desire for a program targeted to their unique needs and challenges. (3) It applies a novel treatment approach and advances the science of ACT for tobacco cessation by testing its effectiveness for tobacco users at all stages of readiness to quit rather than only among those who are ready to quit. (4) The self-guided, digital format makes EQQUAL readily accessible to sexual and gender minority young adults who lack health insurance and who have low engagement and quit rates with currently available public health interventions for cessation. (5) Using avatars and interactive games as engagement strategies is substantially different than existing treatments. These strengths warrant continued development and evaluation of the EQQUAL program in a randomized controlled pilot trial.

Acknowledgments

The authors wish to thank Artemis Theofanous, Masters Candidate, at the University of Cyprus, for translating the Flexiquit program into English; Claudia Rice, BA, for assisting with treatment development; and Melissa Gasser, MS, for providing input into the program design and evaluation. The project also benefitted from the design and development work completed by Cyprus-based Silversky3D Virtual Reality Ltd, as well as Seattle-based Moby Inc. We also thank AsapSCIENCE for permitting us to use their whiteboard video, called What Happens When You Stop Smoking, in the EQQUAL intervention. Finally, we wish to thank the study participants who gave feedback in both the user-centered design and clinical trial phases of the project.

Conflicts of Interest

JLH has received research support from Pfizer.

Multimedia Appendix 1
EQQUAL participant flow diagram.
[DOCX File , 40 KB - formative_v5i7e30241_app1.docx]

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Abbreviations

ACT: acceptance and commitment therapy
COVID-19: coronavirus disease 2019
EQQUAL: Empowered, Queer, Quitting, and Living program
PPA: point prevalence abstinence

Edited by G Eysenbach; submitted 06.05.21; peer-reviewed by O Ganz, R Paz Castro; comments to author 28.05.21; revised version received 09.06.21; accepted 06.07.21; published 30.07.21.

Please cite as:
Heffner JL, Watson NL, Serfozo E, Kelly MM, Reilly ED, Kim D, Baker K, Scout NFN, Karekla M
An Avatar-Led Digital Smoking Cessation Program for Sexual and Gender Minority Young Adults: Intervention Development and Results of a Single-Arm Pilot Trial
JMIR Form Res 2021;5(7):e30241
URL: https://formative.jmir.org/2021/7/e30241
doi:10.2196/30241
PMID:34328430

Original Paper

Improving Diabetes Self-management by Providing Continuous Positive Airway Pressure Treatment to Patients With Obstructive Sleep Apnea and Type 2 Diabetes: Qualitative Exploratory Interview Study

Ditte Hjorth Laursen[1*], BA, MSc, PhD; Gitte Rom[1*], BA; Anne Margareta Banghøj[2*], MD, PhD; Lise Tarnow[2,3*], MD, DMSc; Lone Schou[1*], BA, MPH, PhD

[1]Institute of Nursing, University College Copenhagen, Copenhagen, Denmark

[2]Department of Endocrinology and Nephrology, Hillerød Hospital, Hillerød, Denmark

[3]Steno Diabetes Center Sjælland, Holbæk, Denmark

[*]all authors contributed equally

Corresponding Author:
Ditte Hjorth Laursen, BA, MSc, PhD
Institute of Nursing
University College Copenhagen
Tagensvej 86
Copenhagen, 2200
Denmark
Phone: 45 61303770
Email: dittehjorth@gmail.com

Abstract

Background: There is a high prevalence of unexplained and unexplored obstructive sleep apnea (OSA) among patients with type 2 diabetes. The daytime symptoms of OSA include severe fatigue, cognitive problems, a decreased quality of life, and the reduced motivation to perform self-care. These symptoms impair the management of both diabetes and daily life. OSA may therefore have negative implications for diabetes self-management. Continuous positive airway pressure (CPAP) therapy is used to treat OSA. This treatment improves sleep quality, insulin resistance, and glycemic control. Although the benefits of using CPAP as a treatment for OSA are clear, the noncompliance rate is high, and the evidence for the perceived effect that CPAP treatment has on patients with type 2 diabetes and OSA is poor.

Objective: The purpose of this study was to analyze the impacts that comorbid diabetes and OSA have on the daily lives of older adults and to investigate the perceived effect that CPAP treatment for OSA has on patients' diabetes self-management.

Methods: A qualitative follow-up study that involved in-depth, semistructured dyad interviews with couples before and after CPAP treatment (N=22) was conducted. Patients were recruited from the Hilleroed Hospital in Denmark and were all diagnosed with type 2 diabetes, aged >18 years, and had an apnea-hypopnea index of ≥15. All interviews were coded and analyzed via thematic analysis.

Results: The results showed that patients and their partners did not consider OSA to be a serious disorder, as they believed that OSA symptoms were similar to those of the process of aging. Patients experienced poor nocturnal sleep, took frequent daytime naps, exhibited reduced cognitive function, and had low levels of physical activity and a high-calorie diet. These factors negatively influenced their diabetes self-management. Despite the immediate benefit of CPAP treatment, most patients (11/12, 92%) faced technical challenges when using the CPAP device. Only the patients with severe OSA symptoms that affected their daily lives overcame the challenges of using the CPAP device and thereby improved their diabetes self-management. Patients with less severe symptoms rated CPAP-related challenges as more burdensome than their symptoms.

Conclusions: If used correctly, CPAP has the potential to significantly improve OSA, resulting in better sleep quality; improved physical activity; improved diet; and, in the end, better diabetes self-management. However, there are many barriers to undergoing CPAP treatment, and only few patients manage to overcome these barriers and comply with correct treatment.

(JMIR Form Res 2021;5(7):e27062) doi:10.2196/27062

KEYWORDS

diabetes; diabetes self-management; obstructive sleep apnea; continued positive airway pressure; sleep patterns; sleepiness in daily life; sleep apnea; elderly; sleep

Introduction

Type 2 diabetes is one of the most prevalent chronic diseases worldwide and is a lifelong condition with many complications [1,2] that affect the physical, psychological, and social aspects of everyday life [3]. Effective self-management by patients is an important part of diabetes care [4], but poor sleep reduces their motivation to perform self-care and thus impairs their management of both diabetes and daily life [5-7].

A high prevalence of obstructive sleep apnea (OSA) has been documented among patients with diabetes; prevalence estimates range from 23% to 60% [5,8]. This range is much higher than the estimated prevalence rates of OSA in the general population, which are 6% in men and 4% in women [9]. Patients with OSA are often not aware of the nocturnal apneic events that they experience and the fact that daytime symptoms reflect an underlying disorder; thus, they do not seek help [9]. OSA is of great concern for people with diabetes [10]. Further, OSA can result in many complications that affect diabetes self-management. Some of these complications include impaired short-term memory, dietary challenges, and a lack of energy for performing physical activities and taking medicine [11]. Moreover, both OSA and diabetes substantially increase the risk of cardiovascular diseases [12].

OSA is characterized by recurrent episodes of apnea and hypopnea during sleep. It has varying levels of severity, which range from a few to several hundred apneic events per night [13]. Daytime symptoms vary from none to severe fatigue, cognitive problems, a decreased quality of life, and the reduced motivation to perform self-care [5-7]. Medication management, which is critical to diabetes self-management, can also be influenced by daytime sleepiness. The prevalence of OSA increases with age [14], and OSA increases the risk of mortality [13]. A large gap exists in literature related to the potential negative impact that comorbid OSA and diabetes have on daily life. Continuous positive airway pressure (CPAP) therapy is used to treat OSA. In CPAP therapy, a CPAP device is used to deliver air to a mask that patients wear over their nose and mouth and to help patients breathe consistently. Using CPAP as a treatment for OSA can improve sleep quality, mood, and functional status [6]. Furthermore, CPAP reduces the rate of nocturnal urination, cardiovascular disease risk, and the incidence of daytime sleep problems and car accidents among patients with OSA [6]. In addition, adequate CPAP therapy may improve insulin resistance and glycemic control in the long term [7,14]. However, although there are many benefits to CPAP treatment, in some studies, noncompliance rates reach up to 56%, and many patients stop using the CPAP machine during the first month [15]. There is poor evidence on the perceived effect of CPAP treatment and whether CPAP could be related to an improvement in diabetes management among patients with OSA.

The purpose of this study was to analyze the impacts that comorbid diabetes and OSA have on the daily lives of older adults and to investigate the perceived effect that CPAP treatment for OSA has on patients' diabetes self-management.

Methods

Study Design

This was a qualitative follow-up study in which dyad interviews with couples were conducted before and after CPAP treatment. Dyadic interviews draw on the interdependence of two informants as a source of data. Patients with diabetes and OSA and their partners were interviewed simultaneously via joint interviews before and after the intervention [16,17]. Conducting joint dyadic interviews prompts couples to inspire, contrast with, or support each other when exploring their situation [16] because patients often do not even register that they have sleep apnea. This qualitative study was conducted from 2016 to 2017.

Participants

Participants were recruited from Nordsjællands Hospital, wherein they were a part of a randomized controlled trial—the DiaBOSA (Diabetes and Obstructive Sleep Apnoea) trial (ClinicalTrials.gov identifier: NCT02482584) [18].

The DiaBOSA trial analyzed different disease-related aspects of patients with type 2 diabetes and newly diagnosed OSA. Our qualitative study was a substudy of the DiaBOSA study, which used the same population.

The patient characteristics for this study were a diagnosis of type 2 diabetes; an age of >18 years; and OSA, which was defined as having an apnea-hypopnea index (AHI) ≥15 (measured using ResMed's ApneaLink Air). An AHI of >15 indicates moderate OSA, and an AHI of >30 indicates severe OSA, according to the American Academy of Sleep Medicine guidelines [19]. All participants thus had OSA, even though they were not aware of the diagnosis prior to this study.

During patients' enrollment in the DiaBOSA trial (N=70), the physician informed the participants about the qualitative study. The authors (DHL and GR) invited the participants, seeking to enroll as many as possibly while also seeking diversity among participants in terms of sex and age. More men than women were enrolled in the DiaBOSA trial. This reflected the proportions of men and women with OSA in general. These proportions were also represented in our qualitative study.

Data Collection and Analysis

Participants were included until the interviews revealed no new information and the criteria for information power were met. The criteria included a high quality for all interviews and sufficient data for carrying out the analytical strategy [20]. The semistructured question guide covered sleep-related issues that occurred during daily living, the impact that OSA had on participants' and partners' lives, an exploration of patients' sleeping schedules with a special focus on nightly activities,

the limitations of daily living resulting from both OSA and diabetes, and the correlation between OSA and diabetes. The questions also broadly focused on all of the concerns surrounding CPAP treatment. In the data analysis, the perspective of the patients was our primary focus; the partners' perspectives were used to support the statements of the patients.

All interviews took place in patients' homes, were conducted by 1 or 2 authors, and lasted approximately 60 minutes (range 35-80 minutes). Interviews were recorded, transcribed, and coded using Nvivo version 11 (QSR International).

For the thematic analysis [21], all interviews were read in their entirety and subjected to a systematic coding process. By using Nvivo version 11, a sample of the data was coded individually by the first or second author, after which a coding manual was developed. All interviews were coded by using the manual, which was refined throughout the coding process until all data were organized into meaningful codes. During analyses, the authors discussed any coding uncertainties, and additional codes were developed. Afterward, detailed coded text segments were reviewed and condensed into potential themes [21], and content within themes was reviewed to ensure that they were internally consistent and mutually exclusive.

Ethical Approval

This study was approved by the Danish Data Protection Agency (journal number: 2012-58-0004). All participants provided written consent after being informed about anonymity and their ability to withdraw from the interview at any time without consequences for future care (in accordance with the Helsinki Declaration).

Results

Participants' Characteristics

The recruited patients—9 men and 3 women—were aged 56 to 75 years; their partners were aged 59 to 75 years. AHIs ranged from 16 to 64; 7 patients had moderate OSA with an AHI of 15 to 29, and 5 had severe OSA with an AHI of >30. The average number of years since type 2 diabetes mellitus diagnosis was 17 years (range 1-44 years), and all patients had elevated hemoglobin A_{1c} levels (range 54-85 mmol/mol; Table 1).

Table 1. Patient characteristics (N=12).

Characteristics	Values
Male, n	9
Patient age (years), mean (range)	67 (56-75)
Partner age (years), mean (range)	66 (59-75)
Duration of diabetes (years), mean (range)	17 (1-44)
BMI (kg/m²), mean (range)	33.9 (28.6-39.1)
HbA_{1c}[a] level (mmol/mol), mean (range)	67 (54-85)
Patients with retinopathy, n	2
Patients experiencing elevated urinary albumin excretion[b], n	4
Vibrations perception threshold (V), mean (range)	25 (10-50)
Patients with cardiovascular disease[c], n	4
Systolic blood pressure (mmHg), mean (range)	142 (114-174)
Diastolic blood pressure (mmHg), mean (range)	79 (70-91)
Apnea-hypopnea index (number of events per hour), mean (range)	31 (16-64)

[a]HbA_{1c}: hemoglobin A_{1c}.

[b]A urinary albumin excretion level of above 30 mg/g (albuminuria).

[c]Cardiovascular diseases include myocardial infarction, stroke, and coronary artery bypass graft disease.

Semistructured interviews were conducted with 22 ethnic Danes—12 patients and 10 partners—before they started CPAP treatment. A total of 16 participants (representing both patients and partners) participated in follow-up interviews 3 months after CPAP treatment. Further, 1 patient died during the follow-up period, and 2 patients did not want to participate in the follow-up interviews.

There were large differences in how the participants experienced OSA. Of the 12 patients, 6 had been affected by symptoms of OSA in their everyday lives, while 6 had never anticipated that they would be diagnosed with OSA. Depending on how they experienced their sleep problems, there were differences in how they approached CPAP treatment. These differences had an impact on the structure of the themes for the thematic analysis. A total of 4 overall themes were identified; they are presented in the following sections: *Experiencing Sleep Apnea in Daily Living*, *Changing Sleep Patterns*, *Technical Difficulties in Using the CPAP Device*, and *Part 2: Implications for Diabetes Self-management*. The following results have thus been divided into 2 parts. Part 1 explains the impact that OSA has on daily living and the difficulties in using the CPAP device. Part 2 describes how CPAP treatment has the potential to improve participants' diabetes self-management.

All 9 follow-up patients were treated with CPAP. The time spent using the CPAP machine varied from 3 days to 3 months.

Part 1

Experiencing Sleep Apnea in Daily Living

There was a clear lack of knowledge about OSA among patients with diabetes. When being diagnosed with OSA, all participants expressed surprise about their diagnosis. One patient said:

> *I did not think this sleep apnea was serious, but now I can see how serious it is and how many comorbidities that follow.* [Patient #1]

Both patients and partners frequently commented that they had never anticipated an OSA diagnosis. One patient said:

> *I had no idea that I had sleep apnea. I have never, ever thought about it.* [Patient #5]

Some participants thought that being tired was simply part of becoming older. One patient stated:

> *I have simply interpreted it as old age beginning to present itself.* [Patient #4]

Although they were told that they stopped breathing during the night, the patients had never taken it seriously or considered it to be a symptom of a disease.

A characteristic feature of OSA is constant sleepiness. Although some patients did not recognize a pattern of persistent sleepiness, it was prominently featured in the experiences of others. This was described by a female patient, as follows:

> *I'm tired when I get up and I'm tired when I go to bed, right, and I don't really do anything, because I'm a senior citizen.* [Patient #6]

Many patients explained that when they are awake at night, they spend their time by using the computer while eating unhealthy snacks.

Changing Sleep Patterns

One of the major challenges of sleep apnea is a lack of consistent sleep; patients sleep in short intervals. One patient said:

> *If I sleep three hours straight, it's a lot. But it's usually two hours.* [Patient #6]

Patients did not feel rested when they woke up in the morning after many short intervals of sleep during the night. This often resulted in napping during the day, and up to 4 naps were not uncommon among the study participants. The common belief among patients and partners was that napping was a natural part of becoming older. One partner stated:

> *When you are 67 years old, you have the right to take a nap, right?* [Partner #7]

None of the patients viewed napping as a burden. Some of the partners did express concern about their nightly situations and explained what they did to make the patient breathe again. A partner said:

> *Well, it is not so fun to know that he is lying there not breathing…what if he does not wake up again, right?* [Partner #5]

The patients who were motivated to continue CPAP treatment did not have more than 1 to 2 hours of continuous sleep for a long period before starting treatment. This had had a major impact on their quality of life. Thus, they were motivated to use the CPAP device. They used the CPAP device every night for 4 to 6 hours and experienced immediate beneficial effects. A patient stated:

> *Then in the months I've had CPAP I've been sleeping 5-6 hours every night. The first night I slept for seven hours, uninterrupted.* [Patient #5]

Another benefit that patients experienced was waking up less frequently, and if they did wake up, it was only for a short period. One patient said that before CPAP treatment, he was awake for 2 to 3 hours every night. However, after CPAP treatment, he was only awake for half an hour. Several patients indicated that after CPAP treatment, the quality of their sleep changed; they slept better, quieter, and deeper at night.

Technical Difficulties in Using the CPAP Device

Despite the immediate benefit of CPAP treatment, most of the patients experienced technical challenges when using the CPAP mask and machine. The patients who were motivated to undergo CPAP treatment quickly became accustomed to using the CPAP device. One of the typical difficulties that patients experienced was finding the mask that best fit them. Patients who experienced persistent technical challenges typically used the CPAP device for 1 to 2 hours per night if they could make it work at all. Patient #12 had to try 4 different masks before he found one that worked. A small proportion of patients (2/12, 17%) opted to stop CPAP therapy because they could not make the device work properly. Furthermore, some of the patients only tried using the mask and machine a few times before stopping CPAP therapy. For example, one patient said:

> *Well, I had it one night and I took it off. I could not rest at all.* [Patient #7]

The main technical challenge was that the mask did not fit the shape of patients' faces. The CPAP mask did not fit tightly; therefore, air blew into patients' eyes, which made them very uncomfortable. Patients were also concerned about the hose, which can be too short or too long; they were worried that the hose would crack. Some of the partners felt annoyed by the sound of air and noise from the machine. Further, some patients found that they could not draw air and breathe freely and thus felt like they were being suffocated. One patient stated:

> *Yes, I did [panic], because I wasn't fully awake, and I couldn't get the mask off. It was awful.* [Patient #7]

When using the CPAP device, one must breathe with their mouth shut and exhale with resistance. This was a challenge for most patients, but some became accustomed to it. One patient said:

> *I feel I need to adjust my breathing to the machine, but I shouldn't, it does it for me. But I'm getting used to it and it's getting better and better. And then I learned how to slow down the blowing from the machine which helped.* [Patient #5]

Part 2: Implications for Diabetes Self-management

All participants reported a decline in their memory over the previous few years. This decline in short-term memory was of great concern to all patients and their partners. As several couples were very worried about this, several patients underwent testing for dementia; all tests were negative.

As shown in Table 1, all patients were receiving treatment for diabetes. Nearly all patients had developed daily routines for taking their medications on time, such as placing small notes on a table or using an alarm. Unfortunately, the notes were often misplaced, and patients often forgot to take their medicine. Additionally, two patients reported struggling with medication management due to sleepiness. One patient was often asleep when she was supposed to take her medication and struggled to manage her blood glucose levels. All patients knew that they should have a healthier diet. However, in their daily lives, they ate what they wanted and did not focus on their diabetes. Other couples explained that they often did not plan dinner in advance, which frequently resulted in eating fast food.

Participants reported consuming large amounts of candy and cake. Despite knowing that they should not eat sweets, many could not help themselves. For example, one partner said:

> *He feels like an addict if there is a cake.* [Partner #2]

Even though many participants reported that they ate many sweets, no one thought that this was related to OSA.

Several participants described being physically active during their youth. However, at the time of the baseline interviews, more than half of participating patients (9/12, 75%) did not exercise at all, and those who were still active had reduced their exercise intensity substantially. After initiating CPAP treatment, changes were observed in factors related to patients' diabetes self-management. First, several of the patients felt well rested and healthier in the morning, and this feeling had a direct influence on their memory. They missed fewer appointments with their health care provider and could more easily recall when to take the right medicine. Some of the patients also described having the energy to eat healthier, exercise, and manage work tasks that they were not been able to perform for several years. One of the patients lost 10 kg during the 3-month test phase due to experiencing better sleep, which was the result of no longer eating during the night and being less hungry for snacks during the day. Several participants also explained how they started exercising again due to having more energy and being less tired. A combination of regular medicine intake, a well-regulated diet, and an increase in activity levels also improved several of the participants' glucose levels. Due to improved sleep, patients needed fewer naps during the daytime, which improved their social relationships and had a positive impact on their partners.

Discussion

Principal Findings

Patients with OSA and diabetes and their partners did not consider OSA to be a serious disorder that affected daily living. Despite some patients' experiences with excessive sleepiness during the day, they interpreted sleepiness and napping as natural components of aging and organized their daily activities accordingly. Since the symptoms of OSA were not familiar to participants, they did not associate these symptoms with a disease. The main outcome from the baseline interviews was that these patients performed limited amounts of daily physical activity, experienced challenges with short-term memory, and had a high intake of sweets. These factors had implications for their diabetes self-management. After using the CPAP device for 3 months, wide variations appeared among the patients. Many patients experienced technical difficulties with using the CPAP machine, which made them stop the treatment. This was often related to the fact that the mask did not fit their faces. Only the patients who were motivated to change their sleeping patterns overcame the technical difficulties. The patients who adhered to CPAP treatment after 3 months lost weight, improved their level of physical activity, improved their food intake, and had more energy in their lives. These improvements all correlated with their diabetes self-management.

Disease Management as a Daily Routine

The results show that a chronic condition can become a natural part of everyday routines. Study participants did not make conscious changes to their daily living due to a disease. Rather, their symptoms were integrated into their routines. This has been described in other studies of chronic illness [22,23]. Previous research has shown that patients correlate their feelings of being sleepy with laziness and do not associate such feelings with a medical diagnosis. This may explain why our participants adjusted their daily lives around their symptoms. Moreover, symptoms of OSA are both nonspecific and similar to those of the natural process of becoming older [24]. This provides ample room for patients' personal explanations and interpretations.

Concerned Partners

Very few studies have analyzed partners' perspectives on OSA, and most findings have indicated that partners are afraid and that many partners monitor patients' breathing at night [25,26]. Partners have also indicated that although they consider snoring to be annoying, it also provides reassurance that the patient is still breathing. We observed notable differences in partners' experiences of nighttime disturbances. Some did not mind patients' snoring and could either turn off a hearing aid or use the snoring as a kind of meditative white noise for falling asleep. Others demonstrated the findings described above and were worried that their partner might not wake up after an apneic episode. A lack of worry could be related to ignorance about OSA and its consequences.

Changed Cognitive Function

Several participants experienced challenges with short-term memory and developed corresponding strategies to overcome these challenges. Some even took a dementia test. A review found that patients with OSA and excessive daytime sleepiness may have cognitive impairments related to attention, concentration, learning, memory, and executive functions [14]. The most likely reasons behind cognitive declines are sleep problems and hypoxia. Changes in cognition may negatively affect diabetes self-management behaviors, thereby influencing

self-care outcomes, planning, and problem solving [27-29]. Specifically, a review showed that poor cognitive function negatively influences diabetes-specific numeracy abilities, insulin adjustment skills, adherence to medications, the frequency of performing self-care activities, the number of missed appointments, the frequency of diabetes monitoring, and the accuracy of reported blood glucose levels [29]. It is therefore important to be aware of changes in cognitive function among patients with comorbid diabetes and OSA.

Perceptions of OSA Severity Determines the Use of CPAP

Patients who do not have symptoms of fatigue and a tendency to fall asleep during the day but experience many technical challenges in CPAP treatment are less likely to continue treatment. This may be related to the fact that they doubt their OSA diagnosis and the risk of complications, as they have no obvious symptoms [24]. This was also observed in a study by Sawyer et al [30], who found that perceptions and assessments of the risk of OSA, the recognition of symptoms, and expectations of improvement in sleep are different between patients who adhere to CPAP therapy and those who do not. It was also seen in our study that patients who adhered to CPAP treatment were prepared to cope with technical and breathing challenges if they slept well at night and had more energy during the day. Patients who did not adhere to CPAP treatment did not experience the benefit of the treatment. These results are in line with those of other studies that underline the importance of using the correct mask and machine to improve sleep [31,32]. Several studies have shown that patients' experiences and perceptions of symptoms and the assessment of OSA consequences are of great importance for accepting an OSA diagnosis and undergoing CPAP treatment. Therefore, these factors are also important for increasing patients' motivation to continue treatment and their commitment to the treatment [30,32].

In addition to sleeping better at night, many patients had higher energy levels during the day, resulting in the need for fewer and shorter naps as well as increased desires and energy for performing activities. These findings are supported by several studies that show that patients undergoing CPAP treatment report less snoring, longer coherent sleep, higher energy levels, fewer conflicts with family and others, better memory, and greater activity levels [33,34].

Some partners also experience the changes that patients exhibit, such as being in a better mood during the day as well as being awake for fewer and shorter periods at night. Studies that focus on couples' experiences with CPAP therapy have shown that partners can motivate and support patients both emotionally and practically in their use of a CPAP mask. Patients have shown consideration and do not interfere with their partners at night by using CPAP, thereby motivating patients to adhere to treatment [34,35].

Technical Challenges in Using the CPAP Device

Patients' challenges with mask customization often resulted in adverse consequences in the form of eye inflammation and clogged and runny noses [26,33,34,36-38], which may have reduced their motivation to continue using the CPAP device. Some of the patients and partners also felt annoyed by the sound of "air leaking next to the mask" and noise from the machine. Findings from other studies have suggested that these disturbances in sleep, sleep routines, and intimacy are perceived as barriers, and partners may be concerned about patients' use of the mask and machine [34,35]. Some of the patients in our study had breathing difficulties associated with CPAP treatment and were afraid of being unable to breathe. Studies have shown that patients, especially at the beginning of CPAP treatment, are afraid of wearing the mask and are challenged by the lack of control over their breathing [39,40]. These technical and respiratory challenges present a high risk of discontinuing treatment among patients; CPAP treatment has a tendency to induce feelings of claustrophobia and anxiety, which may affect patients' adherence to CPAP therapy [30,41,42]. Interventions that focus on biomedical, psychological, and social factors in CPAP treatment have resulted in positive adherence to CPAP treatment [30,43].

Dietary Improvements After CPAP Treatment

The dietary implications of OSA are highly relevant to patients with diabetes. Patients with OSA prefer more calorically dense food with a higher fat content [44,45] and have verbalized the importance of maintaining their diet. However, they have also stated that they often feel too sleepy to do anything beyond the minimum for what is expected of them [6]. The increase in their intake of high-calorie foods may be related to the effects that interrupted sleep and apnea have on the secretion of the hormones leptin and ghrelin. These effects result in a resistance to leptin and an increased secretion of ghrelin [45]. Individuals with OSA often feel hungry and prefer high-calorie food. Experiencing wakeful periods several times per night increases the likelihood of nocturnal food intake, which negatively affects glucose balance and obesity and, in turn, negatively impacts both OSA and diabetes [46,47]. Obesity is a major risk factor for OSA. The prevalence of OSA is high among patients with obesity and vice versa [48]. Weight loss may result in an improvement in the severity of OSA and, perhaps, even its resolution [48], which would also improve diabetes.

In our study, some patients and partners benefitted from dietary changes and minor weight loss. This can be understood in the context that several of the patients undergoing CPAP treatment slept better at night and had higher levels of energy and activity during the day. In a study by Bakker et al [37], it was pointed out that improvements in OSA symptoms such as snoring, apnea, and a tendency to fall asleep during the day motivate patients during CPAP treatment, while increased energy levels per day motivate patients to change their lifestyles (eg, some patients change their diet and exercise habits).

One of the patients in our study lost 10 kg during the study period, and this had an immediate effect on his glucose levels. Consequently, dietary changes and weight reduction should be particularly emphasized in the treatment of both OSA and diabetes.

Physical Improvements After CPAP Treatment

With regard to physical functions, OSA has implications for physical activity levels and the experience of subjective vigor [7]. In our study, patients reported a decline in physical activity but did not associate this with sleepiness or OSA. Instead, they described this decline as a result of a lack of motivation, lack of energy, or other chronic diseases. However, patients who were using the CPAP device correctly immediately experienced improvements in their daily levels of activity. In addition to treatment via CPAP, OSA can be improved with physical exercise. Patients with OSA who were involved in a regular, predominantly aerobic exercise program exhibited reduced levels of disease severity and daytime sleepiness as well as increased sleep efficiency and peak oxygen consumption, regardless of weight loss [49,50]. This underscores the potential value of exercise in OSA management and the importance of providing information to patients about the value of physical activity to improve both OSA and diabetes.

Strengths and Limitations

The primary strength of this study lies in our use of qualitative methods. As there is a very high prevalence of undiagnosed OSA in the population [51], new study designs are needed to understand the correlation between the two diseases. By using a qualitative design, we revealed that most patients experienced OSA symptoms. However, such information would not be captured by a questionnaire. Another strength is that we conducted dyadic interviews with patients and partners. Dyadic interviews can inspire informants to provide more information than they would during two individual interviews; however, there is a risk that some things might be left unsaid to avoid confrontation or offense.

There are some limitations to this study. Patients were recruited from a randomized controlled trial study and via self-selected participation. Therefore, they may differ from comparable patients with OSA and diabetes who chose not to participate. Additionally, only patients with moderate or severe OSA (an AHI of >15) were included; they were the most likely to exhibit daily symptoms and feel restricted by OSA. Further, our findings may not be generalizable to patients with an AHI of 5 to 15, about whom little is known in terms of treatment and how they live with OSA during their daily lives. Finally, the OSA diagnoses were made via polygraphy, which probably underestimated the AHI and subsequently misclassified patients with OSA.

Conclusion

In this study, we analyzed a group of older adults with comorbid OSA and diabetes and found that their lives were disrupted due to the two diseases and were characterized by poor sleep and frequent naps. Most often, patients are unaware of their OSA and do not seek treatment. The implications of reduced cognitive function, low levels of physical activity, and a high-calorie diet affect diabetes management and result in exacerbated diabetes. If used correctly, CPAP has the potential to significantly improve OSA, resulting in better sleep quality; improved physical activity; improved diet; and, in the end, better diabetes self-management. Nevertheless, there are many barriers to undergoing CPAP treatment, and only few patients manage to overcome these barriers and comply with correct treatment. Patients' partners play a large role in promoting the correct use of the CPAP device, which can motivate patients to continue with the treatment. Patients who correctly use the CPAP device also exhibit improvements in their diabetes self-management. It is therefore important that CPAP-related barriers are prevented via thorough instruction and assistance from health care professionals.

It is also important that patients and their relatives acquire knowledge about the symptoms of and risk factors for OSA and understand the connection between OSA and diabetes. Patients and their relatives must be aware that changes in sleep patterns, increases in fatigue during the day, and the need for extra naps can be symptoms of OSA. Thus, there is also a great need for increasing OSA awareness among health care professionals, so that they can learn to identify affected individuals and develop skills for providing screening, education, and guidance based on the needs of patients and their partners. As a result, patients can gain an understanding of OSA and skills for managing symptoms in daily life.

Acknowledgments

The authors would like to thank all of the participants for taking the time to participate in this study.

Conflicts of Interest

None declared.

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Abbreviations

AHI: apnea-hypopnea index
CPAP: continuous positive airway pressure

DiaBOSA: Diabetes and Obstructive Sleep Apnoea
OSA: obstructive sleep apnea

Edited by G Eysenbach; submitted 09.01.21; peer-reviewed by S Prior, I Bouloukaki; comments to author 07.02.21; revised version received 03.04.21; accepted 31.05.21; published 20.07.21.

Please cite as:
Laursen DH, Rom G, Banghøj AM, Tarnow L, Schou L
Improving Diabetes Self-management by Providing Continuous Positive Airway Pressure Treatment to Patients With Obstructive Sleep Apnea and Type 2 Diabetes: Qualitative Exploratory Interview Study
JMIR Form Res 2021;5(7):e27062
URL: https://formative.jmir.org/2021/7/e27062
doi:10.2196/27062
PMID:34283032

Original Paper

Social Media as a Platform for Recruitment to a National Survey During the COVID-19 Pandemic: Feasibility and Cost Analysis

Heidi Green[1,2], BN, MPH; Ritin Fernandez[1,2], MN, PhD; Catherine MacPhail[3], BA, PhD

[1]School of Nursing, University of Wollongong, Wollongong, Australia

[2]Centre for Research in Nursing and Health, St George Hospital, Kogarah, Australia

[3]School of Health and Society, University of Wollongong, Wollongong, Australia

Corresponding Author:
Heidi Green, BN, MPH
School of Nursing
University of Wollongong
Northfields Ave
2522
Wollongong
Australia
Phone: 61 0412108532
Email: Heidi.Lord@health.nsw.gov.au

Abstract

Background: With improved accessibility to social media globally, health researchers are capitalizing on social media platforms to recruit participants for research studies. This has particularly been the case during the COVID-19 pandemic, when researchers were not able to use traditional methods of recruitment. Nevertheless, there is limited evidence on the feasibility of social media for recruiting a national sample.

Objective: This paper describes the use of social media as a tool for recruiting a national sample of adults to a web-based survey during the COVID-19 pandemic.

Methods: Between August and October 2020, participants were recruited through Facebook via two advertisement campaigns (paid option and no-cost option) into a web-based survey exploring the relationship between social determinants of health and well-being of adults during the COVID-19 pandemic. Data were analyzed using SPSS software and Facebook metrics that were autogenerated by Facebook Ads Manager. Poststratification weights were calculated to match the Australian population on the basis of gender, age, and state or territory based on the 2016 Australian census data.

Results: In total, 9594 people were reached nationally with the paid option and potentially 902,000 people were reached through the no-cost option, resulting in a total of 1211 survey responses. The total cost of the advertisement campaign was Aus $649.66 (US $489.23), resulting in an overall cost per click of Aus $0.25 (US $0.19).

Conclusions: Facebook is a feasible and cost-effective method of recruiting participants for a web-based survey, enabling recruitment of population groups that are considered hard to reach or marginalized. Recruitment through Facebook facilitated diversity, with participants varying in socioeconomic status, geographical location, educational attainment, and age.

(JMIR Form Res 2021;5(7):e28656) doi:10.2196/28656

KEYWORDS

social media; survey; online recruitment; COVID-19; pandemic; methodology

Introduction

Numerous strategies such as newspaper advertisements, random mail out of surveys, and random digit dialing have been used to recruit participants into population health research. However, implementation of these traditional strategies in modern society has limitations due to the reduced use of landline phones and increased postage costs [1,2], which make these recruitment methods less feasible. Additionally, these approaches have low participation rates ranging from 7.5% [3] to 30% [4]. With improved access to the internet globally, particularly through mobile phones, social media has become an active part of modern society [5]. Public health researchers have harnessed social media and web platforms as a modality for recruitment

into population health research [6,7]. Used as more than just a method to connect with friends and family, social media platforms are increasingly used for sharing content, engaging with news content, entertainment, and receiving health information. The most popular social media platforms globally are Facebook, Twitter, YouTube, and Instagram [8], with over 4 billion users. Social media platforms enable users to connect and share information through both traditional and interactive methods, with most platforms allowing free use [9].

According to the Australian Communications and Media Authority [10], in 2018-19, approximately 91% of all Australians had access to the internet. In 2016-17, 80% of Australians used the internet for social networking [11] compared with 66% in 2011 [12], with an average of 1.2 social media accounts per Australian [8]. Facebook is the most popular social media platform among Australians, with approximately 93% of Australian social media consumers using this platform, followed closely by Instagram at 73% [13]. Moreover, almost 60% of Australians use social media daily [8].

Given the increased prevalence of daily social media use among Australians, social media platforms have been increasingly used as a viable method for recruiting participants into health research [14]. More specifically, social media platforms allow researchers to access hard-to-reach populations as well as target recruitment through the use of advertising campaigns to specific users based on gender, geographical location, interests, and age [9]. Social media use has been harnessed by heath researchers to recruit participants into a range of studies, including cross-sectional studies, observational studies, and interventional studies [5], particularly due to the cost-effectiveness of this recruitment method. There is evidence in the literature that health researchers have recruited participants and delivered health behavior interventions on a variety of topics. The success of these interventions has demonstrated the efficacy of social media as a suitable method for accessing participants [1,5,15-17]. However, a substantial number of studies use a localized sample.

Our study engaged the use of social media with the purpose of generating a national sample of Australian adults to explore the relationship between the social determinants of health and well-being during the COVID-19 pandemic. Currently, there is limited evidence available on the feasibility of social media for recruiting a national sample. Therefore, the aim of this paper is to describe the feasibility of using social media as a tool for recruiting a national sample of adults to a web-based survey during the COVID-19 pandemic. Feasibility was assessed in terms of reach, time invested in recruitment, number of surveys completed, cost-effectiveness, and recruitment of a diverse sample of participants.

Methods

Study Overview

The research study was undertaken to investigate the relationship between social determinants of health and well-being in Australian adults during the COVID-19 pandemic. Ethical approval to conduct this study was received from University of Wollongong Human Ethics Committee (2020/306). The inclusion criteria for the study were individuals aged 18 years and above, with the ability to read English and residing in any state or territory within Australia. Participants were recruited using Facebook over a 9-week period between August and October 2020. Participants were required to complete a web-based survey comprising 49 questions exploring social determinants of health. They were invited to enter a draw to win one of 10 Aus $50 gift vouchers at the end of the survey with winners selected randomly using SPSS software (version 25). A currency exchange rate of Aus $1=US $0.75 is applicable.

Recruitment Strategy

Recruitment for this study using Facebook was achieved by the following two methods: (1) joining existing community noticeboard Facebook groups (ie, no-cost option), and (2) through a paid Facebook advertisement campaign (ie, paid option). Both methods enabled snowball sampling where users could like, share, and circulate the social media post among others.

Joining Existing Community Noticeboard Groups on Facebook (No-Cost Option)

A specific Facebook page was created for the study using a study image. To ensure national representation, the primary author (HG) identified existing Facebook community noticeboard groups, according to Australian states and territories as well as based on urban, regional, and remote areas. The author contacted the administrators of each individual community group for permission to join. Each week, if permitted by the administrators, the advertisement was reposted on each of the community noticeboard group pages. Posting on the existing community noticeboard groups began on August 20, 2020, and ended on October 14, 2020.

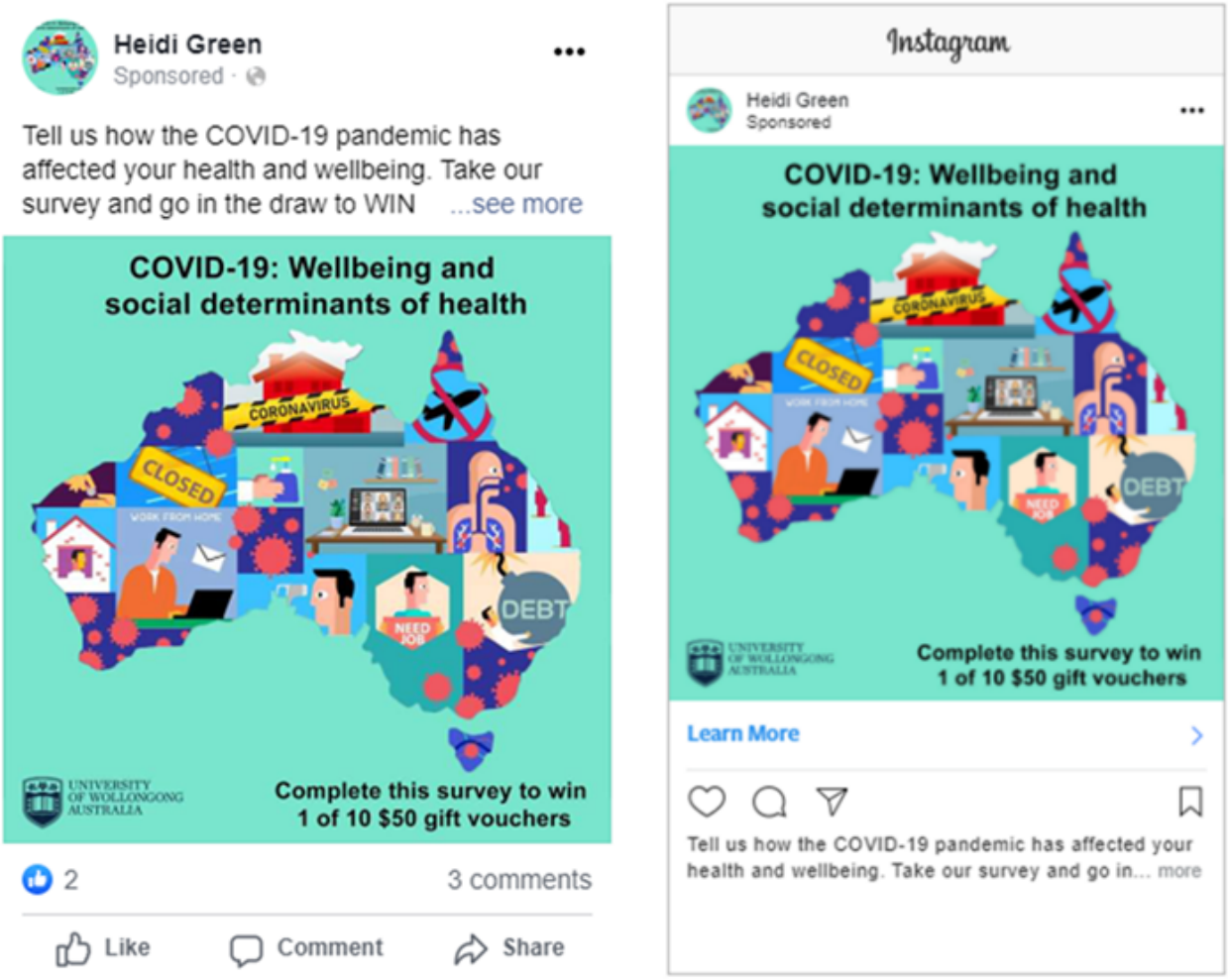
Facebook Advertising Campaign (Paid Option)

To supplement the no-cost Facebook community noticeboard group approach, a paid advertisement through Facebook, which included Instagram, was designed to recruit participants. Two consecutive advertisement campaigns were set up, with the first campaign used to establish the feasibility of this strategy.

The Facebook advertisement platform, Facebook Ads Manager, was used to create paid advertisements. The features available for a payment allows the advertisement to be customized based on objective (eg, links or clicks to a web-based survey), target audience (eg, location, age, gender, interests, and behaviors), budget, and schedule [18]. Selecting the “automatic placements” option when setting up the advertisement in Facebook Ads Manager allowed the advertisements to run across associated services such as Instagram, Messenger, and Facebook Audience Network (ie, off-Facebook in-app advertising network for mobile apps).

These Facebook advertisements comprised a main text (eg, “Tell us how the COVID-19 pandemic has affected your health and wellbeing. Take our survey and go in the draw to WIN 1 of 10 Aus $50 gift vouchers”), an image (ie, the study image and university logo), and display link (Figure 1).

Figure 1. Paid Facebook and Instagram advertisements—example post.



A budget of Aus $650 was set as the maximum recruitment spend for the paid campaigns, with a daily limit of Aus $25. The cost per click can vary depending upon the number of clicks on the advertisement and the amount of the daily budget reached.

The first campaign was set as "engagement" (targeting people most likely to engage with the post through one of the following mechanisms: share, like, or click). The target audience for the first campaign was (1) people residing in Australia, (2) people aged 18-35 years inclusive, (3) people of all genders, and (4) people residing within certain postcodes. The primary researcher used the Australian Bureau of Statistics (ABS) Index of Relative Socio-Economic Advantage and Disadvantage (IRSAD) to set these specific postcodes. These postcodes were used to ensure the distribution of the ad campaign targeted potential participants in both relative advantaged and disadvantaged locations. The "automatic placements" option on Facebook was used, which allows the campaign to maximize the set budget and dissemination of the advertisement to a larger sample relevant to the inclusion criteria [18].

Next, the "post engagement" strategy was selected, enabling delivery to the people who are likely to share, like, and comment on the post at the lowest cost [18]. The first Facebook advertisement campaign ran from August 25, 2020, to September 1, 2020.

The second campaign employed the same strategies as the first advertisement campaign; however, the target audience locations were identified using suburbs set by ABS's IRSAD. This was undertaken as suburbs can contain multiple postcodes thus increasing the target audience. The use of the ABS's IRSAD suburbs allowed a general representation of both advantaged and disadvantaged locations, enabling diversity in targeting potential participants. The second campaign ran from September 6, 2020, to September 22, 2020.

Throughout the recruitment period, the Facebook posts were monitored daily to ensure that any comments, including individuals opportunistically using the advertisement to promote businesses, were hidden from other Facebook users. This was undertaken to ensure potential respondents were not influenced to either participate or be discouraged from participating in the survey. Additionally, monitoring the comments and hiding them from other potential participants was conducted for ethical reasons as a way of protecting any potential participants' identities. Automatic hiding of comments is not available as an option within Facebook's delivery system and, therefore, it had to be conducted manually.

Data Analysis

Data were analyzed using SPSS software (version 25). Poststratification weights were calculated to match the Australian population on the basis of gender, age, and state or

territory based on the 2016 Australian census [19], to account for over- or underrepresentation of certain people.

Facebook metrics were collected through Facebook Ads Manager, which auto generates the engagement activity for each advertisement campaign [18]. Summary and descriptive statistics including reach, impressions, and cost per click were analyzed for each campaign and for the overall campaign. "Reached" refers to the number of people who were shown the advertisement, "impressions" refers to the number of times the advertisement was on-screen for the target audience and could include multiple views of the advertisement by the same individual. "Cost per click" is derived from the total advertisement campaign spend divided by the number of clicks on the advertisement or the link [18].

Results

Recruitment Through Facebook (No-Cost Option)

The primary researcher (HG) made a request to the administrators of 110 existing Facebook community noticeboard groups to join those groups. All community groups approached approved the author's request to join. Posts and reposts to the existing community noticeboard group Facebook pages were conducted 10 times over the 9-week period commencing on August 21, 2020, and the last repost made on October 14, 2020. Using this option implies that no data on the individuals reached or impressions recorded is available to researchers through Facebook Ads Manager; however, the number of members in each community noticeboard group were available with a potential reach of 902,000 individuals. Nationally, each community noticeboard group had an average of 8205 group members, with slightly higher than the national average seen for Queensland and Australian Capital Territory, at 11,097 and 12,230 average total members per noticeboard community group, respectively. In contrast, South Australia and Victoria had marginally lower average members per group than the national average, with 6480 and 6287 members, respectively. Additionally, a comparison between the no-cost and paid options to determine the most cost-effective option was not possible, as both recruitment methods sent participants to the same survey link; therefore, no there was disaggregation between the options the participants used to reach the survey page.

Recruitment Through Facebook (Paid Option)

An aggregated 9594 individuals were reached via the two paid advertisement campaigns; however, a total of 14,232 impressions were recorded. The Facebook advertisement campaign reached 5316 (55.4%) male, 4062 (42.3%) female, and 216 (2.3%) users with uncategorized gender. Using the automatic placements option, most placements were conducted through Instagram, reaching 5846 individuals, whereas Facebook reached 3856 individuals. The remainder of individuals were reached through Facebook Audience Network.

Strengths and Limitations of Facebook (No-Cost Option)

The greatest advantage in using the no-cost option is that there are no monetary costs associated with recruiting participants. However, it must be noted that the researchers had to continually repost the ad to the community noticeboard groups to ensure visibility, as the post would move down a user's feed once posts had been posted by another group or member; this in turn proved to be labor intensive. Additionally, during the first few days of recruitment, responses from the no-cost option were received predominantly from individuals aged 35 years and above. Therefore, to supplement this approach, the paid option was used and intentionally designed to target younger potential respondents.

Strengths and Limitations of Facebook (Paid Option)

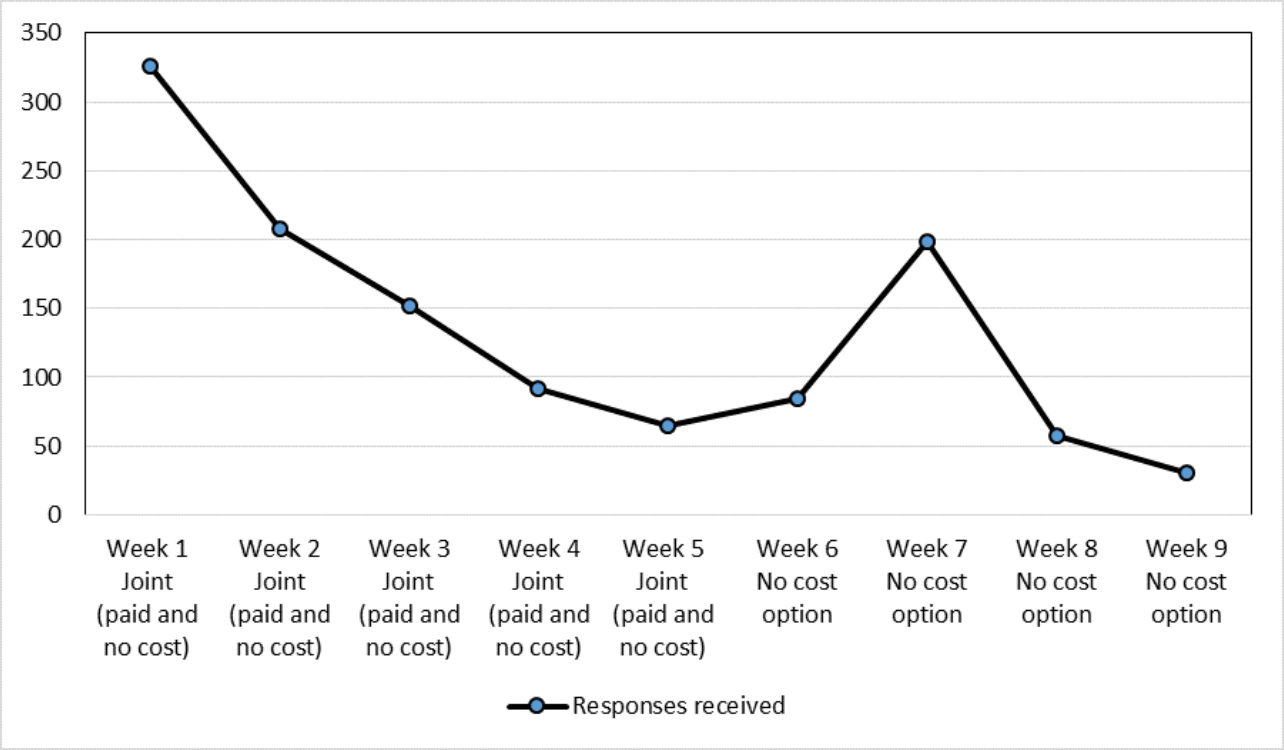
The paid option allowed the researchers to specifically target younger potential respondents across not only Facebook but also Instagram, Messenger, and Facebook Audience Network. Furthermore, the paid option allows the researcher to customize the ad based on their objective and to create a specific schedule of when the ads will be seen [18]. This was particularly important to recruit a diverse national sample of participants. The drawback with using the paid option was the associated monetary costs, albeit being able to design the campaign to have a daily limit, the reach of potential participants did not guarantee actual respondents.

Overall Response to Survey

A total of 1211 individuals responded to the survey, with 100% meeting the eligibility criteria. The survey took respondents approximately 9 minutes to complete. Of the 1211 who commenced the survey, 1137 (93.89%) respondents completed it.

The number of responses received varied per day among the paid and no-cost recruitment options, with the highest number of responses (n=178) received on August 21, 2020, and the lowest (n=0), on October 21, 2020. In the first week the survey was live, a total of 326 responses were received, which was the most responses received over the 9-week period. Due to the no-cost and paid options running concurrently for the first 5 weeks, using the same survey link, the numbers of participants recruited through each option are unknown. Overall response to the survey per week for the no-cost and paid options are outlined in Figure 2.

Figure 2. Overall response to the survey (no-cost and paid options).



Cost Analysis

For the paid option, the total amount spent on the Facebook advertisement campaigns was Aus $649.66, with the average overall cost per click (per post engagement) reported at Aus $0.25. Individuals aged 18-24 years accounted for Aus $419.79 (64.6%) of the total advertisement budget, whereas individuals in the 25-34 age group accounted for Aus $192.49 (37.1%), those aged 35 years accounted for Aus $37.38 (7.6%). The majority of the advertisement spend was using Instagram, with a total spend of Aus $598.39. Facebook advertisement total spend was Aus $50.79, whereas Aus $0.48 of the total spend was through Facebook Audience Network. The lowest cost per click day was on the 8 September 2020 at Aus $0.16, with the highest cost per click of Aus $0.32 on September 18, 2020.

More male participants engaged with the Facebook advertisement campaign compared to female participants, with the former accounting for 60.4% (Aus $392.35) of the total spend. Women in the 25-34 age group account for the highest cost per click at Aus $0.28.

Time

Economically, Facebook advertising campaigns are a feasible method to recruit participants into a web-based survey, requiring the use of a single researcher to create, manage, and maintain the recruitment strategy. The total number of hours spent by the researcher, including management of the no-cost option of posting on existing community noticeboard groups within Facebook, was a total of 30 hours over the 9-week period. The benefit of using Facebook's features of selecting a target audience, and posting on existing community noticeboard groups enabled recruitment of a large sample within a short timeframe, with a relatively low cost of Aus $649.66. The cost-effectiveness and ability to recruit a large sample provides evidence to suggest that Facebook recruitment is a feasible option for public health researchers.

Distribution of Respondents

Participants from diverse geographic, education, and employment backgrounds were recruited through these two Facebook methods. Responses were received from all states (n=6) and territories (n=2) within Australia. Based on weighted data from 1211 participants, most responses received from New South Wales at 34.4% (n=387), whereas 0.4% (n=5) were received from the Northern Territory. Responses were received from 40.4% (n=447) participants living in locations classified as having the two lowest socioeconomic status brackets and 41.2% (n=646) participants living in locations classified as having two highest socioeconomic status brackets. Responses were received from 662 (58.8%) residents in major cities, 373 (23.1%) residents in inner or outer regional areas, and 70 (6.2%) residents in remote or very remote areas of Australia. Educational attainment varied among the respondents, with 36.1% (n=406) having at least a bachelor's degree, 20.2% (n=239) having a completed technical college, and 22.2% (n=250) had completed years 7 to 12 of high school. Responses received from those aged 25-39 years and 40-59 years was 30.2% (n=340) and 35.5% (n=40), respectively. The mean age of the respondents was 46.3 (SD 16.3) years. Responses received from female participants accounted for 51.7% (n=582) and that from male participants accounted for 48.3% (n=545). Unweighted data for transgender or nonbinary population was 2.6% (n=30). Weighted and unweighted distribution of respondents are detailed in Table 1.

Table 1. Distribution of respondents (nonweighted and weighted).

Characteristic	Nonweighted data	Weighted data
Age (years), mean (SD)	43 (14.2)	46.3 (16.3)
Age range (years), n (%)		
18-24	118 (9.7)	101 (8.9)
25-40	413 (34.1)	340 (30.2)
41-60	464 (38.3)	400 (35.5)
61-75	135 (11.1)	227 (20.2)
>75	7 (0.6)	59 (5.2)
Gender, n (%)		
Women	938 (80.7)	582 (51.7)
Men	194 (16.7)	545 (48.3)
Nonbinary or transgender	30 (2.6)	N/A[a]
Education, n (%)		
Completed years 7 to 12 high school	240 (20.7)	250 (22.2)
Vocational	253 (21.8)	239 (21.2)
Bachelor's degree	437 (37.7)	406 (36.1)
Postgraduate degree	230 (19.8)	230 (20.4)
State or territory, n (%)		
New South Wales	695 (59.8)	387 (34.4)
Victoria	181 (15.6)	305 (27.0)
Queensland	127 (10.9)	219 (19.4)
Western Australia	91 (7.8)	118 (10.5)
South Australia	17 (1.5)	57 (5.1)
Northern Territory	19 (1.6)	5 (0.4)
Australian Capital Territory	19 (1.6)	18 (1.6)
Tasmania	13 (1.1)	19 (1.7)
Remoteness, n (%)		
Major cities	709 (62.1)	662 (58.8)
Inner regional	256 (22.4)	224 (19.9)
Outer regional	112 (9.8)	149 (13.2)
Remote	20 (1.8)	12 (1.1)
Very remote	45 (3.9)	58 (5.1)
Socioeconomic status, n (%)		
Lowest (most disadvantaged)	157 (13.8)	188 (16.6)
Low	252 (22.1)	259 (23)
Middle	210 (18.4)	194 (17.2)
High	193 (16.9)	182 (16.1)
Highest (most advantaged)	328 (28.8)	282 (25.1)

[a]N/A: not applicable.

Discussion

Principal Findings

This study reports on the feasibility of using Facebook to recruit a national sample of participants. The findings demonstrate Facebook to be an efficient and effective method to recruit both a large and diverse sample of respondents. We recruited a total of 1211 respondents, with weighted data demonstrating recruitment was representative of the Australian population. The average cost per click for the paid option was Aus $0.25 with 9594 people reached. The no-cost option potentially reached 902,000 people, with an average number of 8205 members in each community noticeboard group. The findings of this study have implications for public health researchers seeking to recruit study participants through social media sites such as Facebook and contribute to the emerging evidence regarding the ability of social media to reach diverse populations groups.

Overall, the no-cost and paid Facebook advertisements used in this study proved to be an effective method for recruiting a large national sample of the Australian population. Although concerns have been raised in the literature regarding the digital divide [20], the accessibility of Facebook and Instagram globally and nationally refutes this notion [8]. The literature confirms that social media advertisement is a viable method to recruit marginalized population groups and those considered hard to reach [21,22]. The focus of this recruitment strategy was a diverse national sample of adults. The targeted paid advertisements for this study were achieved using the ABS's IRSAD postcode and suburbs to target a diverse audience, which proved effective, with respondents varying in socioeconomic status, remoteness, educational attainment and age. The representation of regional and remote area–based participants shows the potential benefit of using social media to recruit a segment that traditionally has been quite difficult to reach [14]; this can also be said from those from low-socioeconomic backgrounds [17]. However, it must be noted that gender was not diverse in this study with participants identifying as female overrepresented. This similar to the experience of other studies, in which male, nonbinary, and transgender participants are underrepresented [23,24]. Traditionally, female participants have been overrepresented in surveys and interviews, suggested to be due to the gender differences in communication [25]. Surveys require a willingness to disclose some personal information and often having to express more socioemotional behaviors. These are traits that are historically characterized by females and may therefore contribute to their greater participation in survey research [25]. Moreover, when engaging on the internet, female users are more likely to communicate and exchange information, whereas male users prefer to information seek [26].

The advantage of using Facebook's paid advertisement campaigns is that it can be set to target a specific audience, and set a daily cost limit. This is especially useful for researchers who are working within limited funding arrangements. Minimizing research costs and maximizing recruitment opportunities can be achieved with the use of social media for population health research. Social media recruitment desirability has also increased during the COVID-19 pandemic [27,28], with traditional methods unable to be used to recruit participants due to the public health measures used to combat the transmission of COVID-19.

Compared with the paid advertisement, the no-cost Facebook method of recruitment was time intensive, by virtue of having to contact administrators for permission to join groups and the ongoing posts and reposts to the group pages to ensure continued visibility. However, it can be said that traditional methods of participant recruitment such as mailed surveys are often more labor intensive and expensive [29]. A number of studies have been conducted comparing social media recruitment and traditional methods, suggesting that social media is more effective for cost and time [16,17,30]. Indeed, social media recruitment through both the paid and no-cost options, as demonstrated in this study, represent a cost-effective method of recruitment into a population health survey.

Surprisingly, in week 7, a total of 198 responses were received; this coincided with a long weekend in 3 Australian States (New South Wales, Queensland, and South Australia) and one territory (Australian Capital Territory) and may have increased the response rates in this week. This finding suggests that targeting social media recruitment over weekends and when people have spare time, particularly during the COVID-19 pandemic when people may have been in lockdown over the long weekend, may provide a good opportunity for recruitment.

Limitations

Although this study used robust methods, there are some limitations that need to be acknowledged. First, there is potential for bias due to exposure to the advertisement being associated with time spent on Facebook (and therefore not the same for each user), especially with the community noticeboard groups where visibility of the post depended on when potential respondents were on Facebook.

Second, the feasibility of Facebook as a recruitment tool can be impacted by Facebook's automated advertising algorithms and metrics. Facebook sets advertising algorithms to determine the most appropriate advertisements to show to a specific audience. However, this is also impacted by Facebook as a business wanting to provide the user with a good experience. The metrics used by Facebook can be difficult to comprehend, which in turn can be challenging for researchers, particularly when they are not familiar with interpreting the metrics or following previously published social media recruitment protocols.

Third, only one online survey link was established for this study, which meant that being able to track respondents from each recruitment option was impossible. Future research employing both no-cost and paid options should use two separate links to enable a more robust comparison of the two options.

Despite male participants engaging with the Facebook advertisement campaigns more than women, they are underrepresented in this study. Approaches to increase male participation in online surveys needs to be explored.

Finally, further qualitative studies need to be conducted to understand why individuals choose or decline to participant in research advertised through social media.

Conclusions

Recruitment through social media, specifically Facebook, allowed for a cost-effective and efficient method for recruiting a national sample of participants for a web-based survey about the relationship between well-being and the social determinants of health during the COVID-19 pandemic. The diversity of participants recruited in this study, in terms of socioeconomic status, remoteness, educational attainment, and age, promotes and confirms the feasibility of social media to recruit hard-to-reach population groups as well as a diverse sample of the national population. The benefits of using Facebook should be considered by population health researchers when implementing health research in the future.

Conflicts of Interest

None declared.

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Abbreviations

ASB: Australian Bureau of Statistics
IRSAD: Index of Relative Socio-Economic Advantage and Disadvantage

Edited by G Eysenbach; submitted 09.03.21; peer-reviewed by S Fletcher-Lartey, Y Kim; comments to author 05.04.21; revised version received 17.04.21; accepted 19.05.21; published 06.07.21.

Please cite as:
Green H, Fernandez R, MacPhail C
Social Media as a Platform for Recruitment to a National Survey During the COVID-19 Pandemic: Feasibility and Cost Analysis
JMIR Form Res 2021;5(7):e28656
URL: https://formative.jmir.org/2021/7/e28656
doi:10.2196/28656
PMID:34133315

Original Paper

Measuring the Impact of COVID-19 on Siyan Mental Health Patients Using the Epidemic-Pandemic Impacts Inventory: Survey Study

Anish Shah[1], MD; Michele Darling[2], PhD; Olivia Arstein-Kerslake[2], BS; Tiffany Morgan[1], MHSA; Aubreen Vance Tovrea[1], LCSW; James Young[1], DO; Helen Laines[1]

[1]Siyan Clinical Corporation, Santa Rosa, CA, United States

[2]LPC Consulting Associates, Sacramento, CA, United States

Corresponding Author:
Anish Shah, MD
Siyan Clinical Corporation
480 Tesconi Cir B
Santa Rosa, CA, 95401
United States
Phone: 1 707 206 7273
Email: ashah@siyanclinical.com

Abstract

Background: Recent research has shown that the impacts of the COVID-19 pandemic and social isolation on people's mental health are quite extensive, but there are limited studies on the effects of the pandemic on patients with mental health disorders.

Objective: The objective of this study was to assess the negative impacts of the COVID-19 pandemic on individuals who have previously sought treatment for a mental health disorder.

Methods: This study uses the newly developed Epidemic-Pandemic Impacts Inventory (EPII) survey. This tool was designed to assess tangible impacts of epidemics and pandemics across personal and social life domains. From November 9, 2020, to February 18, 2021, a total of 245 adults recruited from a mental health clinic completed the consent form and responded to the survey link from the Siyan Clinical Corporation and Siyan Clinical Research practices located in Santa Rosa, California, USA.

Results: We found that the least affected age group included individuals aged 75 years or older. This was followed closely by the 65- to 75-year-old age group. People with children under the age of 18 years also reported both more negative indicators associated with the pandemic and more positive indicators compared to those without children at home. Gender queer, nonconforming, and transgender individuals may also be at higher risk for more negative impacts associated with the pandemic. When respondents were assessed with regard to their mental health diagnosis, no differences were noted. Substance use also increased during the pandemic.

Conclusions: In conclusion, the data collected here may serve as foundational research in the prevention, care, and treatment of mental health disorders during pandemics such as COVID-19. Populations such as those with previously diagnosed mental health disorders are particularly at risk for negative effects of pandemic-related stressors such as social isolation, especially if they have children in the household, are part of a younger age group, or have substance use disorder. Gender may also be a factor. Further, the EPII survey may prove to be a useful tool in understanding these effects. Overall, these data may be a critical step toward understanding the effects of the COVID-19 pandemic on populations with a mental health diagnosis, which may aid mental health practitioners in understanding the consequences of pandemics on their patients' overall well-being.

Trial Registration: ClinicalTrials.gov NCT04568135; https://clinicaltrials.gov/ct2/show/NCT04568135

(JMIR Form Res 2021;5(7):e29952) doi:10.2196/29952

KEYWORDS

COVID-19; coronavirus; pandemic; mental health; social isolation; wellness

Introduction

The World Health Organization announced that the COVID-19 outbreak had become a global pandemic on March 11, 2020. One year later, approximately 29.5 million people within the United States alone had been infected with the COVID-19 virus [1]. To combat this deadly infection, countries such as the United States took actions including social distancing, mask mandates, closures of schools and universities, remote or home-based working, and travel restrictions. However, although effective from a public health perspective, the potential impacts of the pandemic and social isolation on people's mental health and on the mental health care system are extensive.

Research published since the height of the COVID-19 pandemic demonstrates the deleterious effects of this event on psychological well-being. One cross-sectional study conducted across 34 hospitals in China demonstrated that among health care workers exposed to COVID-19, women, nurses, those in Wuhan, and frontline health care workers have a high risk of developing negative mental health outcomes and may need psychological support or interventions [2]. In the early stages of the COVID-19 pandemic, researchers in China observed that 53.8% of survey respondents rated the psychological impact of the outbreak as moderate or severe, 16.5% reported moderate to severe depressive symptoms, and 28.8% reported moderate to severe anxiety symptoms [3]. Finally, another study conducted in China of about 18,000 social media users and their online posts demonstrated that COVID-19 was associated with an increase in negative emotions, such as anxiety, depression, and anger, and a decrease in positive emotions and life satisfaction [4].

The effects of COVID-19 have been far-reaching beyond China, however, and the impact of the virus has been felt across the globe. Within the United States, a survey conducted during the last week of March 2020 showed that 72% of Americans felt that their lives were impacted by the outbreak, a 32% increase from the survey conducted only 2 weeks earlier [5]. In the United Kingdom, the prevalence of clinically significant levels of mental distress rose from 18.9% in 2018-2019 to 27.3% in April 2020, one month into their own lockdown; further, these changes in mental health were greatest among young adults (aged 18 to 34 years), women, and people living with young children [6]. Problems with psychological well-being were also observed in Australia. For instance, during the first month of the stage 2 COVID - 19 restrictions, mental health problems were widespread among Australians; in addition, about one - quarter of survey respondents reported mild to moderate symptoms of depression or anxiety [7].

The primary goal of this study was to describe the impacts of COVID-19 on a population of residents in the United States who had previously sought psychiatric services at the Siyan Clinical Corporation and Siyan Clinical Research practices located in Santa Rosa, California. Our objective was to assess the impact of the current COVID-19 pandemic on participants with previously diagnosed psychiatric disorders to identify areas of needed support and services. We were interested in whether or not there were any differences in the impact of the COVID-19 pandemic based on features such as age, gender, and mental health diagnosis. The data collected may serve as foundational research in the prevention, care, and treatment of mental health disorders during pandemics such as COVID-19. We also used a newly developed tool, the Epidemic-Pandemic Impacts Inventory (EPII) survey, to assess tangible impacts of epidemics and pandemics across personal and social life domains.

Methods

Recruitment

Approximately 3500 adult patients in the Siyan Clinical Corporation and Siyan Clinical Research practices (Santa Rosa, California, USA) were invited to participate in a one-time anonymous survey to assess tangible impacts of epidemics and pandemics across personal and social life domains. Siyan staff derived a list of patients from the Siyan electronic health record system who met eligibility criteria and sent an email inviting them to participate in the survey, explaining the purpose of the survey, how Siyan will use the survey results, and how the survey will be administered. Interested patients signed and returned an informed consent form (ICF) and then received a link to the online survey. A total of 326 patients out of 3500 completed the consent form and received the survey link from Siyan, for a response rate of 9.3%. Of these 326 patients, a total of 245 people responded from November 9, 2020, to February 18, 2021, for a completion rate of 75.2% among those who had completed the consent form. Patients received a US $10 eGift card from Starbucks upon completion of the survey.

These procedures were reviewed by the Advarra Institutional Review Board (IRB) and informed consent was obtained from all participants. The protocol, ICFs, principal investigator curriculum vitae, and all subject-facing and recruitment materials were submitted to the Advarra IRB for review in June 2020. A notice of intent was sent to the authors of the EPII survey prior to IRB submission. The ICF collection process was outlined in the approved protocol and most patients signed the ICFs via Adobe Sign. The data were collected through an approved process utilizing the Alchemer cloud-based integrated feedback platform. In September 2020, the protocol was determined to be IRB exempt by Advarra. This study was conducted using ethical principles derived from international guidelines including the Declaration of Helsinki and the Council for International Organizations of Medical Sciences International Ethical Guidelines.

This study was reviewed and published on ClinicalTrials.gov (NCT04568135) on September 29, 2020.

The Epidemic-Pandemic Impacts Inventory

The EPII is a newly developed, 92-item tool designed to determine the impacts of epidemics and pandemics in personal and social life domains developed by Grasso and colleagues [8,9]. The EPII is divided into 10 subcategories, with a varying number of indicators in each subcategory: work and employment, education and training, home life, social activities, economic activities, emotional health and well-being, physical health problems, physical distancing and quarantine, infection history, and positive change. All domains except for *positive*

change indicate negative or adverse experiences. Respondents were presented with indicators in each subcategory and asked, "Since the coronavirus disease pandemic began, what has changed for you or your family?" Participants then responded with *yes, me;yes, person in home;no*; or *N/A* (not applicable).

Inclusion and Exclusion Criteria

Inclusion Criteria

A participant had to meet the following criteria to be eligible to participate in this study:

1. Voluntarily agreed to participate in the study under their own free will and was willing and able to agree to an e-ICF indicating that he or she understood the purpose of the study, he or she understood the procedures that were required for the study, and that he or she was willing to participate in the study.
2. Was female or male and between the ages of 18 and 80 years, inclusive, at the time of consent.
3. Was receiving or had previously received psychiatric services from Siyan Clinical Corporation and/or Siyan Clinical Research practices.
4. Was capable of understanding and complying with study requirements.
5. Had agreed to the e-ICF. No study-related procedures would be performed before the participant had agreed to the consent letter.

Exclusion Criteria

A participant who met any of the following criteria were excluded from this study:

1. Had a known diagnosis of dementia.
2. Was under the age of 18 years or over the age of 80 years.

Data Analysis

Following the analytic approach taken in a preliminary report [9] using the EPII, the two *yes* responses (*yes, me*; *yes, person in home*) were collapsed, as were the *no* and *N/A* responses, to create dichotomous indicators. For the sake of this analysis, the nine *negative* subcategories were combined to form an overall *negative impacts* category, reporting the average number of indicators with *yes* responses. Results from the subcategories were also reported. Exploratory statistical analyses have also been performed. One-way analysis of variance (ANOVA) followed by Tukey post hoc tests, Student *t* tests, or chi-square tests were used, where appropriate. Results are reported as mean (SD) throughout the text, while figures show mean ± standard error of the mean (SEM). Statistical significance was defined as $P<.05$.

Results

Sample Characteristics

Table 1 details the sociodemographic characteristics of the sample. Most of the sample self-identified as female (76.3%) and White (84.5%). About half (54.2%) of the sample reported being currently employed. The majority of the sample reported being diagnosed with mood disorders (76.3%) or anxiety disorders (76.3%). Note that individuals could select multiple mental health diagnoses on the survey. Additionally, nearly half (47.8%) of the sample reported earning a bachelor's degree or higher. We also compared the age and gender distributions in our sample against the population that sample was drawn from in chi-square analyses. We found no differences in the expected distribution of the age of the subjects ($\chi^2_2=7.2$, $P=.33$; N=245). However, we did find a significant effect of sex distribution between the sample and the population ($\chi^2_6=107.5$, $P<.001$; N=245). This large effect was likely driven by the disproportionate number of women that completed the survey (women comprised 76.3% of the sample but only 57.9% of the population).

Table 1. Sociodemographic characteristics of the sample.

Variable	Respondents (N=245), n (%)
Age (years)	
18 to 24	25 (10.2)
25 to 34	39 (15.9)
35 to 44	57 (23.3)
45 to 54	40 (16.3)
55 to 64	47 (19.2)
65 to 74	24 (9.8)
75 or older	13 (5.3)
Gender	
Female	187 (76.3)
Male	52 (21.2)
Other (gender queer, nonconforming, or transgender)	6 (2.4)
Ethnicity	
American Indian or Alaska Native	7 (2.1)
Asian	5 (2.0)
Black or African American	5 (2.0)
Hispanic or Latino	24 (9.8)
White	207 (84.5)
Other	6 (2.4)
Undisclosed	9 (3.7)
Education	
Less than high school	3 (1.2)
Graduated high school	20 (8.2)
Trade or technical school	8 (3.3)
Some college, no degree	62 (25.3)
Associate degree	34 (13.9)
Bachelor's degree	74 (30.2)
Advanced degree (master's degree, PhD, or MD)	43 (17.6)
Undisclosed	1 (0.4)
Children under 18 years of age living at home	
Yes	80 (32.7)
No	162 (66.1)
Undisclosed	3 (1.2)
Employment status	
Employed, full time	98 (40.0)
Employed, part time	35 (14.3)
Unemployed, disabled	22 (9.0)
Unemployed, looking for work	19 (7.8)
Unemployed, not looking for work	6 (2.4)
Unemployed, retired	32 (13.1)
Unemployed, volunteer work	1 (0.4)
Other—write in	29 (11.8)

Variable	Respondents (N=245), n (%)
Undisclosed	3 (1.2)
Mental health diagnosis	
Anxiety disorders	187 (76.3)
Eating disorders	50 (20.4)
Mood disorders	187 (76.3)
Personality disorders	8 (3.3)
Psychotic disorders	2 (0.8)
Substance abuse disorders	29 (11.8)
Trauma-related disorders	75 (30.6)
Other	19 (7.8)
Undisclosed	7 (2.9)
Marital status	
Divorced	33 (13.5)
Married or domestic partner	135 (55.1)
Separated	7 (2.9)
Single or never married	58 (23.7)
Widowed	9 (3.7)
Other	1 (0.4)
Undisclosed	1 (0.4)

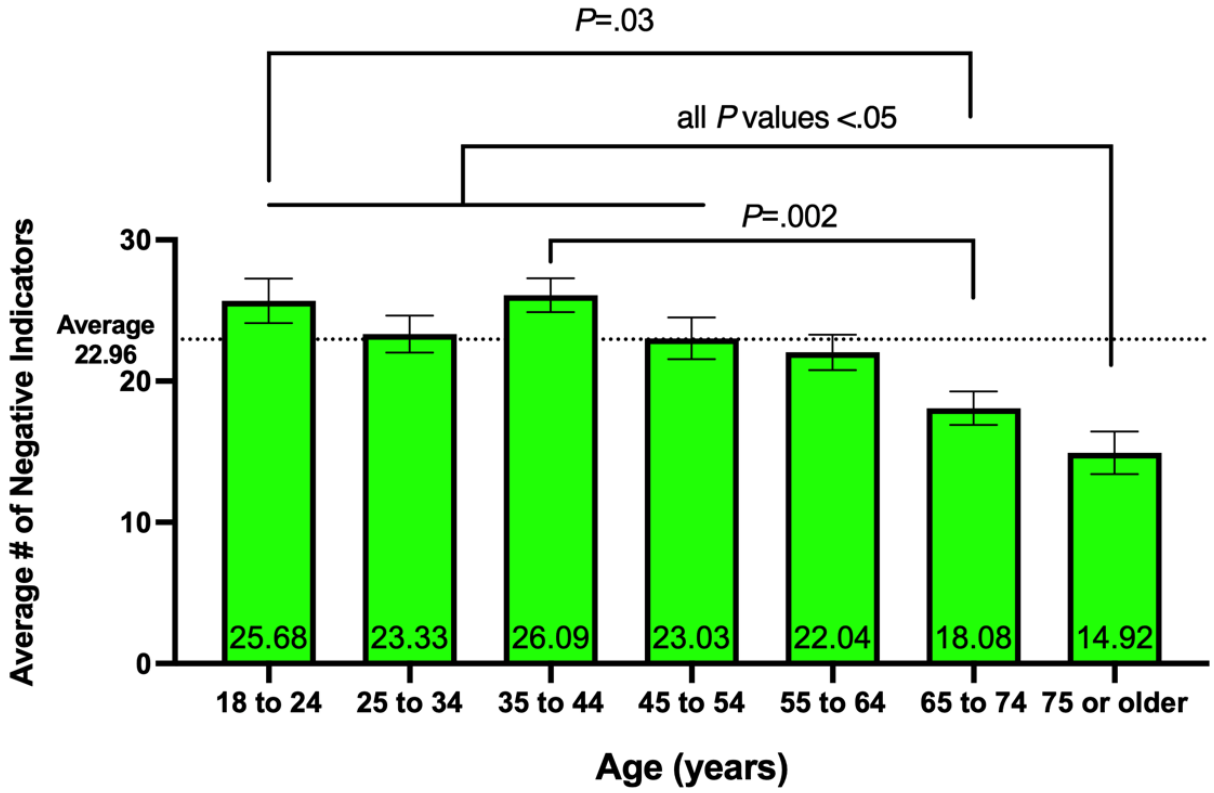
Overall Analysis

On average, respondents selected *yes* to 22.96 (SD 8.75) negative indicators, out of a total of 73 negative indicators. Respondents selected *yes* to 6.76 (SD 3.61) positive indicators on average, out of a total of 19 positive indicators.

Age

Overall, there was a significant effect of age ($F_{6, 238}$= 5.292, *P*<.001) (Figure 1). The 75-years-or-older age group (n=13) had the lowest number of negative indicators, with an average of 14.92 (SD 5.45) across all negative categories (ie, work and employment, education and training, home life, social activities, economic activities, emotional health and well-being, physical health problems, physical distancing and quarantine, and infection history). Tukey post hoc comparisons showed that the 75-years-or-older age group had significantly fewer negative indicators compared to the 18- to 24-year-old age group (*P*=.004), the 25- to 34-year-old age group (*P*=.03), the 35- to 44-year-old age group (*P*<.001), and the 45- to 54-year-old age group (*P*=.04). The 65- to 75-year-old age group (n=24) reported the next lowest number of negative indicators, with an average of 18.08 (SD 5.83) negative indicators. Specifically, they reported fewer negative indicators compared to the 18- to 24-year-old age group (*P*=.03) and the 35- to 44-year-old age group (*P*=.002).

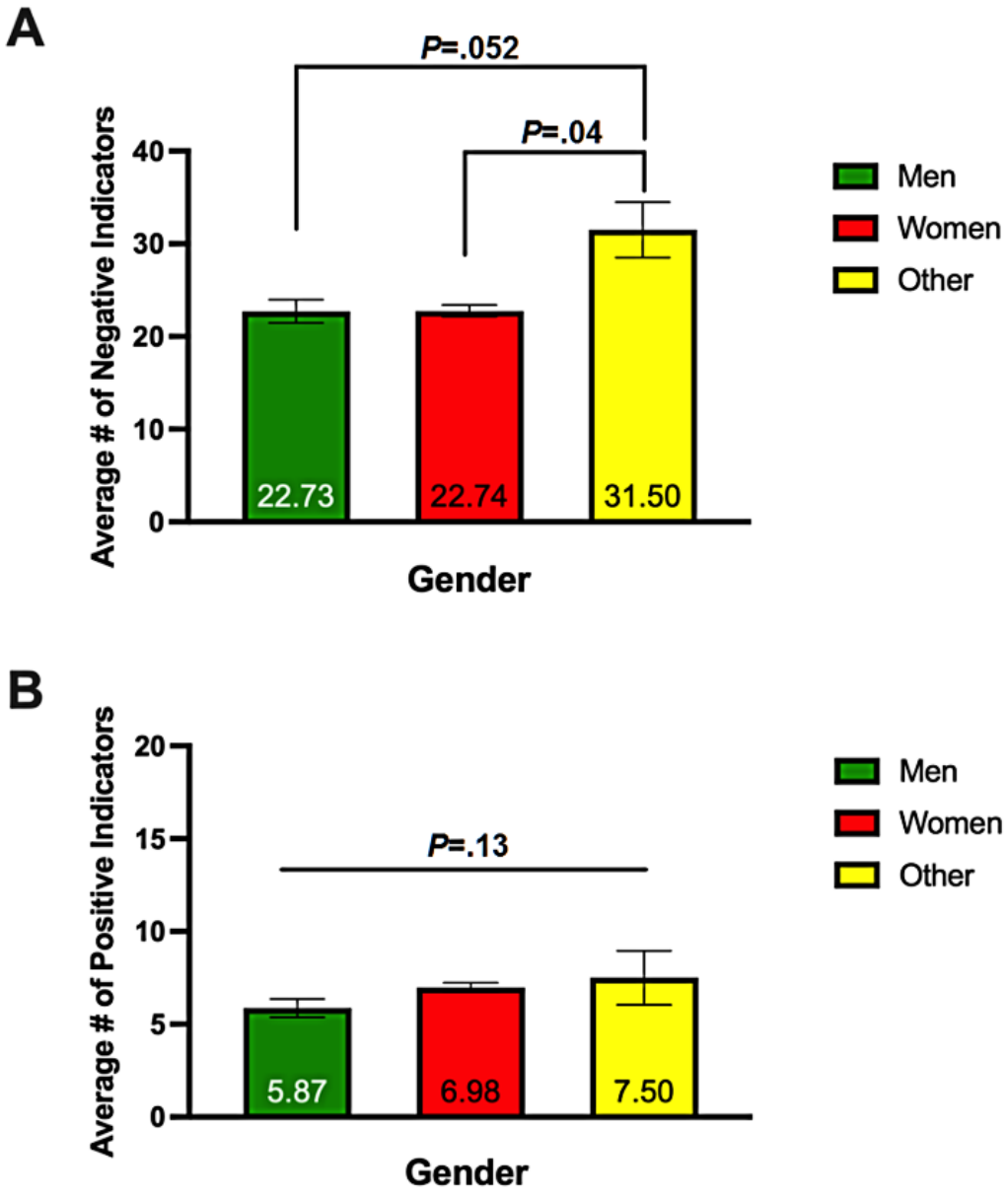
Figure 1. Average number of negative indicators by age. Respondents who were 75 years of age or older reported the lowest number of negative indicators (mean 14.92) on the Epidemic-Pandemic Impacts Inventory. The 65- to 75-year-old respondents reported the next lowest number of negative indicators (mean 18.08). Results are shown as mean (displayed on the bars) ± standard error of the mean (whiskers). *P* values were derived from a Tukey post hoc test.



Gender

We also analyzed the reported number of negative and positive indicators as a function of gender. In a one-way ANOVA analysis, the average negative indicators trended toward significance between men, women, and other gender queer, nonconforming, or transgender individuals ($F_{2,\ 242}$=2.980, *P*=.053) (Figure 2A). Tukey post hoc comparisons showed that men tended to report fewer negative indicators than gender queer, nonconforming, or transgender individuals (*P*=.052), while women also reported significantly fewer negative indicators than this group (*P*=.04). There was a nonsignificant effect of positive indicators across genders ($F_{2, 242}$=2.073, *P*=.13) (Figure 2B).

Figure 2. Negative (A) and positive (B) indicators were analyzed as a function of gender. Gender queer, nonconforming, and transgender individuals reported more negative indicators than men and women, on average. Results are reported as mean (displayed on the bars) ± standard error of the mean (whiskers). *P* values are overlaid on the figure.



Stay at Home

An additional topic of interest was whether there would be any differences between respondents who completed the survey before, during, or after the stay-at-home order. Time frames aligned with the dates when the California regional stay-at-home order was implemented (December 3, 2020) and lifted (January 25, 2021). Therefore, the time frames before, during, and after the stay-at-home order were defined as follows, and surveys were aggregated along these dates:

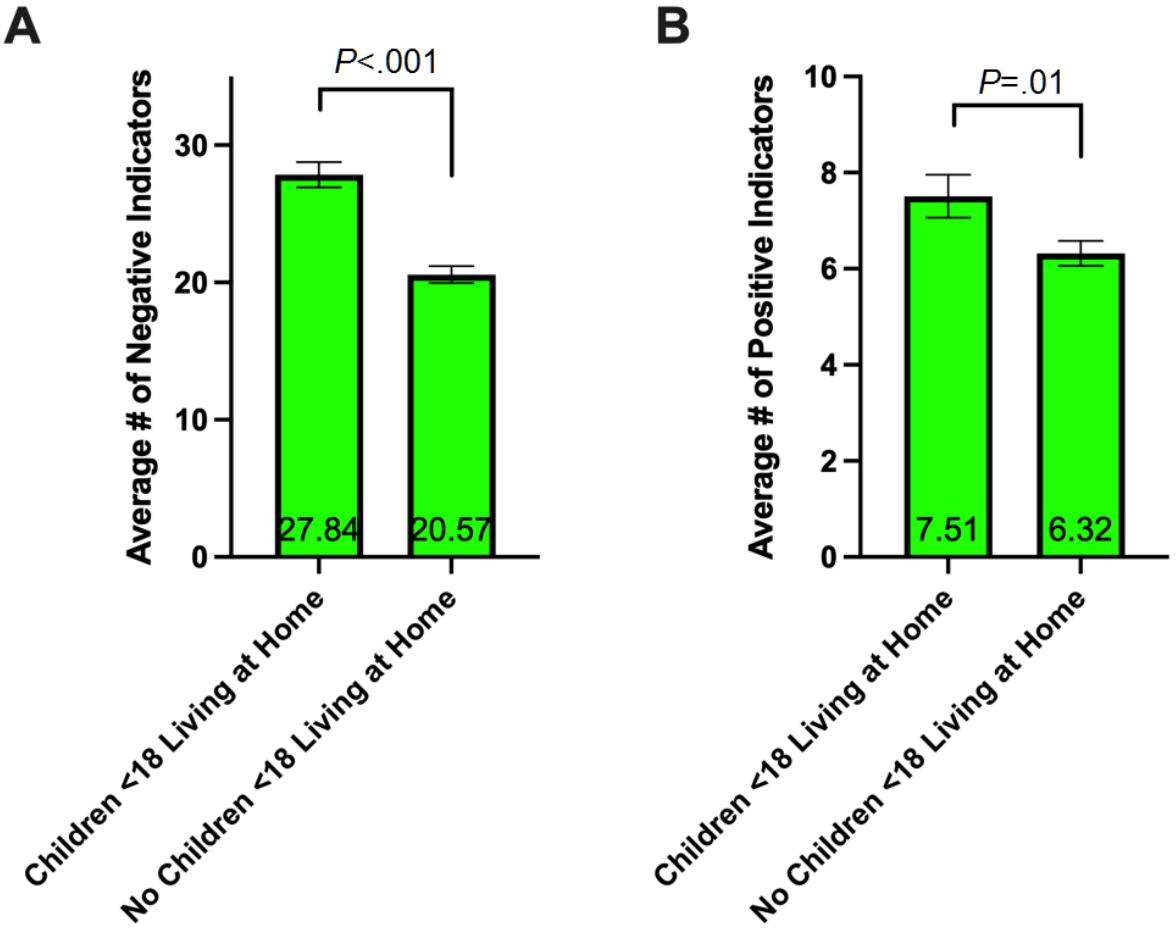
1. Pre–stay-at-home order: surveys completed before December 3, 2020.
2. During stay-at-home order: surveys completed from December 4, 2020, to January 25, 2021.
3. Post–stay-at-home order: surveys completed on January 26, 2021, or after.

It is relevant to note that the sample size for the pre–stay-at-home order group was much smaller (n=17) than that of the during stay-at-home order group (n=135) and the post–stay-at-home order group (n=93). There were minimal differences across groups: the average number of negative indicators was 22.53 (SD 7.04) for the pre–stay-at-home order group, 23.3 (SD 8.93) for the during stay-at-home order group, and 22.54 (SD 8.83) for the post–stay-at-home order group ($F_{2, 242}$=0.2281, *P*=.80). The average number of positive indicators was 5.06 (SD 3.05) for the pre–stay-at-home order group, 7.07 (SD 3.89) for the during stay-at-home order group, and 6.61 (SD 3.20) for the post–stay-at-home order group ($F_{2, 242}$=2.491, *P*=.09).

Having Children

Respondents with children under 18 years living at home (n=80) reported a significantly higher number of overall negative impacts (mean 27.84, SD 8.20), on average, compared to respondents without children under 18 years living at home (n=162) (mean 20.57, SD 7.95) (t_{240}=6.623, P<.001) (Figure 3A). However, respondents with children under 18 years living at home also had a significantly higher number of positive impacts (mean 7.51, SD 4.00), on average, compared to respondents without children under 18 years living at home (mean 6.32, SD 3.28) (t_{240}=2.465, P=.01) (Figure 3B). The difference between respondents with and without children was greatest in the *home life* subcategory, with an average number of impacts of 4.34 (SD 2.18) for respondents with children under 18 years living at home compared to 1.27 (SD 1.76) for respondents without children under 18 years living at home (t_{240}=11.77, P<.001).

Figure 3. Average number of negative indicators (A) and positive indicators (B) as a function of having children living at home. Respondents with children under 18 years of age living at home (n=80) reported higher numbers of overall negative and positive impacts compared to respondents without children under 18 years of age living at home (n=162). Results are shown as mean (displayed on the bars) ± standard error of the mean (whiskers). *P* values were calculated from Student *t* tests.



Most Impacted Subcategories

Overview

The *social activities* subcategory showed the greatest impact from COVID-19. This category had 10 questions in total, with an average of 5.88 (SD 1.90) *yes, me* or *yes, person in home* responses. The next most impacted category was *emotional health and well-being*, with an average of 3.96 (SD 1.61) *yes* responses, followed by *physical health and well-being*, with an average of 3.93 (SD 1.55) *yes* responses.

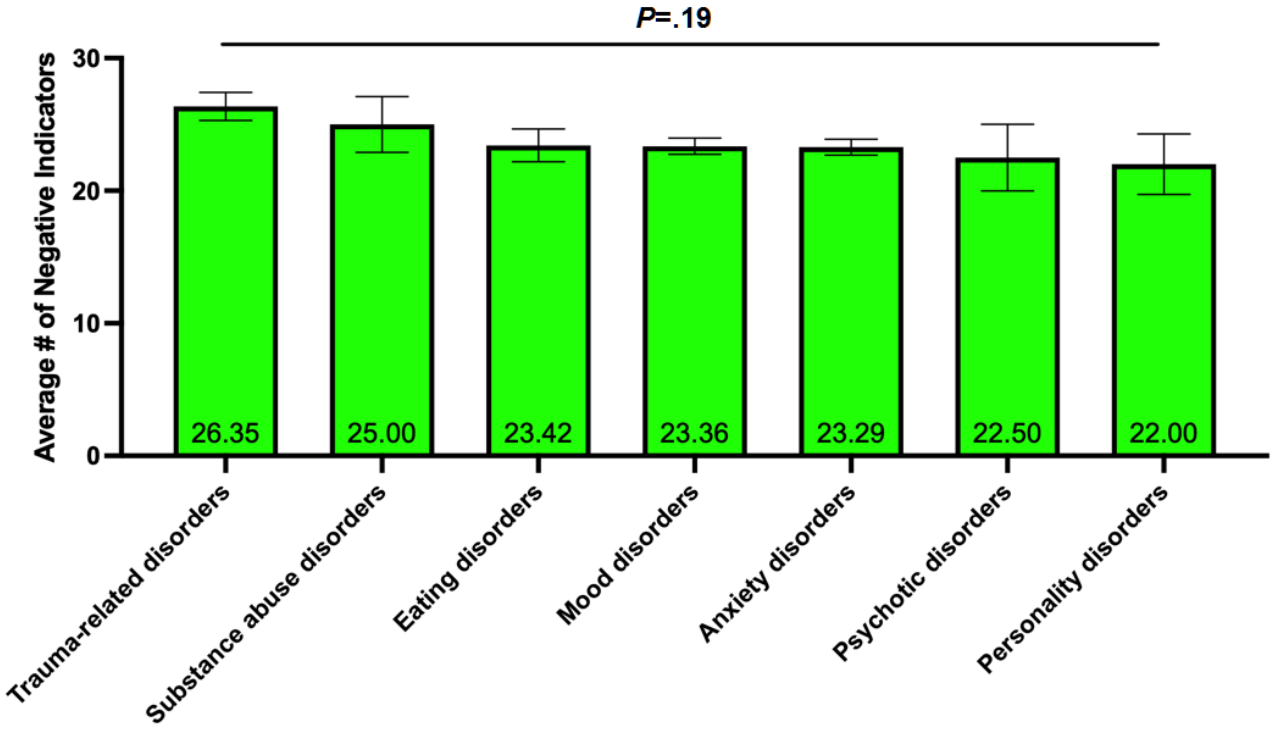
Substance Abuse During COVID-19

About one-third (86/245, 35.1%) of the respondents reported an increase in the use of alcohol or substances.

Mental Health Diagnosis

The most prevailing *mental health diagnosis* in the data set was mood disorder (187/245, 76.3%) and anxiety disorders (187/245, 76.3%); the next most prevalent diagnosis was trauma-related disorder (75/245, 30.6%). However, there was no effect of mental health diagnosis on the number of negative indicators reported on the EPII ($F_{6, 531}$=1.452, P=.19) (Figure 4).

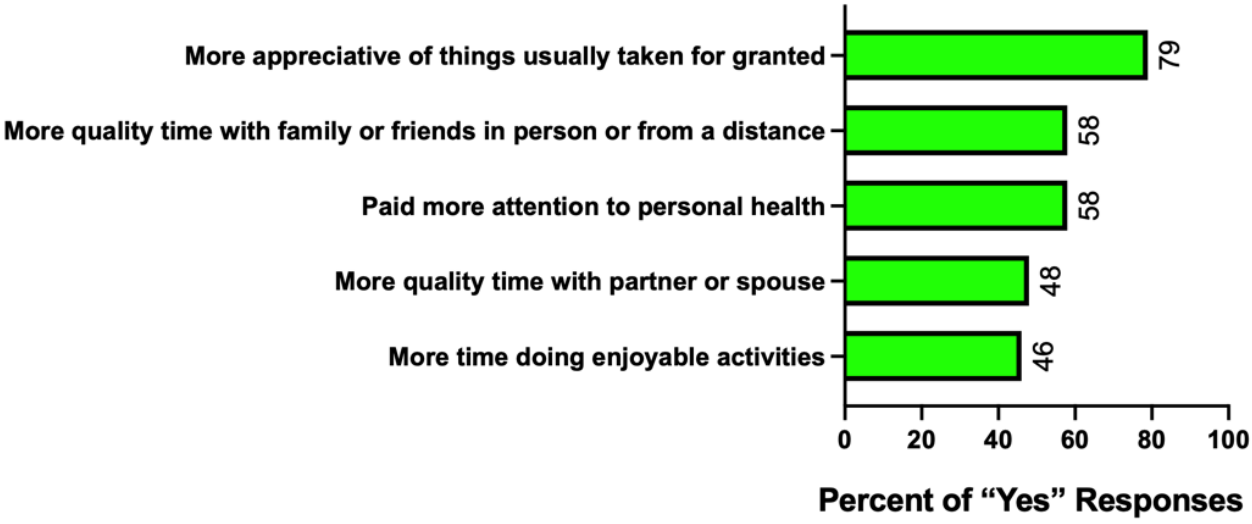
Figure 4. Average number of negative indicators as a function of mental health diagnosis. Results are shown as mean (displayed on the bars) ± standard error of the mean (whiskers).



Positive Change

The most reported indicator in *positive change* was “More appreciative of things usually taken for granted” (192/245, 78.4%), followed by “More quality time with family or friends in person or from a distance” (eg, on the phone, email, social media, video conferencing, and online gaming) (141/245, 57.6%) and “Paid more attention to personal health” (141/245, 57.6%) (Figure 5).

Figure 5. Top five positive indicators. The most reported indicator in positive change was "More appreciative of things usually taken for granted," followed by "More quality time with family or friends in person or from a distance".



Most Impacted Indicators

Table 2 outlines the top two indicators in each subcategory with the highest percentage of respondents reporting *yes, me* or *yes, person in home*.

Table 2. The most impacted indicators.

Subcategory and survey items[a]	Respondents (N=245), n (%)[b]
Work and employment	
Increase in workload or work responsibilities.	121 (49.4)
Had to continue to work even though in close contact with people who might be infected (eg, customers, patients, and coworkers)	113 (46.1)
Education and training (only two indicators in this subcategory)	
Had a child in the home who could not go to school	91 (37.1)
Adult unable to go to school or training for weeks or had to withdraw	48 (19.6)
Home life	
Increase in verbal arguments or conflict with a partner or spouse	94 (38.4)
Had to spend a lot more time taking care of a family member	68 (27.8)
Social activities	
Family celebrations canceled or restricted	235 (95.9)
Separated from family or close friends	218 (89.0)
Economic activities	
Unable to pay important bills like rent or utilities	43 (17.6)
Difficulty getting places due to less access to public transportation or concerns about safety	33 (13.5)
Emotional health and well-being	
Spent more time on screens and devices (eg, looking at phone, playing video games, and watching TV)	228 (93.1)
Increase in mental health problems or symptoms (eg, mood, anxiety, and stress)	223 (91.0)
Physical health problems	
More time sitting down or being sedentary	227 (92.7)
Less physical activity or exercise	206 (84.1)
Physical distancing and quarantine	
Isolated or quarantined due to possible exposure to this disease	134 (54.7)
Limited physical closeness with child or loved one due to concerns of infection	130 (53.1)
Infection history	
Death of close friend or family member from this disease	41 (16.7)
Had symptoms of this disease but was never tested	18 (7.3)
Positive change	
More appreciative of things usually taken for granted	192 (78.4)
More quality time with family or friends in person or from a distance (eg, on the phone, email, social media, video conferencing, and online gaming)	141 (57.6)

[a]The top two indicators in each subcategory with the highest percentage of respondents reporting yes, me or yes, person in home are listed.

[b]Values reported are the number of respondents combined who answered yes, me or yes, person in home.

Discussion

Overall, in this study, we showed that people who have previously sought mental health treatment reported many negative indicators associated with the COVID-19 pandemic. The least affected age groups included individuals who were 75 years or older and 65 to 75 years old. People with children under the age of 18 years living in the household also reported both more negative indicators and more positive indicators than those without minors living in the home. A marginal effect of gender was noted, but these results should be carefully interpreted, as the sample was not absolutely representative of the population. No effect of mental health diagnosis was noted. Furthermore, this study demonstrates the utility of Grasso and colleagues' [8] EPII survey in measuring the impacts of epidemics and pandemics in personal and social life domains. Surveys such as this one can help us determine which groups of patients are most at risk of experiencing deleterious effects during stressful situations, such as pandemic lockdowns.

The results of this study are largely in line with other recent findings. For instance, other survey-based research during the

COVID-19 pandemic has also shown that older adults appeared to have a more optimistic outlook and better mental health during the early stages of the pandemic [10]. Similarly, other work has shown that younger age predicted more concerns about the threat of COVID-19 across multiple life domains, lower positive affect, higher negative affect, and less frequent positive events [11]. Although we did not see any notable differences in the answers of respondents who completed the survey before, during, or after the stay-at-home orders in the state of California, one study conducted in New Zealand did, in fact, find that the countrywide lockdown had a significant psychological toll on a demographically representative sample of 2010 adult New Zealanders [12].

Our finding that people with minor children living at home experienced more negative indicators is also in line with other recent studies. For example, one survey of parents in the United States during the pandemic found that 27% of parents reported worsening mental health for themselves, and 14% reported worsening behavioral health for their children; further, this worsening of mental health for parents occurred alongside worsening behavioral health for children in nearly 10% of families, among whom 48% reported loss of regular child care, 16% reported change in insurance status, and 11% reported worsening food security due to the pandemic [13]. However, interestingly, these same individuals with children living at home also reported more positive indicators. Taken together with the results of our study, future policy decisions during pandemics, as well as decisions made by mental health practitioners, should keep in mind the special needs of families, particularly those with young children.

Other researchers have also observed, such as we did, that substance use increased during the COVID-19 pandemic, as did other negative mental health outcomes. In one survey of Americans, 40.9% of respondents reported at least one adverse mental or behavioral health condition, including symptoms of anxiety disorder or depressive disorder (30.9%), symptoms of a trauma- and stressor-related disorder related to the pandemic (26.3%), and having started or increased substance use to cope with stress or emotions related to COVID-19 (13.3%) [14].

The data collected here may serve as foundational research in the prevention, care, and treatment of mental health disorders during pandemics such as COVID-19. Dissemination of this new tool, the EPII survey, may be a useful way of measuring the impacts of epidemic- and pandemic-level events not only in this country, but across the world. Understanding how individuals, particularly those individuals at risk due to mental illness, are impacted by events such as COVID-19 may be helpful for determining ways to mitigate the effects of this stress. Further dissemination of this knowledge could be achieved through additional papers, such as this one, that utilize the EPII and presentations or posters at mental health conferences. Without a doubt, more can be done.

In conclusion, we found that people with children under the age of 18 years were most affected by the pandemic. Older age also seemed to be associated with fewer indications of experiencing negative impacts of COVID-19. Gender queer, nonconforming, and transgender individuals may also be at higher risk for negative impacts of COVID-19. No effect of mental health diagnosis was noted. Substance use also tended to increase during the pandemic. Finally, the EPII survey can indeed assess tangible impacts of epidemics and pandemics across personal and social life domains, and it may be a useful tool for future studies that aim to examine the impact of stressful situations on at-risk populations.

Acknowledgments

This research was funded, in part, by a grant from SAMHSA (Substance Abuse and Mental Health Services Administration) Emergency Response for Suicide Prevention (grant 5 H79 TI081478-03).

Conflicts of Interest

None declared.

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Abbreviations

ANOVA: analysis of variance
EPII: Epidemic-Pandemic Impacts Inventory
ICF: informed consent form
IRB: Institutional Review Board
N/A: not applicable
SAMHSA: Substance Abuse and Mental Health Services Administration
SEM: standard error of the mean

Edited by G Eysenbach; submitted 26.04.21; peer-reviewed by M Vallis, M Jordan; comments to author 25.05.21; revised version received 05.06.21; accepted 25.06.21; published 29.07.21.

Please cite as:
Shah A, Darling M, Arstein-Kerslake O, Morgan T, Vance Tovrea A, Young J, Laines H
Measuring the Impact of COVID-19 on Siyan Mental Health Patients Using the Epidemic-Pandemic Impacts Inventory: Survey Study
JMIR Form Res 2021;5(7):e29952
URL: https://formative.jmir.org/2021/7/e29952
doi:10.2196/29952
PMID:34323851

Corrigenda and Addenda

Authorship Correction: A Clinician-Controlled Just-in-time Adaptive Intervention System (CBT+) Designed to Promote Acquisition and Utilization of Cognitive Behavioral Therapy Skills in Bulimia Nervosa: Development and Preliminary Evaluation Study

Adrienne Juarascio[1], PhD; Paakhi Srivastava[1], PhD; Emily Presseller[1], BA; Kelsey Clark[1], MA; Stephanie Manasse[1], PhD; Evan Forman[1], PhD

Center for Weight, Eating and Lifestyle Science, Drexel University, Philadelphia, PA, United States

Corresponding Author:
Paakhi Srivastava, PhD
Center for Weight, Eating and Lifestyle Science
Drexel University
3141 Chestnut Street, Stratton Hall, Suite 232
Philadelphia, PA, 19104
United States
Phone: 1 2678156511
Email: ps887@drexel.edu

Related Article:

Correction of: https://formative.jmir.org/2021/5/e18261

(JMIR Form Res 2021;5(7):e31964) doi:10.2196/31964

In "A Clinician-Controlled Just-in-time Adaptive Intervention System (CBT+) Designed to Promote Acquisition and Utilization of Cognitive Behavioral Therapy Skills in Bulimia Nervosa: Development and Preliminary Evaluation Study" (JMIR Form Res 2021;5(5):e18261), one error was noted.

In the originally published article, the authorship order was incorrect. The article was originally published with the following authorship order:

> *Adrienne Juarascio, Paakhi Srivastava, Kelsey Clark, Emily Presseller, Stephanie Manasse, Evan Forman*

In the corrected article, the authorship order has been updated as follows:

> *Adrienne Juarascio, Paakhi Srivastava, Emily Presseller, Kelsey Clark, Stephanie Manasse, Evan Forman*

The correction will appear in the online version of the paper on the JMIR Publications website on July 29, 2021, together with the publication of this correction notice. Because this was made after submission to PubMed, PubMed Central, and other full-text repositories, the corrected article has also been resubmitted to those repositories.

Submitted 13.07.21; this is a non–peer-reviewed article;accepted 15.07.21; published 29.07.21.

Please cite as:
Juarascio A, Srivastava P, Presseller E, Clark K, Manasse S, Forman E
Authorship Correction: A Clinician-Controlled Just-in-time Adaptive Intervention System (CBT+) Designed to Promote Acquisition and Utilization of Cognitive Behavioral Therapy Skills in Bulimia Nervosa: Development and Preliminary Evaluation Study
JMIR Form Res 2021;5(7):e31964
URL: https://formative.jmir.org/2021/7/e31964
doi:10.2196/31964
PMID:34324426

Publisher:
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